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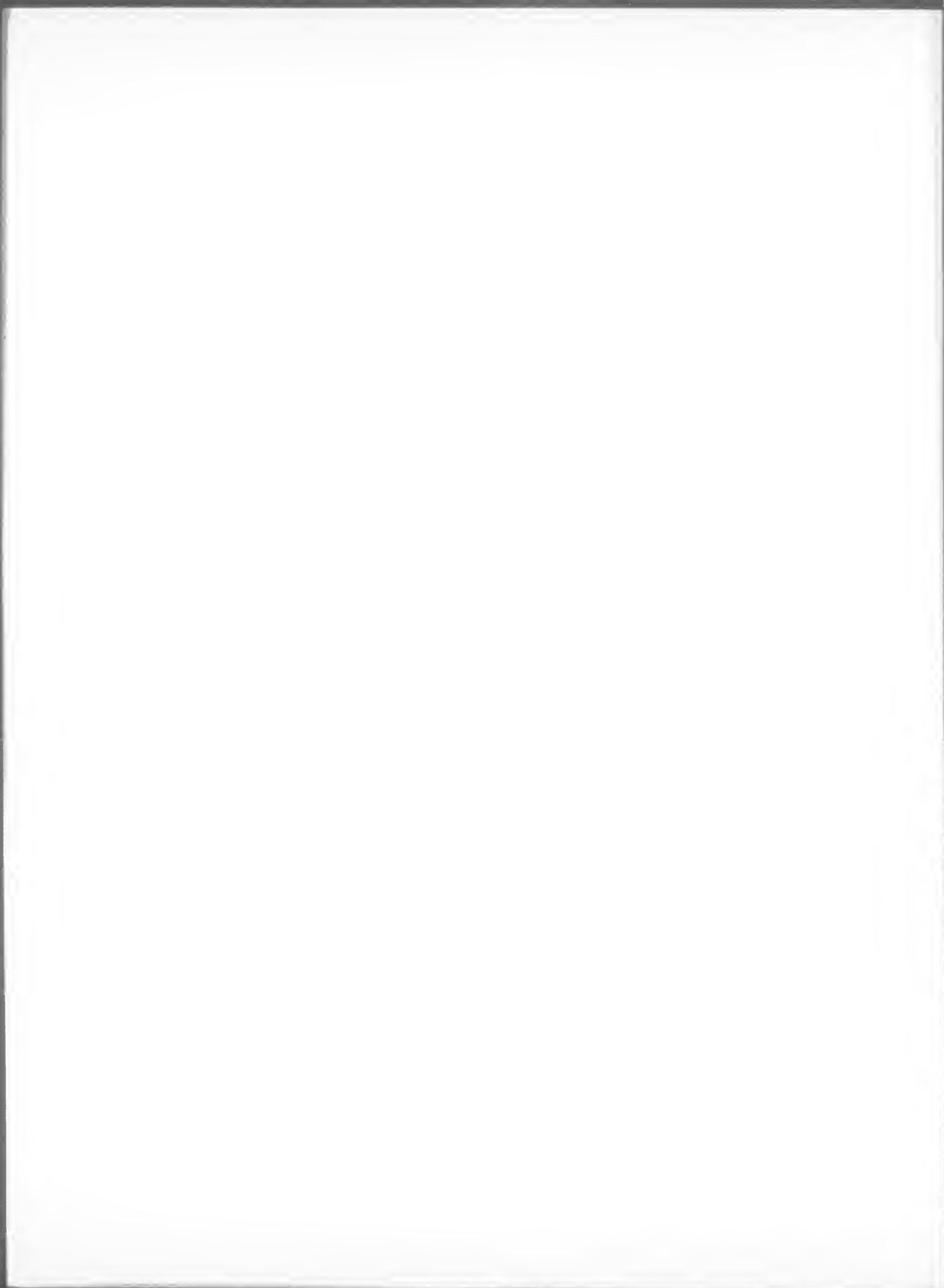
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Contents

Federal Register

Vol. 65, No. 4

Thursday, January 6, 2000

Bonneville Power Administration

NOTICES

Meetings:

Columbia River Basin; regional fish and wildlife policy; implementation, 765-766

Coast Guard

RULES

Drawbridge operations:

Massachusetts, 710

Pollution:

Marine transportation-related facilities and tank vessels; response plans; on-water oil recovery capacity; cap increases review, 710-716

NOTICES

Committees; establishment, renewal, termination, etc.:

Prince William Sound Regional Citizens' Advisory Council, 800-801

Environmental statements; notice of intent:

District of Columbia, Prince George's County, MD, and Alexandria and Fairfax County, VA, 801-802

Meetings:

Merchant Marine Personnel Advisory Committee, 802-803

Commerce Department

See International Trade Administration

See National Oceanic and Atmospheric Administration

Customs Service

NOTICES

Automation program test:

Electronic processing of quota-class apparel merchandise, 806-807

Energy Department

See Bonneville Power Administration

See Federal Energy Regulatory Commission

NOTICES

Grants and cooperative agreements; availability, etc.:

Forest products industry; black liquor/biomass gasification development and demonstration, 762-763

Meetings:

Environmental Management Site-Specific Advisory Board—

Hanford Site, WA, 764

Savannah River Site, SC, 763-764

Fusion Energy Sciences Advisory Committee, 764-765

Secretary of Energy Advisory Board, 765

Environmental Protection Agency

RULES

Air programs:

Stratospheric ozone protection—
Essential-use allowances; allocation, 716-728

PROPOSED RULES

Air quality implementation plans; approval and promulgation; various States:

California, 732

NOTICES

Pesticide registration, cancellation, etc.:

Cyanazine, 771-773

Superfund; response and remedial actions, proposed settlements, etc.:

WICO Site, St. Thomas, VI, 773

Executive Office of the President

See Presidential Documents

Federal Aviation Administration

RULES

Airworthiness directives:

Airbus, 697-699

CFE Co., 691-692

Fokker, 695-697

General Electric Co., 692-695

Class E airspace, 699-701

PROPOSED RULES

Airworthiness directives:

British Aerospace, 729-730

NOTICES

Airport noise compatibility program:

Noise exposure map—

Lanai Airport, HI, 803

Exemption petitions; summary and disposition, 803-805

Federal Election Commission

NOTICES

Meetings; Sunshine Act, 773

Federal Energy Regulatory Commission

RULES

Electric utilities (Federal Power Act):

Rate schedules filing—

Regional Transmission Organizations, 809-959

NOTICES

Electric rate and corporate regulation filings:

Energy East Corp. et al., 766-769

Saguaro Power Co. et al., 769-771

Practice and procedure:

Off-the-record communications, 771

Federal Highway Administration

NOTICES

Environmental statements; notice of intent:

District of Columbia, Prince George's County, MD, and Alexandria and Fairfax County, VA, 801-802

Federal Reserve System

NOTICES

Banks and bank holding companies:

Change in bank control, 773

Formations, acquisitions, and mergers, 773-774

Permissible nonbanking activities, 774

Federal Trade Commission

NOTICES

Premerger notification waiting periods; early terminations, 774-777

Prohibited trade practices:

MacDermid, Inc., et al., 777-779

Fish and Wildlife Service**NOTICES**

Endangered and threatened species permit applications, 787

Environmental statements; availability, etc.:

Thurston, Mason, and Grays Harbor Counties, WA; marbled murrelet, etc.; habitat conservation plan, 761-762

Food and Drug Administration**RULES**

Food for human consumption:

Food labeling—

Dietary supplements; effect on structure or function of body; types of statements, definition, 999-1050

NOTICES

Agency information collection activities:

Proposed collection; comment request, 779-782

Food additive petitions:

Alcide Corp., 782

Meetings:

National Mammography Quality Assurance Advisory Committee, 783

Vaccines and Related Biological Products Advisory Committee, 783-784

Geological Survey**NOTICES**

Grants and cooperative agreements; availability, etc.:

Brucellosis vaccination of free-ranging elk and bison in Greater Yellowstone Area; ballistic delivery systems, 787

Health and Human Services Department

See Food and Drug Administration

See Public Health Service

Indian Affairs Bureau**NOTICES**

Agency information collection activities:

Submission for OMB review; comment request, 787-789

Interior Department

See Fish and Wildlife Service

See Geological Survey

See Indian Affairs Bureau

PROPOSED RULES

Watches, watch movements, and jewelry:

Duty-exemption allocations—

Virgin Islands, Guam, American Samoa, and Northern Mariana Islands, 731-732

Internal Revenue Service**RULES**

Income taxes:

Insurance companies other than life insurance; underwriting income determination; deductions for unearned premiums increase, 701-710

NOTICES

Agency information collection activities:

Proposed collection; comment request, 807-808

International Development Cooperation Agency

See Overseas Private Investment Corporation

International Trade Administration**PROPOSED RULES**

Watches, watch movements, and jewelry:

Duty-exemption allocations—

Virgin Islands, Guam, American Samoa, and Northern Mariana Islands, 731-732

NOTICES

Antidumping:

Brass sheet and strip from—

Netherlands, 735-752

Carbon steel butt-weld pipe fittings from—

Various countries, 753

Mechanical transfer presses from—

Japan, 753-758

Silicon metal from—

Argentina, 758-759

Cheese quota; foreign government subsidies:

Annual list, 759-760

Export trade certificates of review, 760-761

Labor Department**NOTICES**

Agency information collection activities:

Submission for OMB review; comment request, 789-790

National Credit Union Administration**NOTICES**

Agency information collection activities:

Proposed collection; comment request, 790

Submission for OMB review; comment request, 790-791

National Oceanic and Atmospheric Administration**NOTICES**

Environmental statements; availability, etc.:

Thurston, Mason, and Grays Harbor Counties, WA;

marbled murrelet, etc.; habitat conservation plan, 761-762

National Science Foundation**NOTICES**

Meetings; Sunshine Act, 791

Nuclear Regulatory Commission**NOTICES**

Environmental statements; availability, etc.:

FirstEnergy Nuclear Operating Co., 794-795

Applications, hearings, determinations, etc.:

Carolina Power & Light Co., 791-793

Commonwealth Edison Co., 793-794

Overseas Private Investment Corporation**NOTICES**

Agency information collection activities:

Submission for OMB review; comment request, 789

Presidential Documents**ADMINISTRATIVE ORDERS**

Venezuela; emergency disaster relief assistance

(Presidential Determination No. 2000-9 of December 23, 1999), 689

Public Health Service

See Food and Drug Administration

NOTICES

National Toxicology Program:

Low-dose issues for endocrine disruptors; peer review; comment request, 784-787

Securities and Exchange Commission**NOTICES**

Investment Company Act of 1940:

Exemption applications—

Manufacturers Investment Trust et al., 797-799

New Covenant Funds et al., 795-797

Joint industry plan:

National Association of Securities Dealers, Inc., et al.,
799-800**Surface Transportation Board****PROPOSED RULES**

Rail carriers:

Carload waybill sample and public use file regulations;
modification, 732-734**NOTICES**

Rail carriers:

Cost recovery procedures—

Adjustment factor, 805-806

Transportation Department*See* Coast Guard*See* Federal Aviation Administration*See* Federal Highway Administration*See* Surface Transportation Board**Treasury Department***See* Customs Service*See* Internal Revenue Service**NOTICES**

Agency information collection activities:

Submission for OMB review; comment request, 806

Veterans Affairs Department**RULES**

Medical benefits:

Nursing home care of veterans in State homes; per diem
payments, 961-997**Separate Parts in This Issue****Part II**

Federal Energy Regulatory Commission, 809-959

Part III

Veterans Administration, 961-997

Part IV

Food and Drug Administration, 999-1050

Reader AidsConsult 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**Administrative Orders:**

Presidential Determinations:

No. 2000-9 of

December 23,

1999689

14 CFR

39 (4 documents)691,

691, 692, 695, 697

71 (4 documents)699,

700

Proposed Rules:

39729

15 CFR**Proposed Rules:**

303731

18 CFR

35810

21 CFR

1011000

26 CFR

1701

33 CFR

117710

154710

155710

38 CFR

17762

51762

58762

40 CFR

82716

Proposed Rules:

52732

49 CFR**Proposed Rules:**

1244732

Presidential Documents

Title 3—

Presidential Determination No. 2000-9 of December 23, 1999

The President

Drawdown Under Section 506(a)(2) of the Foreign Assistance Act of 1961, as Amended, To Provide Emergency Disaster Relief Assistance to Venezuela**Memorandum for the Secretary of State [and] the Secretary of Defense**

Pursuant to the authority vested in me by section 506(a)(2) of the Foreign Assistance Act of 1961, as amended, 22 U.S.C. 2318(a)(2) ("the Act"), I hereby determine that it is in the national interest of the United States to draw down articles and services from the inventory and resources of the Department of Defense, for the purpose of providing international disaster relief assistance to Venezuela.

I therefore direct the drawdown of up to \$20 million of articles and services from the inventory and resources of the Department of Defense for the Government of Venezuela for the purposes and under the authorities of chapter 9 of part I of the Act.

The Secretary of State is authorized and directed to report this determination to the Congress immediately and to arrange for its publication in the **Federal Register**.

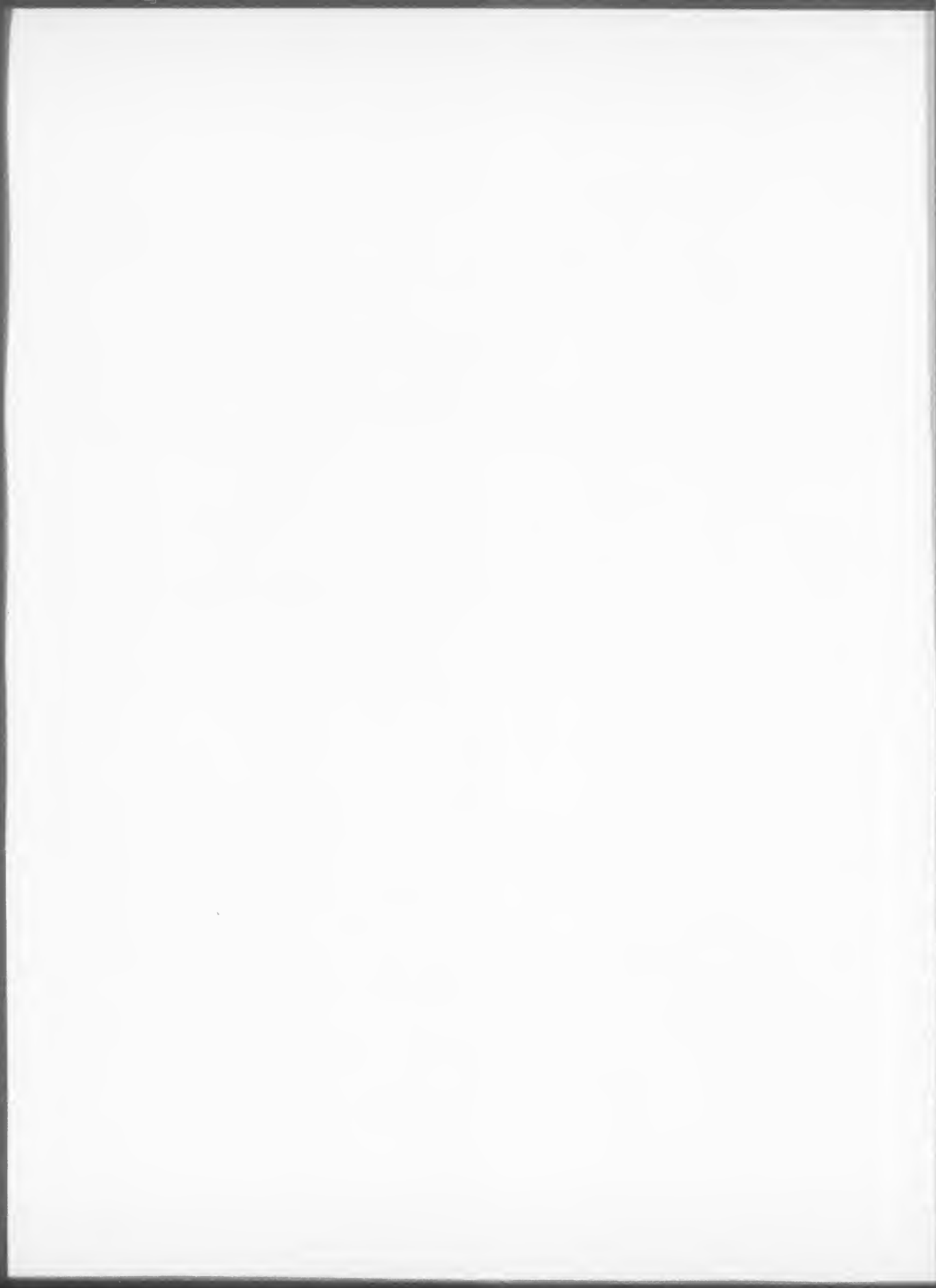


THE WHITE HOUSE,
Washington, December 23, 1999.

[FR Doc. 00-381

Filed 1-5-00; 8:45 am]

Billing code 4710-10-M



Rules and Regulations

Federal Register

Vol. 65, No. 4

Thursday, January 6, 2000

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

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99-NE-39-AD; Amendment 39-11497; AD 99-27-16]

RIN 2120-AA64

Airworthiness Directives; CFE Company Model CFE738-1-1B Turbofan Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to CFE Company Model CFE738-1-1B turbofan engines. This AD requires, on certain engines identified by serial numbers: a one-time visual inspection of Stage 2 high pressure turbine (HPT) aft cooling plates for nicks, dents, and scratches, and if present, dimensional inspection of indentation depth; repair, if indentation is within acceptable limits, and, if necessary, replacement with serviceable parts. This AD also requires inspection for raised metal on the Stage 2 HPT rotor disk post aft surface that mates with the Stage 2 HPT aft cooling plate, and removal of the raised metal, if present. This amendment is prompted by reports of Stage 2 HPT aft cooling plates that were dented during the assembly of the cooling plate to the Stage 2 disk due to raised metal on the stage 2 HPT disk post aft mating surface. The actions specified by this AD are intended to prevent aft HPT cooling plate failure, which could result in an uncontained engine failure and damage to the airplane.

DATES: Effective February 10, 2000.

The incorporation by reference of certain publications listed in the regulations is approved by the Director

of the Federal Register as of February 10, 2000.

ADDRESSES: The service information referenced in this AD may be obtained from CFE Company, Data Distribution, MS 64-03/2101-201, PO Box 29003 Phoenix, AZ 85038-9003; telephone (602) 365-2493, fax (602) 365-5577. This information may be examined at the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Keith Mead, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803-5299; telephone (781) 238-7744, fax (781) 238-7199.

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 CFE Company Model CFE738-1-1B turbofan engines was published in the *Federal Register* on September 28, 1999 (64 FR 52259). That action proposed to require, on certain engines identified by serial numbers: a one-time visual inspection of Stage 2 high pressure turbine (HPT) aft cooling plates for nicks, dents, and scratches, and if present, dimensional inspection of indentation depth; repair, if indentation is within acceptable limits, and, if necessary, replacement with serviceable parts. This AD also requires inspection for raised metal on the Stage 2 HPT rotor disk post aft surface that mates with the Stage 2 HPT aft cooling plate, and removal of the raised metal, if present. That action was prompted by reports of Stage 2 HPT aft cooling plates that were dented during the assembly of the cooling plate to the Stage 2 disk due to raised metal on the stage 2 HPT disk post aft mating surface. That condition, if not corrected, could result in aft HPT cooling plate failure, which could result in an uncontained engine failure and damage to the airplane.

No Comments Received

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were received on the

proposal or the FAA's determination of the cost to the public. The FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

Economic Analysis

There are approximately 72 engines of the affected design in the worldwide fleet. The FAA estimates that 48 engines installed on aircraft of US registry will be affected by this AD, that it will take approximately 4 work hours per engine to accomplish the required inspection if the inspection does not take place during scheduled maintenance, and that the average labor rate is \$60 per work hour. Required parts cost approximately \$1,536 per engine. Based on these figures, the total cost impact of the AD on US operators is estimated to be \$106,560.

Regulatory Impact

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order (EO) 13132.

For the reasons discussed above, I certify that this action (1) is not a "significant regulatory action" under EO 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:

99-27-16 CFE Company: Amendment 39-11497. Docket 99-NE-39-AD.

Applicability: CFE Model CFE738-1-1B turbofan engines, serial numbers (S/Ns) 105267 through 105339, inclusive. These engines are installed on but not limited to Dassault-Breguet Falcon 2000 series aircraft.

Note 1: This airworthiness directive (AD) applies to each engine 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 engines 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 (b) 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 aft HPT cooling plate failure, which could result in an uncontained engine failure and damage to the airplane, accomplish the following:

Inspections and Follow-On Actions

(a) At the next engine shop visit after the effective date of this AD where the HPT assembly is sufficiently disassembled to afford access to the Stage 2 HPT aft cooling plate, but not later than 4500 part cycles-since-new (CSN), accomplish the following in accordance with CFE Alert Service Bulletin (ASB) No. CFE738-A72-8031, Revision 1, dated June 23, 1999, as follows:

(1) Inspect the stage 2 HPT aft cooling plate for nicks, dents, and scratches on surface D in accordance with the requirements of ASB No. CFE738-A72-8031, paragraph 2.B.(1).

(2) Repair those stage 2 HPT aft cooling plates with indentation less than 0.003 inch deep in accordance with ASB No. CFE738-A72-8031, paragraph 2.B.(1).

(3) Remove from service prior to further flight those stage 2 HPT aft cooling plates that have nicks, dents, and/or scratches that exceed the acceptance limits in accordance

with ASB No. CFE738-A72-8031 paragraph 2.B.(1), and replace with serviceable parts.

(4) Inspect the stage 2 HPT rotor disk post aft mating surface for raised metal, and remove raised metal if present in accordance with ASB No. CFE738-A72-8031, paragraph 2.B.(2).

Alternative Methods of Compliance

(b) 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, Engine Certification Office (ECO). Operators shall submit their request through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, ECO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the ECO.

Ferry Flights

(c) Special flight permits may be issued in accordance with sections 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 inspection requirements of this AD can be accomplished.

Incorporation by Reference

(d) The actions required by this AD shall be done in accordance with the following CFE ASB:

Document No.	Revision	Pages	Date
CFE738-A72-8031	1	1	June 23, 1999.
Total pages: 5.	Original ..	2-5	May 17, 1999.

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 CFE Company, Data Distribution, MS 64-03/2101-201, P.O. , PO Box 29003 Phoenix, AZ 85038-9003; telephone (602) 365-2493, fax (602) 365-5577. Copies may be inspected at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

(e) This amendment becomes effective on February 10, 2000.

Issued in Burlington, Massachusetts, on December 29, 1999.

Jay J. Pardee,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 00-133 Filed 1-5-00; 8:45 am]

BILLING CODE 4910-13-U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99-NE-62-AD; Amendment 39-11496; AD 99-27-15]

RIN 2120-AA64

Airworthiness Directives; General Electric Company GE90 Series Turbofan Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that is applicable to certain General Electric Company GE90 series turbofan engines. This action requires visually inspecting Ps3 and P3B sense lines and full authority digital engine control (FADEC) Ps3 and P3B sensing ports and fittings, cleaning Ps3 and P3B fittings and sensing ports, purging the Ps3 and P3B systems of moisture, and, if necessary,

blending of high metal, nicks, burrs, or scratches on Ps3 and P3B fitting threads. This amendment is prompted by seven reports of loss of thrust control due to corruption of the signals to the FADEC caused by water freezing in the Ps3 sensing system. The actions specified in this AD are intended to prevent loss of thrust control due to corruption of the Ps3 and P3B signals to the FADEC which if it occurs in a critical phase of flight, could result in loss of aircraft control.

DATES: Effective January 11, 2000.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of January 11, 2000.

Comments for inclusion in the Rules Docket must be received on or before March 6, 2000.

ADDRESSES: Submit comments to the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 99-NE-62-AD, 12 New England Executive Park, Burlington, MA

01803-5299. Comments may also be sent via the Internet using the following address: "9-ane-adcomment@faa.gov". Comments sent via the Internet must contain the docket number in the subject line.

The service information referenced in this AD may be obtained from General Electric Company via Lockheed Martin Technology Services, 10525 Chester Road, Suite C, Cincinnati, OH 45215; telephone 513-672-8400, fax 513-672-8422. This information may be examined at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: John E. Golinski, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803-5299; telephone 781-238-7135, fax 781-238-7199.

SUPPLEMENTARY INFORMATION: The Federal Aviation Administration (FAA) has received seven reports of loss of thrust control (LOTC) on General Electric Company (GE) Model GE90 turbofan engines installed on Boeing 777 series aircraft. Five LOTC events occurred in-flight and two occurred on the ground. The five in-flight LOTC events were temporary in that the engine recovered and continued to operate normally for the remainder of the flight.

Investigation

The investigation revealed that water can accumulate in the Ps3 and P3B pressure sensing system, which can freeze in the full authority digital engine control (FADEC) sensing ports or pressure line. Frozen water can result in a restriction or a blocked signal to the FADEC. This blocked signal can cause a corruption of the FADEC signal and result in abnormal engine start characteristics on the ground or lack of engine response to commanded thrust levels in flight. Although there have been no LOTC events attributed to icing of the P3B sensing system in the field, inspections have identified moisture in this system, which could freeze and corrupt the P3B signal to the FADEC as well. This condition, if not corrected, could result in LOTC due to blockage of the FADEC sense lines, which if it occurs in a critical phase of flight, could result in loss of aircraft control.

Simultaneous LOTC Events

The FAA is especially concerned about the possibility of simultaneous

LOTC events on both engines installed on the Boeing 777 series aircraft due to common mode threats, such as certain atmospheric conditions that may result in ice in the Ps3 or P3B pressure sensing system and causing corrupted signals to the FADEC in both engines.

Interim Action

Both Ps3 and P3B pressure systems incorporate weep holes that allows drainage of water in the lines that may accumulate from condensation or ingested water; however, the field events and the investigation have determined that these design features may not always be effective in eliminating water from these systems. GE is assessing design changes that will prevent water from freezing in these systems and causing corruption of the signals to the FADEC. The requirements of this AD may change based on the ongoing investigation of the root cause and field inspection results, and future rulemaking may be necessary.

Service Information

The FAA has reviewed and approved the technical contents of GE Alert Service Bulletin (ASB) GE90 73-A0060, dated December 23, 1999, that describes procedures for visually inspecting Ps3 and P3B sense lines and FADEC sensing ports and fittings, cleaning Ps3 and P3B fittings and sensor ports, purging the Ps3 and P3B systems of moisture, and, if necessary, blending of high metal, nicks, burrs, or scratches on Ps3 and P3B fitting threads.

Difference between ASB and AD

This AD contains provisions for initial actions, and the ASB assumes that all operators have completed the initial actions based on field reports. If, however, operators have already accomplished the required initial actions, they need not repeat those actions, but may proceed directly to accomplishing the repetitive actions.

Required Actions

Since an unsafe condition has been identified that is likely to exist or develop on other engines of the same type design, this airworthiness directive (AD) is being issued to prevent engine LOTC events. This AD requires:

- Visual inspections for high metal, nicks, burrs, or scratches on Ps3 and P3B fitting threads, and, if necessary, blending.
- Visual inspections for moisture, debris, or ice in Ps3 and P3B FADEC fittings, ports, and open sense lines.
- Cleaning of Ps3 and P3B FADEC fittings and sensing ports.

- Purging of any moisture from the Ps3 and P3B sense system.
- Engine idle leak check run following the maintenance activity to confirm no Ps3 or P3B sense system faults are present.

Compliance Times

One of the GE90 series engines installed on the Boeing 777 series airplane must have the initial inspection, cleaning, moisture purging, and, if necessary, blending of high metal, nicks, burrs, or scratches on Ps3 and P3B fitting threads, within 10 cycles-in-service (CIS) after the effective date of this AD. The other engine installed on the airplane must have the initial inspection, cleaning, moisture purging, and, if necessary, blending of high metal, nicks, burrs, or scratches, on Ps3 and P3B fitting threads, within 20 CIS after the effective date of this AD. Based on concerns over concurrent engine maintenance, engines installed on the same Boeing 777 series airplane must not have the inspection, cleaning, moisture purging and, if necessary, blending of high metal, nicks, burrs, or scratches on Ps3 and P3B fitting threads performed concurrently.

Credit for Previous Inspections, Cleaning, and Moisture Purging

Engines that have been inspected, cleaned, and moisture purged in accordance with GE90 All Reps Wire, JSB99-11-24-1, Revision 1, dated November 25, 1999, may count those inspections, cleaning, and moisture purging as accomplished and must be inspected, cleaned, moisture purged, and, if necessary, have high metal, nicks, burrs, or scratches on Ps3 and P3B fitting threads blended, within 30 CIS since those last actions. Engines that have accumulated 30 CIS or greater since previous inspection, cleaning, and moisture purging on the effective date of the AD must repeat the required procedures within 5 CIS after the effective date of this AD. Engines that have accumulated less than 30 CIS since previous inspection, cleaning, and moisture purging on the effective date of this AD must repeat the required procedures within 30 CIS since last inspection, or within 5 CIS after the effective date of this AD, whichever occurs later.

Repetitive Actions

Thereafter, operators must inspect, clean, moisture purge, and, if necessary, blend high metal, nicks, burrs, or scratches on Ps3 and P3B fitting threads at intervals not to exceed 30 CIS since last inspection.

Immediate Adoption

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an 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 should identify the Rules Docket number and be submitted 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 notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 99-NE-62-AD." The postcard will be date stamped and returned to the commenter.

Regulatory Impact

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order (EO) 13132.

The FAA has determined that this regulation is an emergency regulation

that must be issued immediately to correct an unsafe condition in aircraft, and is not a "significant regulatory action" under EO 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, 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:

99-27-15 General Electric Company:
Amendment 39-11496. Docket 99-NE-62-AD.

Applicability: General Electric Company (GE) Models GE90-76B, -77B, -85B, -90B, and -92B turbofan engines, installed on but not limited to Boeing 777 series airplanes.

Note 1: This airworthiness directive (AD) applies to each engine 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 engines 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 (f) 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 loss of thrust control due to corruption of the Ps3 and P3B signals to the

full authority digital engine control (FADEC), which if it occurs in a critical phase of flight, could result in loss of aircraft control, accomplish the following:

Initial Inspection, Cleaning, Moisture Purging, and Blending

(a) Perform the following initial actions in accordance with the Accomplishment Instructions, Section (3) of GE Alert Service Bulletin (ASB) No. 73-A0060, dated December 23, 1999:

(1) Inspect, clean, moisture purge, and if necessary, blend any high metal, nicks, or burrs on fitting threads, on one engine installed on Boeing 777 series aircraft, within 10 cycles-in-service (CIS) after the effective date of this AD.

(2) Inspect, clean, moisture purge, and if necessary, blend any high metal, nicks, or burrs on fitting threads, on the other engine installed on the Boeing 777 series aircraft, within 20 CIS after the effective date of this AD.

Credit for Previous Inspections, Cleaning, and Moisture Purging

(b) Engines that have been inspected, cleaned, and moisture purged in accordance with GE90 All Reps Wire, JSB99-11-24-1, Revision 1, dated November 25, 1999, may count those inspections, cleaning, and moisture purging as accomplished and must be inspected, cleaned, moisture purged, and if necessary, have any high metal, nicks, or burrs on fitting threads blended, in accordance with the Accomplishment Instructions, Section (3) of GE ASB No. 73-A0060, dated December 23, 1999, and the following schedule:

(1) Engines that have accumulated 30 CIS or greater since previous inspection, cleaning, and moisture purging on the effective date of the AD must repeat the required procedures within 5 CIS after the effective date of this AD.

(2) Engines that have accumulated less than 30 CIS since previous inspection, cleaning, and moisture purging on the effective date of this AD must repeat the required procedures within 30 CIS since last inspection, or within 5 CIS after the effective date of this AD, whichever occurs later.

New and Replacement Engines

(c) For new and replacement engines, perform the initial inspection, cleaning, and moisture purging, and if necessary, blend any high metal, nicks, or burrs on fitting threads, prior to accumulating 30 CIS since entering service in accordance with the Accomplishment Instructions, Section (3) of GE ASB No. 73-A0060, dated December 23, 1999.

Repetitive Inspections

(d) Thereafter, inspect, clean, and moisture purge, and if necessary, blend any high metal, nicks, or burrs on fitting threads each engine within 30 CIS since last inspection, in accordance with the Accomplishment Instructions, Section (3) of GE ASB No. 73-A0060, dated December 23, 1999.

Idle Leak Check

(e) After accomplishing the required actions of this AD, and prior to entry into

service, perform an idle leak check to confirm no Ps3 or P3B sense system faults in accordance with the Accomplishment Instructions, Section (3), paragraph (14), of GE ASB No. 73-A0060, dated December 23, 1999.

No Simultaneous Actions

(f) Do not perform the actions required by this AD concurrently on both engines installed on a Boeing 777 series aircraft.

Alternative Methods of Compliance

(g) 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, Engine Certification Office (ECO). Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, ECO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the ECO.

Ferry Flights

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

Incorporation by Reference

(i) The actions required by this AD shall be done in accordance with GE ASB No. 73-A0060, dated December 23, 1999. 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 General Electric Company via Lockheed Martin Technology Services, 10525 Chester Road, Suite C, Cincinnati, OH 45215; telephone 513-672-8400, fax 513-672-8422. Copies may be inspected at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

(j) This amendment becomes effective on January 11, 2000.

Issued in Burlington, Massachusetts, on December 29, 1999.

Jay J. Pardee,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 00-134 Filed 1-5-00; 8:45 am]

BILLING CODE 4910-13-U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99-NM-236-AD; Amendment 39-11494; AD 99-27-13]

RIN 2120-AA64

Airworthiness Directives; Fokker Model F27 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 all Fokker Model F27 Mark 050 series airplanes. This action requires using a torque wrench to repetitively tighten the screws for the attachment of the leading edges of the elevators, rudder, and ailerons. 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 prevent loose attachment screws on the leading edges of the elevators, rudder, and ailerons due to vibration, which could result in interference with adjacent structure and consequent reduced controllability of the airplane.

DATES: Effective January 21, 2000.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of January 21, 2000.

Comments for inclusion in the Rules Docket must be received on or before February 7, 2000.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM-114, Attention: Rules Docket No. 99-NM-236-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 all Fokker Model F27 Mark 050 series airplanes. The RLD advises that, after an airplane landed, the elevator control was found binding in the fully "UP" position. Subsequent investigation of the elevator revealed that an attachment screw had come loose and moved out of the elevator leading edge section against the horizontal stabilizer. The leading edges of the elevators are attached by screws in anchor nuts on the elevator front spar. The screws are thought to have come loose due to vibration. The subject screws on the leading edge of the rudder and ailerons are identical to those on the affected elevators.

Loose attachment screws on the leading edges of the elevators, rudder, or ailerons, if not corrected, could result in interference of the leading edges with adjacent structure and consequent reduced controllability of the airplane.

Explanation of Relevant Service Information

Fokker has issued Service Bulletin SBF50-55-007, dated June 5, 1998, which describes procedures for using a torque wrench to repetitively tighten the screws for the attachment of the leading edges of the elevator.

Fokker also has issued Service Bulletin SBF50-57-020, Revision 1, dated July 23, 1999, which describes procedures for using a torque wrench to repetitively tighten the screws for the attachment of the leading edges of the aileron.

In addition, Fokker has issued Service Bulletin SBF50-55-009, Revision 1, dated July 23, 1999, which describes procedures for using a torque wrench to repetitively tighten the screws for the attachment of the leading edges of the rudder.

The RLD classified these service bulletins as mandatory and issued Dutch airworthiness directive 1998-070/3, dated August 31, 1999, in order to assure the continued airworthiness of these airplanes in the Netherlands.

FAA's Conclusions

These airplane models are manufactured in the Netherlands and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.19) 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 prevent loose attachment screws on the leading edges of the elevators, rudder, and ailerons due to vibration, which could result in interference with adjacent structure and consequent reduced controllability of the airplane. This AD requires accomplishment of the actions specified in the service bulletins described previously.

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 12 work hours to accomplish the required tightening, at an average labor rate of \$60 per work hour. Based on these figures, the cost impact of this AD would be \$720 per airplane, per inspection cycle.

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-236-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:

99-27-13 Fokker Services B.V.:
Amendment 39-11494. Docket 99-NM-236-AD.

Applicability: All Model F27 Mark 050 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 (d) 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 loose attachment screws on the leading edges of the elevators, rudder, and ailerons due to vibration, which could result in interference of the leading edges with adjacent structure and consequent reduced controllability of the airplane; accomplish the following:

Repetitive Corrective Action

(a) Within 30 days after the effective date of this AD, use a torque wrench to tighten the screws for the attachment of the leading edges of the elevators in accordance with Fokker Service Bulletin SBF50-55-007, dated June 5, 1998. Repeat the tightening thereafter at intervals not to exceed 12 months.

(b) Within 24 months after the effective date of this AD, use a torque wrench to tighten the screws for the attachment of the leading edges of the rudder in accordance with Fokker Service Bulletin SBF50-55-009, Revision 1, dated July 23, 1999. Repeat the tightening thereafter at intervals not to

exceed 4,000 flight hours or 24 months, whichever occurs first.

(c) Within 6 months after the effective date of this AD, use a torque wrench to tighten the screws for the attachment of the leading edges of the ailerons in accordance with Fokker Service Bulletin SBF50-57-020, Revision 1, dated July 23, 1999. Repeat the tightening thereafter at intervals not to exceed 12 months.

Alternative Methods of Compliance

(d) 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

(e) Special flight permits may be issued in accordance with sections 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

(f) The actions shall be done in accordance with the following Fokker service bulletins, which contain the specified effective pages:

Service bulletin referenced and date	Page No.	Revision level shown on page	Date shown on page
SBF50-55-007, June 5, 1998	1-5	Original	June 5, 1998.
SBF50-55-009, Revision 1, July 23, 1999	1-4, 7, 5, 6.	1, Original	July 23, 1999, April 23, 1999.
SBF50-57-020, Revision 1, July 23, 1999	1-4, 6, 5, 7.	1, Original	July 23, 1999, April 23, 1999.

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 3: The subject of this AD is addressed in Dutch airworthiness directive 1998-070/3, dated August 31, 1999.

(g) This amendment becomes effective on January 21, 2000.

Issued in Renton, Washington, on December 28, 1999.

D.L. Riffin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 00-46 Filed 1-5-00; 8:45 am]

BILLING CODE 4910-13-U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99-NM-336-AD; Amendment 39-11495; AD 99-27-14]

RIN 2120-AA64

Airworthiness Directives; Airbus Model A340-211, -212, -213, -311, -312, and -313 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), applicable to all Airbus Model A340-

211, -212, -213, -311, -312, and -313 series airplanes, that currently requires repetitive operational tests to ensure proper operation of the actuator of the secondary locks of the thrust reversers, and corrective actions, if necessary. The previously optional modifications that would have allowed an extension of the repetitive test intervals have been removed from this amendment. 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 prevent the inadvertent opening of a thrust reverser door in the event of failure of the primary and secondary locks of the thrust reverser. Such inadvertent opening could result in reduced controllability of the airplane. **DATES:** Effective January 21, 2000.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of January 21, 2000.

The incorporation by reference of certain other publications, as listed in the regulations, was approved previously by the Director of the Federal Register as of January 25, 1999 (64 FR 1108, January 8, 1999).

Comments for inclusion in the Rules Docket must be received on or before February 7, 2000.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM-114, Attention: Rules Docket No. 99-NM-336-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

The service information referenced in this AD may be obtained from Airbus

Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. 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: On December 28, 1998, the FAA issued AD 99-01-15, amendment 39-10980 (64 FR 1108, January 8, 1999), applicable to all Airbus Model A340-211, -212, -213, -311, -312, and -313 series airplanes, to require repetitive operational tests (inspections) to ensure proper operation of the actuator of the secondary locks of the thrust reversers; and corrective actions, if necessary. That action was prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The actions required by that AD are intended to prevent the inadvertent opening of a thrust reverser door in the event of failure of the primary and secondary locks of the thrust reverser. Such inadvertent opening could result in reduced controllability of the airplane.

Actions Since Issuance of Previous Rule

The existing AD provides for accomplishment of certain optional modifications (Airbus Modifications 45150 and 45486), which, if accomplished, would have allowed an extension of the repetitive test intervals.

However, service experience has shown that these modifications have not proven to be successful in reducing the rate of "REV. UNLOCKED" warnings to the flight crew, and new failure modes have been reported.

Explanation of Relevant Service Information

Airbus has issued Service Bulletin A340-78-4012, Revision 05, dated July 6, 1999. The provision for extension of the test interval if certain modifications are accomplished has been removed from Revision 05.

The Direction Générale de l'Aviation Civile (DGAC), which is the airworthiness authority for France, issued airworthiness directive 1999-265-117(B), dated June 30, 1999, to ensure the continued airworthiness of these airplanes in France.

FAA's Conclusions

This airplane model is manufactured in France and is type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.19) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the DGAC has kept the FAA informed of the situation described above. The FAA has examined the findings of the DGAC, 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 prevent the inadvertent opening of a thrust reverser door in the event of failure of the primary and secondary locks of the thrust reverser, which could result in reduced controllability of the airplane. This AD requires accomplishment of the actions specified in the service bulletin described previously.

Interim Action

This is considered to be interim action until final action is identified, at which time the FAA may consider further rulemaking.

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 8 work hours to accomplish the currently required operational test, at an average labor rate of \$60 per work hour. Based on these figures, the cost impact of this AD would be \$480 per airplane, per test cycle.

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-336-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, it is determined that this final rule does not have federalism implications under Executive Order 13132.

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39-10980 (64 FR 1108, January 8, 1999), and by adding a new airworthiness directive (AD),

amendment 39-11495, to read as follows:

99-27-14 Airbus Industrie: Amendment 39-11495. Docket 99-NM-336-AD. Supersedes AD 99-01-05, Amendment 39-10980.

Applicability: All Model A340-211, -212, -213, -311, -312, and -313 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 the inadvertent opening of a thrust reverser door in the event of failure of the primary and secondary locks of the thrust reverser, which could result in reduced controllability of the airplane, accomplish the following:

Operational Test

(a) Prior to the accumulation of 1,300 total flight hours, or within 500 flight hours after January 25, 1999 (the effective date of AD 99-01-15, amendment 39-10980), whichever occurs later, perform an operational test (inspection) to ensure proper operation of the actuator of the secondary locks of the thrust reversers, in accordance with Airbus Service Bulletin A340-78-4012, Revision 01, dated December 19, 1996, or Revision 05, dated July 6, 1999. Thereafter, repeat the operational test at intervals not to exceed 1,300 flight hours. After the effective date of this AD, only Revision 05 of the service bulletin shall be used.

Note 2: The Airbus service bulletin references ROHR Service Bulletin RA34078-47, Revision 1, dated November 30, 1996, as an additional source of service information for accomplishment of the operational test.

Corrective Action

(b) If any discrepancy is detected during any operational test (inspection) required by paragraph (a) of this AD, prior to further flight, replace the actuator of the secondary lock with a new or serviceable actuator, in accordance with ROHR Service Bulletin RA34078-47, Revision 1, dated November 30, 1996.

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 sections 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 operational tests and replacement shall be done in accordance with Airbus Service Bulletin A340-78-4012, Revision 01, dated December 19, 1996; Airbus Service Bulletin A340-78-4012, Revision 05, dated July 6, 1999; and ROHR Service Bulletin RA3478-47, Revision 1, dated November 30, 1996, which contains the following list of effective pages:

Page No.	Revision level shown on page	Date shown on page
1, 5, 6	1	November 30, 1996.
2-4, 7	Original	September 16, 1996.

(1) The incorporation by reference of Airbus Service Bulletin A340-78-4012, Revision 05, dated July 6, 1999, is approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(2) The incorporation by reference of Airbus Service Bulletin A340-78-4012, Revision 01, dated December 19, 1996; and ROHR Service Bulletin RA34078-47, Revision 1, dated November 30, 1996; was approved previously by the Director of the Federal Register as of January 25, 1999 (64 FR 1108, January 8, 1999).

(3) Copies may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; and ROHR, Inc., 850 Lagoon Drive, Chula Vista, California 91912. 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 French airworthiness directive 1999-265-117(B), dated June 30, 1999.

(f) This amendment becomes effective on January 21, 2000.

Issued in Renton, Washington, on December 28, 1999.

D.L. Riggins,
Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.
[FR Doc. 00-49 Filed 1-5-00; 8:45 am]
BILLING CODE 4910-13-U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 99-ASW-25]

Revision of Class E Airspace; Beaumont, TX

AGENCY: Federal Aviation Administration (FAA), 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 Beaumont, TX.

EFFECTIVE DATE: The direct final rule published at 64 FR 58331 is effective 0901 UTC, February 24, 2000.

FOR FURTHER INFORMATION CONTACT: Donald J. Day, Airspace Branch, Air Traffic Division, Southwest Region, Federal Aviation Administration, Fort Worth, TX 76193-0520, telephone: 817-222-5593.

SUPPLEMENTARY INFORMATION: The FAA published this direct final rule with a request for comments in the **Federal Register** on October 29, 1999, (64 FR 58331). The FAA uses the direct final rulemaking procedure for a noncontroversial 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 February 24, 2000. No adverse comments were received, and, thus, this action confirms that this direct final rule will be effective on that date.

Issued in Fort Worth, TX, on December 27, 1999.

JoEllen Casilio,

*Assistant Manager, Air Traffic Division,
Southwest Region.*

[FR Doc. 00-243 Filed 1-5-00; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 99-ASW-26]

Revision of Class E Airspace; El Paso, TX

AGENCY: Federal Aviation Administration (FAA), 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 El Paso, TX.

EFFECTIVE DATE: The direct final rule published at 64 FR 58332 is effective 0901 UTC, February 24, 2000.

FOR FURTHER INFORMATION CONTACT: Donald J. Day, Airspace Branch, Air Traffic Division, Southwest Region, Federal Aviation Administration, Fort Worth, TX 76193-0520, telephone: 817-222-5593.

SUPPLEMENTARY INFORMATION: The FAA published this direct final rule with a request for comments in the *Federal Register* on October 29, 1999, (64 FR 58332). The FAA uses the direct final rulemaking procedure for a noncontroversial 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 February 24, 2000. No adverse comments were received, and, thus, this action confirms that this direct final rule will be effective on that date.

Issued in Fort Worth, TX, on December 27, 1999.

JoEllen Casilio,

*Assistant Manager, Air Traffic Division,
Southwest Region.*

[FR Doc. 00-244 Filed 1-5-00; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 99-ASW-24]

Revision of Class E Airspace; Hebronville, TX

AGENCY: Federal Aviation Administration (FAA), 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 Hebronville, TX.

EFFECTIVE DATE: The direct final rule published at 64 FR 58329 is effective 0901 UTC, February 24, 2000.

FOR FURTHER INFORMATION CONTACT: Donald J. Day, Airspace Branch, Air Traffic Division, Southwest Region, Federal Aviation Administration, Fort Worth, TX 76193-0520, telephone: 817-222-5593.

SUPPLEMENTARY INFORMATION: The FAA published this direct final rule with a request for comments in the *Federal Register* on October 29, 1999 (64 FR 58329). The FAA uses the direct final rulemaking procedure for a noncontroversial 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 February 24, 2000. No adverse comments were received, and, thus, this action confirms that this direct final rule will be effective on that date.

Issued in Fort Worth, TX, on December 27, 1999.

JoEllen Casilio,

*Assistant Manager, Air Traffic Division,
Southwest Region.*

[FR Doc. 00-245 Filed 1-5-00; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 99-ASW-34]

Revision of Class E Airspace; Bonham, TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule; request for comments.

SUMMARY: This amendment revises the Class E airspace at Bonham, TX. The development of a Nondirectional Radio Beacon (NDB) Standard Instrument Approach Procedure (SIAP), at Jones Field, Bonham, TX, has made this rule necessary. This action is intended to provide adequate controlled airspace extending upward from 700 feet or more above the surface for Instrument Flight Rules (IFR) operations to Jones Field, Bonham, TX.

DATES: Effective 0901 UTC, April 20, 2000. Comments must be received on or before February 22, 2000.

ADDRESSES: Send comments on the rule in triplicate to Manager, Airspace Branch, Air Traffic Division, Federal Aviation Administration, Southwest Region, Docket No. 99-ASW-34, Fort Worth, TX 76193-0520. The official docket may be examined in the Office of the Regional Counsel, Southwest Region, Federal Aviation Administration, 2601 Meacham Boulevard, Room 663, Fort Worth, TX, between 9:00 AM and 3:00 PM, Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the Airspace Branch, Air Traffic Division, Federal Aviation Administration, Southwest Region, Room 414, Fort Worth, TX.

FOR FURTHER INFORMATION CONTACT: Donald J. Day, Airspace Branch, Air Traffic Division, Southwest Region, Federal Aviation Administration, Fort Worth, TX 76193-0520, telephone 817-222-5593.

SUPPLEMENTARY INFORMATION: This amendment to 14 CFR part 71 revises the Class E airspace at Bonham, TX. The development of a NDB SIAP, at Jones Field, Bonham, TX, has made this rule necessary. This action is intended to provide adequate controlled airspace extending upward from 700 feet or more above the surface for Instrument Flight Rules (IFR) operations to Jones Field, Bonham, TX.

Class E airspace designations are published in Paragraph 6005 of FAA Order 7400.9G, dated September 1, 1999, and effective September 16, 1999, which is incorporated by reference in 14 CFR § 71.1. The Class E airspace designation listed in this document will be published subsequently in the order.

The Direct Final Rule Procedure

The FAA anticipates that this regulation will not result in adverse or negative comment and therefore is issuing it as a direct final rule. A

substantial number of previous opportunities provided to the public to comment on substantially identical actions have resulted in negligible adverse comments or objections. Unless a written adverse or negative comment, or a written notice of intent to submit an adverse or negative comment is received within the comment period, the regulation will become effective on the date specified above. After the close of the comment period, the FAA will publish a document in the **Federal Register** indicating that no adverse or negative comments were received and confirming the date on which the final rule will become effective. If the FAA does receive, within the comment period, an adverse or negative comment, or written notice of intent to submit such a comment, a document withdrawing the direct final rule will be published in the **Federal Register**, and a notice of proposed rulemaking may be published with a new comment period.

Comments Invited

Although this action is in the form of a final rule and was not preceded by a notice of proposed rulemaking, 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 desire. Communications should 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 or withdrawn in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of this action and determining whether additional rulemaking action is 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 action 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 No. 99-ASW-34." The postcard

will be date stamped and returned to the commenter.

Agency Findings

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, it is determined that this final rule will not have federalism implications under Executive Order 13132.

Further, the FAA has determined that this regulation is noncontroversial and unlikely to result in adverse or negative comments and only involves an established body of technical regulations that require frequent and routine amendments to keep them operationally current. Therefore, I certify that this regulation (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) if promulgated, 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. Since this rule involves routine matters that will only affect air traffic procedures and air navigation, it does not warrant preparation of a Regulatory Flexibility Analysis because the anticipated impact is so minimal.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854; 24 FR 9565, 3 CFR, 1959-1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9G, *Airspace Designations and Reporting Points*, dated September 1, 1999, and effective September 16, 1999, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ASW TX E5 Bonham, TX [Revised]

Bonham, Jones Field, TX

(Lat. 33°36'42"N., long. 96°10'46"W.)

Bonham VORTAC

(Lat. 33°32'15"N., long. 96°14'03"W.)

Rayburn NDB

(Lat. 33°36'50"N., long. 96°10'34"W.)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Jones Field and within 4 miles east and 8 miles west of the 030° radial of the Bonham VORTAC extending from the 6.4-mile radius to 15 miles northeast of the airport and within 2.5 miles each side of the 347° bearing from the Rayburn NDB extending from the 6.4-mile radius to 7.5 miles northwest of the airport.

* * * * *

Issued in Fort Worth, TX, on December 27, 1999.

JoEllen Casilio,

Assistant Manager, Air Traffic Division, Southwest Region.

[FR Doc. 00-242 Filed 1-5-00; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8857]

RIN 1545-AU60

Determination of Underwriting Income

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to the determination of underwriting income by insurance companies other than life insurance companies. In computing underwriting income, non-life insurance companies are required to reduce by 20 percent their deductions for increases in unearned premiums. This requirement was enacted as part of the Tax Reform Act of 1986. These regulations provide guidance to non-life insurance companies for purposes of determining the amount of unearned premiums that are subject to the 20 percent reduction rule.

DATES: The regulations are effective January 5, 2000.

FOR FURTHER INFORMATION CONTACT: Gary Geisler, (202) 622-3970 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On January 2, 1997, the IRS published in the *Federal Register* a notice of proposed rulemaking (REG-209839-96, 1997-1 C.B. 780 [62 FR 72]) proposing amendments to the Income Tax Regulations (26 CFR part 1) under section 832(b) of the Internal Revenue Code. The IRS received a number of written comments on the proposed regulations. On April 30, 1997, the IRS held a public hearing on the proposed regulations. After consideration of all written and oral comments regarding the proposed regulations, those regulations are adopted as revised by this Treasury decision.

Explanation of Revisions and Summary of Comments Underwriting Income

A non-life insurance company's underwriting income equals its premiums earned on insurance contracts during the taxable year less its losses incurred on insurance contracts and its expenses incurred.¹ See section 832(b)(3). To compute premiums earned, the company starts with the gross premiums written on insurance contracts during the taxable year, subtracts return premiums and premiums paid for reinsurance, and makes an adjustment to reflect the change in its unearned premiums over the course of the taxable year. See section 832(b)(4). This computation results in premiums being recognized in underwriting income over the term of the insurance contract, rather than in the taxable year in which the premiums are billed or received from the policyholder.

Prior to 1987, 100 percent of the change in unearned premiums during the taxable year was taken into account as an increase or decrease to written premiums in computing premiums earned. This treatment "generally reflect[ed]" the accounting conventions (often referred to as "statutory accounting principles") used to prepare a non-life insurance company's annual statement for state insurance regulatory purposes. See 2 H.R. Conf. Rep. No. 841, 99th Cong., 2d Sess. II-354 (1986), 1986-3 C.B. (Vol. 4) 354; S. Rep. No. 313, 99th Cong., 2d Sess. 495 (1986), 1986-3 C.B. (Vol. 3) 495, H.R. Rep. No. 426, 99th Cong., 1st Sess. 668 (1985),

1986-3 C.B. (Vol. 2) 668. Because unearned premiums are computed on the basis of the gross premiums for an insurance contract, the amount of unearned premiums reflects not only the portion of the gross premium allocable to future insurance claims but also the portion allocable to the insurance company's expenses and profit on the insurance contract.

In 1986, Congress determined that deferring unearned premium income and currently deducting premium acquisition expenses attributable to unearned premiums resulted in a mismatch of an insurance company's net income and expense. Congress decided to require a better measurement of net income for Federal income tax purposes. See H.R. Rep. No. 426, 1986-3 C.B. (Vol. 2) at 669; S. Rep. No. 313, 1986-3 C.B. (Vol. 3) at 496. Rather than defer the deduction for premium acquisition expenses attributable to unearned premiums, Congress reduced by 20 percent the adjustment for unearned premiums. For taxable years beginning on or after January 1, 1993, a non-life insurance company's premiums earned is an amount equal to: (1) its gross premiums written, less both return premiums and premiums paid for reinsurance; plus (2) 80 percent of unearned premiums at the end of the prior taxable year, less 80 percent of unearned premiums at the end of the current taxable year. Section 832(b)(4). The acceleration of income that is typically generated by the 20 percent reduction of unearned premiums is intended to be roughly equivalent to denying current deductibility for the portion of the insurance company's premium acquisition expenses allocable to the unearned premiums. See 2 H.R. Conf. Rep. No. 841, 1986-3 C.B. (Vol. 4) at 354-55; S. Rep. No. 313, 1986-3 C.B. (Vol. 3) at 495-98; H.R. Rep. No. 426, 1986-3 C.B. (Vol. 2) at 668-70.

Role of the Annual Statement

The proposed regulations provide definitions of the items used to determine premiums earned under section 832(b)(4) and timing rules for taking these items into account for Federal income tax purposes. The treatment provided in the proposed regulations would apply regardless of the classification or method of reporting the items used on an insurance company's annual statement.

Several comments questioned whether there is legal authority to require an insurance company to use a method to calculate premiums earned for Federal income tax purposes that differs from the method that the

company is permitted to use to calculate premiums earned on its annual statement. As noted in the preamble to the proposed regulations, the existing regulations under § 1.832-4(a)(2) state that the annual statement " * * * insofar as it is not inconsistent with the provisions of the Code * * *" will be recognized and used as a basis for computing the net income of a non-life insurance company. Also, if statutory accounting principles permit alternative practices, one or more of which do not clearly reflect income as defined by the Code, the company is required for Federal income tax purposes to use a method that clearly reflects income. Section 446(b) and § 1.446-1(a)(2).

Gross Premiums Written

The proposed regulations generally define gross premiums written as the total amounts payable for insurance coverage under insurance or reinsurance contracts issued or renewed during the taxable year. The proposed regulations, however, do not address situations where the amounts charged for insurance coverage may change due to increases or decreases in coverage limits, additions or deletions in property or risks covered, changes in location or status of insureds, or other similar factors.

The final regulations define an insurance company's "gross premiums written" on insurance contracts (which includes premiums attributable to reinsurance contracts) as amounts payable for insurance coverage for the effective periods of the contracts. The label placed on a payment in a contract does not determine whether an amount is a gross premiums written. The effective period of a contract is the period over which one or more rates for insurance coverage are guaranteed in the contract. If a new rate for insurance coverage is guaranteed after the effective date of an insurance contract, the making of the guarantee generally is treated as the issuance of a new insurance contract with an effective period equal to the duration of the new guaranteed rate for insurance coverage.

Under the final regulations, gross premiums written include: (1) Additional premiums resulting from increases in risk exposure during the effective period of an insurance contract; (2) amounts subtracted from a premium stabilization reserve that are used to pay premiums; and (3) consideration for assuming insurance liabilities under contracts not issued by the insurance company (that is, a payment or transfer of property in an assumption reinsurance transaction).

¹ For this purpose, expenses incurred generally refers to the expenses reported on the company's annual statement approved by the National Association of Insurance Commissioners (NAIC) and filed for state insurance regulatory purposes, less expenses incurred which are not allowed as deductions under section 832(c). See section 832(b)(6). Expenses incurred generally include premium acquisition expenses attributable to unearned premiums on insurance contracts.

Gross premiums written, however, do not include other items of gross income described in section 832(b)(1)(C). To the extent that amounts paid or payable to an insurance company with respect to an arrangement are not gross premiums written, the insurance company may not treat amounts payable to customers with respect to the applicable portion of such arrangements as losses incurred described in section 832(b)(5).

Method of Reporting Gross Premiums Written

The proposed regulations provide that a non-life insurance company reports the full amount of gross premiums written for an insurance contract for the earlier of the taxable year which includes the effective date of the contract or the year in which all or a portion of the premium for the contract is received. A variety of comments were received with respect to the application of this timing rule to insurance contracts with installment premiums. In response to comments, the final regulations provide a number of exceptions from the general rule with respect to when an insurance company reports gross premiums written.

Advance Premiums

Under the proposed regulations, a non-life insurance company that receives a portion of the premium for an insurance contract prior to the effective date of the contract includes the full amount of the premium in gross premiums written for the taxable year during which the portion of the premium was received.

Several comments addressed the treatment of advance premiums in the proposed regulations. One comment endorsed the proposed treatment of advance premiums, noting that it is proper under statutory accounting principles to record the full amount of gross premiums written and expenses incurred with respect to a casualty insurance policy for the year in which an advance premium is received.² Other comments argued that since the policyholder may demand a refund of an advance premium prior to the policy's effective date, the company should be permitted to treat an advance

² Prior to 1989, advance premiums were required to be reported in written premiums and unearned premiums on a non-life insurance company's annual statement. However, statutory accounting principles were later modified to permit advance premiums to be accumulated in a suspense account and reported as a write-in liability on the annual statement. A company electing to use this alternative treatment would not report advance premiums in either written premiums or unearned premiums on its annual statement until the effective date of the underlying coverage.

premium as a nontaxable deposit until such time as coverage begins under the contract. Alternatively, these comments urged that the company be permitted to report only the advance premium (rather than the entire gross premium for the contract) in gross premiums written for the taxable year of receipt, and to report the remainder of the gross premium for the taxable year that includes the contract's effective date. These comments also indicated that companies generally do not deduct the full amount of premium acquisition expenses for the contract in the taxable year in which they receive advance premiums.

In response to comments, the final regulations permit an insurance company that receives part of the gross premium for an insurance contract prior to the effective date of the contract to report only the advance premium (rather than the full amount of the gross premium written for the contract) in gross premiums written for the taxable year of receipt. The remainder of the gross premium for the insurance contract is included in gross premiums written for the taxable year which includes the effective date of the contract. This method of reporting gross premiums written is available only if the company's deduction for premium acquisition expenses attributable to the contract does not exceed a limitation specified in the regulations, which is intended to ensure that a company does not deduct premium acquisition expenses attributable to an insurance contract more rapidly than the company includes premiums for the insurance contract in its gross premiums written. Companies that adopt this method of reporting gross premiums written must use this method for all insurance contracts with advance premiums.

Accident and Health Insurance Contracts

The proposed regulations have no special rules for determining gross premiums written with respect to accident and health insurance contracts. Several comments indicated that the longstanding practice of insurance companies that issue accident and health insurance contracts with installment premiums is to include amounts in gross premiums written for the taxable year in which the installment premiums become due under the contracts. These comments also stated that companies generally do not deduct premium acquisition expenses allocable to installment premiums not yet due or received with

respect to accident and health insurance contracts.

In response to comments, the final regulations permit a non-life insurance company that either issues or proportionally reinsures cancellable accident and health insurance contracts with installment premiums to report the installment premiums in gross premiums written for the earlier of the taxable year in which the installment premiums become due under the terms of the contract or the taxable year in which the installment premiums are received. This method of reporting gross premiums written for cancellable accident and health insurance contracts with installment premiums is available only if the company's deduction for premium acquisition expenses attributable to those contracts does not exceed the matching limitation specified in the regulations. Companies that adopt this method of reporting gross premiums written must use it for all cancellable accident and health insurance contracts with installment premiums.

Multi-year Contracts With Installment Premiums

The final regulations also provide an exception with respect to the reporting of gross premiums written for a multi-year insurance contract for which the gross premium is payable in installments over the effective period of the contract. Under the final regulations, a company may treat this type of multi-year insurance contract as a series of separate insurance contracts. The first insurance contract in the series will be treated as having an effective period of 12 months. Subsequent insurance contracts in the series will be treated as having an effective period equal to the lesser of 12 months or the remainder of the period for which the rates for insurance coverage are guaranteed in the multi-year insurance contract. This method of reporting gross premium written for a multi-year insurance contract with installment premiums is available only if the company's deduction for premium acquisition expenses attributable to the contract does not exceed the matching limitation specified in the regulations. Companies that adopt this method of reporting gross premiums written for a multi-year insurance contract must use it for all multi-year contracts with installment premiums.

Contracts That Give Rise to Life Insurance Reserves

Some insurance companies that are taxable under Part II of Subchapter L

issue or reinsure risks relating to guaranteed renewable accident and health insurance contracts or other contracts that give rise to "life insurance reserves" (as defined in section 816(b)). For these companies, section 832(b)(4) provides that unearned premiums includes the amount of the company's life insurance reserves, as determined under section 807. However, under section 832(b)(7), the unearned premiums for contracts giving rise to life insurance reserves are not reduced by 20 percent. Instead, an amount of otherwise deductible expenses equal to a percentage of the net premiums for the contracts must be capitalized and amortized as specified policy acquisition expenses under section 848.³ For purposes of determining the amount of specified policy acquisition expenses under section 848, a non-life insurance company computes net premiums for the contracts in accordance with section 811(a). See section 848(d)(2). Thus, with respect to contracts described in section 832(b)(7), a non-life insurance company does not take into account unpaid premiums attributable to insurance coverage not yet provided (such as deferred and uncollected premium installments) in determining the amount of specified policy acquisition expenses required to be amortized under section 848.

The proposed regulations do not provide special rules for determining gross premiums written with respect to contracts described in section 832(b)(7). Under the final regulations, a non-life insurance company that issues or reinsures the risks related to a contract described in section 832(b)(7) may report gross premiums written for the contract in the manner required for life insurance companies under sections 803 and 811. This method of reporting gross premiums written for contracts described in section 832(b)(7) is available only if the company also determines its deduction for premium acquisition expenses for the contracts in accordance with section 811(a), as adjusted by the amount required to be amortized under section 848 based on the net premiums of the contracts. Thus, the final regulations ensure that the rules for determining premium income and amortizing premium acquisition expenses for contracts described in section 832(b)(7) operate consistently, whether the issuing company is a non-life insurance company or a life insurance company.

³ Under section 848(e)(5), a contract that reinsures a contract subject to section 848 is treated in the same manner as the reinsured contract.

Fluctuating Risk Contracts

The method of reporting gross premiums written for certain insurance contracts covering fluctuating risks is reserved in the proposed regulations. Some comments requested that the final regulations not address the method of reporting gross premiums written for insurance contracts covering fluctuating risks, noting that the method of recording gross written premiums for these policies for annual statement reporting purposes was being considered by the NAIC as part of its project to codify statutory accounting principles. Subsequently, the NAIC issued guidance permitting an insurance company for annual statement purposes to report written premiums on workers' compensation policies (but not on other casualty contracts involving "fluctuating risks," such as commercial automobile liability and product liability policies) either on the effective date of the insurance contract or based on installment billings to the policyholder. By contrast, with respect to other types of casualty insurance policies, the NAIC reaffirmed the general rule that gross premiums with respect to these policies must be recorded on the annual statement on the effective date of the insurance contract.

The final regulations do not permit a non-life insurance company to report gross premiums written for a fluctuating risk contract based on installment billings to the policyholder. Rather, the final regulations require a company generally to report the gross premiums written for the contract for the earlier of the taxable year which includes the effective date of the contract or the year in which all or a portion of the premium for the contract is received, with special rules for advance premiums, cancellable accident and health contracts, multi-year insurance contracts, and contracts described in section 832(b)(7). The company reports any additional premiums resulting from an increase in risk exposure in gross premiums written for the taxable year in which the change in risk exposure occurs. Unless the increase in risk exposure is of temporary duration, the company determines the additional premium resulting from a change in risk exposure based on the remainder of the effective period of the contract.

Return Premiums

The proposed regulations define return premiums as amounts (other than policyholder dividends or claims and benefit payments) paid or credited to the policyholder in accordance with the terms of an insurance contract. Under

the final regulations, return premiums are amounts previously included in an insurance company's gross premiums written, which are refundable to the policyholder (or the ceding company with respect of a reinsurance agreement) if the amounts are fixed by the insurance contract and do not depend on the experience of the insurance company or the discretion of its management. This rule incorporates a specific definition of policyholder dividends.

The final regulations list a number of items which are included in return premiums, to the extent they have previously been included in gross premiums written. These items include: (1) amounts that are refundable due to policy cancellations or decreases in risk exposure during the effective period of an insurance contract; (2) the unearned portion of unpaid premiums for an insurance contract that is canceled or for which there is a decrease in risk exposure during its effective period; and (3) amounts that are either refundable or that reflect the unearned portion of unpaid premiums for an insurance contract, arising from the redetermination of the premium due to correction of posting or other similar errors.

In addition, the final regulation provides timing rules for the deduction of return premiums. If a contract is canceled, the return premium arising from that cancellation is deducted in the taxable year in which the contract is canceled. If there is a reduction in risk exposure under an insurance contract that gives rise to a return premium, such return premium is deductible in the taxable year in which the reduction in risk exposure occurs.

Retrospectively Rated Insurance Contracts

The proposed regulations provide that gross written premiums include an insurance company's estimate of additional premiums (retro debits) to be received with regard to the expired portion of a retrospectively rated insurance or reinsurance contract. The proposed regulations also provide that return premiums include an insurance company's estimate of amounts to be refunded to policyholders (retro credits) with regard to the expired portion of a retrospectively rated insurance or reinsurance contract. The proposed regulations, therefore, would modify the treatment of retro credits under § 1.832-4(a)(3)(ii) of the existing regulations, which treat retro credits as unearned premiums. At the option of the taxpayer, however, the proposed

regulations permit a company to continue to include gross retro credits (but not gross retro debits) in the amount of unearned premiums subject to the 20 percent reduction under section 832(b)(4)(B).

A variety of comments were received with respect to the treatment of retro debits and retro credits in the proposed regulations. Most comments approved of the proposed rule to modify the treatment of retro credits in § 1.832-4(a)(3)(ii) and, instead, to permit retro credits to be accounted for as part of return premiums. Some comments contended, however, that the method of netting retro debits and retro credits as an adjustment to unearned premiums was required under NAIC accounting rules, prior case law, and the Service's published rulings interpreting § 1.832-4(a)(3)(ii). These comments argued that the enactment of the 20 percent reduction rule in 1986 did not authorize the Service to change the items included in unearned premiums, including the historical treatment of retro debits and retro credits as part of unearned premiums. Other comments contended that retro debits (but not retro credits) should be discounted using the applicable discount factors for unpaid losses under section 846. These comments argued that there is a direct correlation between amounts reported by an insurance company as retro debits and the company's related liabilities for unpaid losses and unpaid loss adjustment expenses. Therefore, the comments urged that, to achieve proper matching of these items, a non-life insurance company should be permitted either to report retro debits as a subtraction from unearned premiums or to discount the retro debits using the applicable discount factors under section 846 for the related line of business.

The treatment of retro debits and retro credits in the proposed regulations was premised on the assumptions that retrospectively rated arrangements could qualify as insurance contracts for tax purposes, and that all amounts payable under such arrangements could be considered to have been paid for insurance coverage. The final regulations provide that gross premiums are amounts paid for insurance coverage. Similarly, unearned premiums and return premiums only include amounts included in gross written premiums. The final regulations also provide that retro credits are not included in unearned premiums, and retro debits cannot be subtracted from unearned premiums. The final regulations do not permit amounts

includable in gross premiums written to be discounted, regardless of when such amounts are paid to the insurance company.

The final regulations do not provide any inference as to whether some or all of a retrospective arrangement can qualify as an insurance contract, or as to whether or the extent to which amounts paid or payable to an insurance company with respect to a retrospective arrangement are for insurance coverage.

Premium Stabilization Reserves

Several comments asked for clarification of the treatment of premium stabilization reserves.⁴ As noted below, the final regulations provide that retro credits are not unearned premiums for Federal income tax purposes. Thus, retro credits added to premium stabilization reserves are not unearned premiums for Federal income tax purposes. The final regulations also provide that amounts withdrawn from a premium stabilization reserve to pay premiums are included in gross premiums written for the taxable year in which these amounts are withdrawn from the stabilization reserve for that purpose.

Unearned Premiums

The proposed regulations define unearned premiums as the portion of the gross premiums written that is attributable to future insurance coverage to be provided under an insurance or reinsurance contract. The final regulations generally retain the rules relating to unearned premiums. Consistent with the existing regulations under § 1.801-4(a), the final regulations provide that an insurance company must exclude from unearned premiums amounts attributable to the net value of risks reinsured with, or retroceded to, another insurance company. The final regulations also provide that unearned premiums do not include a liability established by an insurance company on its annual statement to cover premium deficiencies.

The proposed regulations provide that an insurance company may consider the incidence or pattern of the insured risks in determining the portion of the gross premium written that is attributable to the unexpired portion of the insurance coverage. The final regulations clarify

that, if the risk of loss under an insurance contract does not vary significantly over the effective period of the contract, the unearned premium attributable to the unexpired portion of the effective period of the contract is determined on a pro rata basis. However, if the risk of loss under an insurance contract varies significantly over the effective period of the contract, the insurance company may consider the pattern and incidence of the risk in determining the portion of gross premium which are attributable to the unexpired portion of the effective period of the contract, provided that the company maintains sufficient information to demonstrate that its method of computing unearned premiums accurately reflects the pattern and incidence of the risk for the insurance contract.

Effective Date and Transition Rules

Under the proposed regulations, the new rules apply to the determination of premiums earned for insurance contracts issued or renewed during taxable years beginning after the date on which final regulations are published in the **Federal Register**. Several comments requested that the regulations permit an insurance company to adopt the new rules for determining premiums earned as a change in method of accounting deemed made with the Commissioners' consent, with audit protection for prior years. These comments also urged that the insurance company be given the option of either implementing the change in method of accounting on a cut-off basis or spreading the section 481(a) adjustments resulting from the change over a number of years consistent with the Commissioner's general administrative procedures when a taxpayer files a request to change a method of accounting under section 446(e).

In response to these comments, the final regulations permit taxpayers to change their method of accounting for determining premiums earned to comply with the final regulations under the automatic change in method of accounting provisions of Rev. Proc. 99-49, 1999-52 I.R.B. 725, subject to certain limitations. A taxpayer makes the automatic change in method of accounting on its Federal income tax return for the first taxable year beginning after December 31, 1999. The scope limitations in section 4.02 of Rev. Proc. 99-49 do not apply to a taxpayer's automatic change in method of accounting pursuant to this regulation. The timely duplicate filing requirement in section 6.02 of Rev. Proc. 99-49 also

⁴ In Rev. Rul. 97-5, 1997-1 C.B. 136, the Service revoked Rev. Rul. 70-480, 1970-2 C.B. 142, which had held that amounts held by a non-life insurance company in a premium stabilization reserve funded by retro credits are not unearned premiums under section 832(b)(4). Rev. Rul. 97-5 reasoned that the assumption in Rev. Rul. 70-480 that stabilization reserves are part of the insurance company's surplus was erroneous.

does not apply to this change. If the taxpayer's method of computing earned premiums was an issue under consideration (within the meaning of section 3.09 of Rev. Proc. 99-49) on January 5, 2000, however, then the audit protection rule in section 7.01 of Rev. Proc. 99-49 does not apply to the taxpayer's change in method of accounting.

Special Analyses

It has been determined that this Treasury Decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and, because these regulations do not impose on small entities a collection of information requirement, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Therefore, a Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, the notice of proposed rulemaking preceding these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Drafting Information. The principal author of these regulations is Gary Geisler, Office of the Assistant Chief Counsel (Financial Institutions and Products), IRS. However, other personnel from the IRS and Treasury Department participated in their development.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

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

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

Par. 2. Section 1.832-4 is amended as follows:

1. Paragraph (a)(3) is revised.
2. Paragraphs (a)(4) and (a)(5) are redesignated as paragraphs (a)(13) and (a)(14).
3. New paragraphs (a)(4) through (a)(12) are added.

The additions and revisions read as follows:

§ 1.832-4 Gross income.

(a) * * *

(3) **Premiums earned.** The determination of premiums earned on insurance contracts during the taxable year begins with the insurance company's gross premiums written on insurance contracts during the taxable year, reduced by return premiums and premiums paid for reinsurance. Subject to the exceptions in sections 832(b)(7), 832(b)(8), and 833(a)(3), this amount is increased by 80 percent of the unearned premiums on insurance contracts at the end of the preceding taxable year, and is decreased by 80 percent of the unearned premiums on insurance contracts at the end of the current taxable year.

(4) **Gross premiums written—(i) In general.** Gross premiums written are amounts payable for insurance coverage. The label placed on a payment in a contract does not determine whether an amount is a gross premium written. Gross premiums written do not include other items of income described in section 832(b)(1)(C) (for example, charges for providing loss adjustment or claims processing services under administrative services or cost-plus arrangements). Gross premiums written on an insurance contract include all amounts payable for the effective period of the insurance contract. To the extent that amounts paid or payable with respect to an arrangement are not gross premiums written, the insurance company may not treat amounts payable to customers under the applicable portion of such arrangements as losses incurred described in section 832(b)(5).

(ii) **Items included.** Gross premiums written include—

(A) Any additional premiums resulting from increases in risk exposure during the effective period of an insurance contract;

(B) Amounts subtracted from a premium stabilization reserve to pay for insurance coverage; and

(C) Consideration in respect of assuming insurance liabilities under insurance contracts not issued by the taxpayer (such as a payment or transfer of property in an assumption reinsurance transaction).

(5) **Method of reporting gross premiums written—(i) In general.** Except as otherwise provided under this paragraph (a)(5), an insurance company reports gross premiums written for the earlier of the taxable year that includes the effective date of the insurance contract or the year in which the company receives all or a portion of the gross premium for the insurance contract. The effective date of the insurance contract is the date on which the insurance coverage provided by the

contract commences. The effective period of an insurance contract is the period over which one or more rates for insurance coverage are guaranteed in the contract. If a new rate for insurance coverage is guaranteed after the effective date of an insurance contract, the making of such a guarantee generally is treated as the issuance of a new insurance contract with an effective period equal to the duration of the new guaranteed rate for insurance coverage.

(ii) **Special rule for additional premiums resulting from an increase in risk exposure.** An insurance company reports additional premiums that result from an increase in risk exposure during the effective period of an insurance contract in gross premiums written for the taxable year in which the change in risk exposure occurs. Unless the increase in risk exposure is of temporary duration (for example, an increase in risk exposure under a workers' compensation policy due to seasonal variations in the policyholder's payroll), the company reports additional premiums resulting from an increase in risk exposure based on the remainder of the effective period of the insurance contract.

(iii) **Exception for certain advance premiums.** If an insurance company receives a portion of the gross premium for an insurance contract prior to the first day of the taxable year that includes the effective date of the contract, the company may report the advance premium (rather than the full amount of the gross premium for the contract) in gross premiums written for the taxable year in which the advance premium is received. An insurance company may adopt this method of reporting advance premiums only if the company's deduction for premium acquisition expenses for the taxable year in which the company receives the advance premium does not exceed the limitation of paragraph (a)(5)(vii) of this section. A company that reports an advance premium in gross premiums written under this paragraph (a)(5)(iii) takes into account the remainder of the gross premium written and premium acquisition expenses for the contract in the taxable year that includes the effective date of the contract. A company that adopts this method of reporting advance premiums must use the method for all contracts with advance premiums.

(iv) **Exception for certain cancellable accident and health insurance contracts with installment premiums.** If an insurance company issues or proportionally reinsures a cancellable accident and health insurance contract

(other than a contract with an effective period that exceeds 12 months) for which the gross premium is payable in installments over the effective period of the contract, the company may report the installment premiums (rather than the total gross premium for the contract) in gross premiums written for the earlier of the taxable year in which the installment premiums are due under the terms of the contract or the year in which the installment premiums are received. An insurance company may adopt this method of reporting installment premiums for a cancellable accident and health insurance contract only if the company's deduction for premium acquisition expenses for the first taxable year in which an installment premium is due or received under the contract does not exceed the limitation of paragraph (a)(5)(vii) of this section. A company that adopts this method of reporting installment premiums for a cancellable accident and health contract must use the method for all of its cancellable accident and health insurance contracts with installment premiums.

(v) *Exception for certain multi-year insurance contracts.* If an insurance company issues or proportionally reinsures an insurance contract, other than a contract described in paragraph (a)(5)(vi) of this section, with an effective period that exceeds 12 months, for which the gross premium is payable in installments over the effective period of the contract, the company may treat the insurance coverage provided under the multi-year contract as a series of separate insurance contracts. The first contract in the series is treated as having been written for an effective period of twelve months. Each subsequent contract in the series is treated as having been written for an effective period equal to the lesser of 12 months or the remainder of the period for which the rates for insurance coverage are guaranteed in the multi-year insurance contract. An insurance company may adopt this method of reporting premiums on a multi-year contract only if the company's deduction for premium acquisition expenses for each year of the multi-year contract does not exceed the limitation of paragraph (a)(5)(vii) of this section. A company that adopts this method of reporting premiums for a multi-year contract must use the method for all multi-year contracts with installment premiums.

(vi) *Exception for insurance contracts described in section 832(b)(7).* If an insurance company issues or reinsures the risks related to a contract described in section 832(b)(7), the company may

report gross premiums written for the contract in the manner required by sections 803 and 811(a) for life insurance companies. An insurance company may adopt this method of reporting premiums on contracts described in section 832(b)(7) only if the company also determines the deduction for premium acquisition costs for the contract in accordance with section 811(a), as adjusted by the amount required to be taken into account under section 848 in connection with the net premiums of the contract. A company that adopts this method of reporting premiums for a contract described in section 832(b)(7) must use the method for all of its contracts described in that section.

(vii) *Limitation on deduction of premium acquisition expenses.* An insurance company's deduction for premium acquisition expenses (for example, commissions, state premium taxes, overhead reimbursements to agents or brokers, and other similar amounts) related to an insurance contract is within the limitation of this paragraph (a)(5)(vii) if—

(A) The ratio obtained by dividing the sum of the company's deduction for premium acquisition expenses related to the insurance contract for the taxable year and previous taxable years by the total premium acquisition expenses attributable to the insurance contract; does not exceed

(B) The ratio obtained by dividing the sum of the amounts included in gross premiums written with regard to the insurance contract for the taxable year and previous taxable years by the total gross premium written for the insurance contract.

(viii) *Change in method of reporting gross premiums.* An insurance company that adopts a method of accounting for gross premiums written and premium acquisition expenses described in paragraph (a)(5)(iii), (iv), (v), or (vi) of this section must continue to use the method to report gross premiums written and premium acquisition expenses unless the company obtains the consent of the Commissioner to change to a different method under section 446(e) and § 1.446-1(e).

(6) *Return premiums—(i) In general.* An insurance company's liability for return premiums includes amounts previously included in an insurance company's gross premiums written, which are refundable to a policyholder or ceding company, provided that the amounts are fixed by the insurance contract and do not depend on the experience of the insurance company or the discretion of its management.

(ii) *Items included.* Return premiums include amounts—

(A) Which were previously paid and become refundable due to policy cancellations or decreases in risk exposure during the effective period of an insurance contract;

(B) Which reflect the unearned portion of unpaid premiums for an insurance contract that is canceled or for which there is a decrease in risk exposure during its effective period; or

(C) Which are either previously paid and refundable or which reflect the unearned portion of unpaid premiums for an insurance contract, arising from the redetermination of a premium due to correction of posting or other similar errors.

(7) *Method of reporting return premiums.* An insurance company reports the liability for a return premium resulting from the cancellation of an insurance contract for the taxable year in which the contract is canceled. An insurance company reports the liability for a return premium attributable to a reduction in risk exposure under an insurance contract for the taxable year in which the reduction in risk exposure occurs.

(8) *Unearned premiums—(i) In general.* The unearned premium for a contract, other than a contract described in section 816(b)(1)(B), generally is the portion of the gross premium written that is attributable to future insurance coverage during the effective period of the insurance contract. However, unearned premiums held by an insurance company with regard to the net value of risks reinsured with other solvent companies (whether or not authorized to conduct business under state law) are subtracted from the company's unearned premiums. Unearned premiums also do not include any additional liability established by the insurance company on its annual statement to cover premium deficiencies. Unearned premiums do not include an insurance company's estimate of its liability for amounts to be paid or credited to a customer with regard to the expired portion of a retrospectively rated contract (retro credits). An insurance company's estimate of additional amounts payable by its customers with regard to the expired portion of a retrospectively rated contract (retro debits) cannot be subtracted from unearned premiums.

(ii) *Special rules for unearned premiums.* For purposes of computing "premiums earned on insurance contracts during the taxable year" under section 832(b)(4), the amount of unearned premiums includes—

(A) Life insurance reserves (as defined in section 816(b), but computed in accordance with section 807(d) and sections 811(c) and (d));

(B) In the case of a mutual flood or fire insurance company described in section 832(b)(1)(D) (with respect to contracts described in that section), the amount of unabsorbed premium deposits that the company would be obligated to return to its policyholders at the close of the taxable year if all its insurance contracts were terminated at that time;

(C) In the case of an interinsurer or reciprocal underwriter that reports unearned premiums on its annual statement net of premium acquisition expenses, the unearned premiums on the company's annual statement increased by the portion of premium acquisition expenses allocable to those unearned premiums; and

(D) In the case of a title insurance company, its discounted unearned premiums (computed in accordance with section 832(b)(8)).

(9) *Method of determining unearned premiums.* If the risk of loss under an insurance contract does not vary significantly over the effective period of the contract, the unearned premium attributable to the unexpired portion of the effective period of the contract is determined on a pro rata basis. If the risk of loss varies significantly over the effective period of the contract, the insurance company may consider the pattern and incidence of the risk in determining the portion of the gross premium that is attributable to the unexpired portion of the effective period of the contract. An insurance company that uses a method of computing unearned premiums other than the pro rata method must maintain sufficient information to demonstrate that its method of computing unearned premiums accurately reflects the pattern and incidence of the risk for the insurance contract.

(10) *Examples.* The provisions of paragraphs (a)(4) through (a)(9) of this section are illustrated by the following examples:

Example 1. (i) IC is a non-life insurance company which, pursuant to section 843, files its returns on a calendar year basis. IC writes a casualty insurance contract that provides insurance coverage for a one-year period beginning on July 1, 2000 and ending on June 30, 2001. IC charges a \$500 premium for the insurance contract, which may be paid either in full by the effective date of the contract or in quarterly installments over the contract's one year term. The policyholder selects the installment payment option. As of December 31, 2000, IC collected \$250 of installment premiums for the contract.

(ii) The effective period of the insurance contract begins on July 1, 2000 and ends on June 30, 2001. For the taxable year ending December 31, 2000, IC includes the \$500 gross premium, based on the effective period of the contract, in gross premiums written under section 832(b)(4)(A). IC's unearned premium with respect to the contract was \$250 as of December 31, 2000. Pursuant to section 832(b)(4)(B), to determine its premiums earned, IC deducts \$200 ($\$250 \times .8$) for the insurance contract at the end of the taxable year.

Example 2. (i) The facts are the same as *Example 1*, except that the insurance contract has a stated term of 5 years. On each contract anniversary date, IC may adjust the rate charged for the insurance coverage for the succeeding 12 month period. The amount of the adjustment in the charge for insurance coverage is not substantially limited under the insurance contract.

(ii) Under paragraph (a)(5)(i) of this section, IC is required to report gross premiums written for the insurance contract based on the effective period for the contract. The effective period of the insurance contract is the period for which a rate for insurance coverage is guaranteed in the contract. Although the insurance contract issued by IC has a stated term of 5 years, a rate for insurance coverage is guaranteed only for a period of 12 months beginning with the contract's effective date and each anniversary date thereafter. Thus, for the taxable year ending December 31, 2000, IC includes the \$500 gross premium for the 12 month period beginning with the contract's effective date in gross premiums written. IC's unearned premium with respect to the contract was \$250 as of December 31, 2000. Pursuant to section 832(b)(4)(B), to determine its premiums earned, IC deducts \$200 ($\$250 \times .8$) for the insurance contract at the end of the taxable year.

Example 3. (i) The facts are the same as *Example 1*, except that coverage under the insurance contract begins on January 1, 2001 and ends on December 31, 2001. On December 15, 2000, IC collects the first \$125 premium installment on the insurance contract. For the taxable year ended December 31, 2000, IC deducts \$20 of premium acquisition expenses related to the insurance contract. IC's total premium acquisition expenses, based on the insurance contract's \$500 gross premium, are \$80.

(ii) Under paragraph (a)(5)(iii) of this section, IC may elect to report only the \$125 advance premium (rather than the contract's \$500 gross premium) in gross premiums written for the taxable year ended December 31, 2000, provided that IC's deduction for the premium acquisition expenses related to the insurance contract does not exceed the limitation in paragraph (a)(5)(vii). IC's deduction for premium acquisition expenses is within this limitation only if the ratio of the insurance contract's premium acquisition expenses deducted for the taxable year and any previous taxable year to the insurance contract's total premium acquisition expenses does not exceed the ratio of the amounts included in gross premiums written for the taxable year and any previous taxable year for the contract to the total gross premium written for the contract.

(iii) For the taxable year ended December 31, 2000, IC deducts \$20 of premium acquisition expenses related to the insurance contract. This deduction represents 25% of the total premium acquisition expenses for the insurance contract ($\$20/\$80 = 25\%$). This ratio does not exceed the ratio of the \$125 advance premium to the insurance contract's \$500 gross premium ($\$125/\$500 = 25\%$). Therefore, under paragraph (a)(5)(iii) of this section, IC may elect to report only the \$125 advance premium (rather than the \$500 gross premium) in gross premiums written for the taxable year ending December 31, 2000. IC reports the balance of the gross premium for the insurance contract (\$375) and deducts the remaining premium acquisition expenses (\$60) for the insurance contract in the taxable year ending December 31, 2001.

Example 4. (i) The facts are the same as *Example 3*, except that for the taxable year ending December 31, 2000, IC deducts \$60 of premium acquisition expenses related to the insurance contract.

(ii) For the taxable year ended December 31, 2000, IC deducted 75% of total premium acquisition expenses for the insurance contract ($\$60/\$80 = 75\%$). This ratio exceeds the ratio of the \$125 advance premium to the \$500 gross premium ($\$125/\$500 = 25\%$). Because IC's deduction for premium acquisition expenses allocable to the contract exceeds the limitation in paragraph (a)(5)(vii) of this section, paragraph (a)(5)(i) of this section requires IC to report the \$500 gross premium in gross premiums written for the taxable year ending December 31, 2000. IC's unearned premium with respect to the contract was \$500 as of December 31, 2000. Pursuant to section 832(b)(4)(B), to determine its premiums earned, IC deducts \$400 ($\$500 \times .8$) for the insurance contract at the end of the taxable year.

Example 5. (i) IC is a non-life insurance company which, pursuant to section 843, files its returns on a calendar year basis. On August 1, 2000, IC issues a one-year cancellable accident and health insurance policy to X, a corporation with 80 covered employees. The gross premium written for the insurance contract is \$320,000. Premiums are payable in monthly installments. As of December 31, 2000, IC has collected \$150,000 of installment premiums from X. For the taxable year ended December 31, 2000, IC has paid or incurred \$21,000 of premium acquisition expenses related to the insurance contract. IC's total premium acquisition expenses for the insurance contract, based on the \$320,000 gross premium, are \$48,000.

(ii) Under paragraph (a)(5)(iv) of this section, IC may elect to report only the \$150,000 of installment premiums (rather than the \$320,000 estimated gross premium) in gross premiums written for the taxable year ended December 31, 2000, provided that its deduction for premium acquisition expenses allocable to the insurance contract does not exceed the limitation in paragraph (a)(5)(vii). For the taxable year ended December 31, 2000, IC deducts \$21,000 of premium acquisition expenses related to the insurance contract, or 43.75% of total premium acquisition expenses for the insurance contract ($\$21,000/\$48,000 = 43.75\%$). This ratio does not exceed

the ratio of installment premiums to the gross premium for the contract (\$150,000/\$320,000 = 46.9%). Therefore, under paragraph (a)(5)(iv) of this section, IC may elect to report only \$150,000 of installment premiums for the insurance contract (rather than \$320,000 of gross premium) in gross premiums written for the taxable year ending December 31, 2000.

Example 6. (i) IC is a non-life insurance company which, pursuant to section 843, files its returns on a calendar year basis. On July 1, 2000, IC issues a one-year workers' compensation policy to X, an employer. The gross premium for the policy is determined by applying a monthly rate of \$25 to each of X's employees. This rate is guaranteed for a period of 12 months, beginning with the effective date of the contract. On July 1, 2000, X has 1,050 employees. Based on the assumption that X's payroll would remain constant during the effective period of the contract, IC determines an estimated gross premium for the contract of \$315,000 ($1,050 \times \$25 \times 12 = \$315,000$). The estimated gross premium is payable by X in equal monthly installments. At the end of each calendar quarter, the premiums payable under the contract are adjusted based on an audit of X's actual payroll during the preceding three months of coverage.

(ii) Due to an expansion of X's business in 2000, the actual number of employees covered under the contract during each month of the period between July 1, 2000 and December 31, 2000 is 1,050 (July), 1,050 (August), 1,050 (September), 1,200 (October), 1,200 (November), and 1,200 (December). The increase in the number of employees during the year is not attributable to a temporary or seasonal variation in X's business activities and is expected to continue for the remainder of the effective period of the contract.

(iii) Under paragraph (a)(5)(i) of this section, IC is required to report gross premiums written for the insurance contract based on the effective period of the contract. The effective period of X's contract is based on the 12 month period for which IC has guaranteed rates for insurance coverage. Under paragraph (a)(5)(ii), IC must also report the additional premiums resulting from the change in risk exposure under the contract for the taxable year in which the change in such exposure occurs. Unless the change in risk exposure is of temporary duration, the additional gross premiums are included in gross premiums written for the remainder of the effective period of the contract. Thus, for the taxable year ending December 31, 2000, IC reports gross premiums written of \$348,750 with respect to the workers' compensation contract issued to X, consisting of the sum of the initial gross premium for the contract (\$315,000) plus the additional gross premium attributable to the 150 employees added to X's payroll who will be covered during the last nine months of the contract's effective period ($150 \times \$25$ (monthly premium) $\times 9 = \$33,750$). IC's unearned premium with respect to the contract was \$180,000 as of December 31, 2000, which consists of the sum of the remaining portion of the original gross premium ($\$315,000 \times 6/12 = \$157,500$), plus

the additional premiums resulting from the change in risk exposure ($\$33,750 \times 6/9 = \$22,500$) that are allocable to the remaining six months of the contract's effective period. Pursuant to section 832(b)(4)(B), to determine its premiums earned, IC deducts \$144,000 ($\$180,000 \times .8$) for the insurance contract at the end of the taxable year.

Example 7. (i) The facts are the same as **Example 6**, except that the increase in the number of X's employees for the period ending December 31, 2000 is attributable to a seasonal variation in X's business activity.

(ii) Under paragraph (a)(5)(ii) of this section, for the taxable year ending December 31, 2000, IC reports gross premiums written of \$326,500, consisting of the sum of the initial gross premium for the contract (\$315,000) plus the additional premium attributable to the temporary increase in risk exposure during the taxable year ($150 \times \$25 \times 3 = \$11,250$). The unearned premium that is allocable to the remaining six months of the effective period of the contract is \$157,500. Pursuant to section 832(b)(4)(B), to determine its premiums earned, IC deducts \$126,000 ($\$157,500 \times .8$) for the insurance contract at the end of the taxable year.

Example 8. (i) IC, a non-life insurance company, issues a noncancellable accident and health insurance contract (other than a qualified long-term care insurance contract, as defined in section 7702B(b)) to A, an individual, on July 1, 2000. The contract has an entry-age annual premium of \$2,400, which is payable by A in equal monthly installments of \$200 on the first day of each month of coverage. IC incurs agents' commissions, premium taxes, and other premium acquisition expenses equal to 10% of the gross premiums received for the contract. As of December 31, 2000, IC has collected \$1,200 of installment premiums for the contract.

(ii) A noncancellable accident and health insurance contract is a contract described in section 832(b)(7). Thus, under paragraph (a)(5)(vi) of this section, IC may report gross premiums written in the manner required for life insurance companies under sections 803 and 811. Accordingly, for the taxable year ending December 31, 2000, IC may report gross premiums written of \$1,200, based on the premiums actually received on the contract. Pursuant to section (a)(5)(vi) of this section, IC deducts a total of \$28 of premium acquisition costs for the contract, based on the difference between the acquisition costs actually paid or incurred under section 811(a) ($\$1,200 \times .10 = \120) and the amount required to be taken into account under section 848 in connection with the net premiums for the contract ($\$1,200 \times .077 = \92).

(iii) Under paragraph (a)(8)(ii)(A) of this section, IC includes the amount of life insurance reserves (as defined in section 816(b), but computed in accordance with section 807(d) and sections 811(c) and (d)) in unearned premiums under section 832(b)(4)(B). Section 807(d)(3)(A)(iii) requires IC to use a two-year preliminary term method to compute the amount of life insurance reserves for a noncancellable accident and

health insurance contract (other than a qualified long-term care contract). Under this tax reserve method, no portion of the \$1,200 gross premium received by IC for A's contract is allocable to future insurance coverage. Accordingly, for the taxable year ending December 31, 2000, no life insurance reserves are included in IC's unearned premiums under section 832(b)(4)(B) with respect to the contract.

Example 9. (i) IC, a non-life insurance company, issues an insurance contract with a twelve month effective period for \$1,200 on December 1, 2000. Immediately thereafter, IC reinsures 90% of its liability under the insurance contract for \$900 with IC-2, an unrelated and solvent insurance company. On December 31, 2000, IC-2 has an \$825 unearned premium with respect to the reinsurance contract it issued to IC. In computing its earned premiums, pursuant to section 832(b)(4)(B), IC-2 deducts \$660 of unearned premiums ($\$825 \times .8$) with respect to the reinsurance contract.

(ii) Under paragraph (a)(8)(i) of this section, unearned premiums held by an insurance company with regard to the net value of the risks reinsured in other solvent companies are deducted from the ceding company's unearned premiums taken into account for purposes of section 832(b)(4)(B). If IC had not reinsured 90% of its risks, IC's unearned premium for the insurance contract would have been \$1,100 ($\$1,200 \times 11/12$) and IC would have deducted \$880 ($\$1,100 \times .8$) of unearned premiums with respect to such contract. However, because IC reinsured 90% of its risks under the contract with IC-2, as of December 31, 2000, the net value of the risks retained by IC for the remaining 11 months of the effective period of the contract is \$110 ($\$1,100 - \990). For the taxable year ending December 31, 2000, IC includes the \$1,200 gross premium in its gross premiums written and deducts the \$900 reinsurance premium paid to IC-2 under section 832(b)(4)(A). Pursuant to section 832(b)(4)(B), to determine its premiums earned, IC deducts \$88 ($\$110 \times .8$) for the insurance contract at the end of the taxable year.

(11) **Change in method of accounting—(i) In general.** A change in the method of determining premiums earned to comply with the provisions of paragraphs (a)(3) through (a)(10) of this section is a change in method of accounting for which the consent of the Commissioner is required under section 446(e) and § 1.446-1(e).

(ii) **Application.** For the first taxable year beginning after December 31, 1999, a taxpayer is granted consent of the Commissioner to change its method of accounting for determining premiums earned to comply with the provisions of paragraphs (a)(3) through (a)(10) of this section. A taxpayer changing its method of accounting in accordance with this section must follow the automatic change in accounting provisions of Rev. Proc. 99-49, 1999-52 I.R.B. 725 (see § 601.601(d)(2) of this chapter), except that—

(A) The scope limitations in section 4.02 of Rev. Proc. 99-49 shall not apply;

(B) The timely duplicate filing requirement in section 6.02(2) of Rev. Proc. 99-49 shall not apply; and

(C) If the method of accounting for determining premiums earned is an issue under consideration within the meaning of section 3.09 of Rev. Proc. 99-49 as of January 5, 2000, then section 7.01 of Rev. Proc. 99-49 shall not apply.

(12) *Effective date.* Paragraphs (a)(3) through (a)(11) of this section are applicable with respect to the determination of premiums earned for taxable years beginning after December 31, 1999.

* * * * *

Robert E. Wenzel,
Deputy Commissioner of Internal Revenue.

Approved: December 23, 1999.

Jonathan Talisman,
Acting Assistant Secretary of the Treasury.
[FR Doc. 00-13 Filed 1-5-00; 8:45 am]

BILLING CODE 4830-01-U

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 177

[CGD01-99-193]

Drawbridge Operation Regulations: Saugus River, MA

AGENCY: Coast Guard, DOT.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, First Coast Guard District has issued a temporary deviation from the existing drawbridge regulations for the Fox Hill SR107 Bridge, mile 2.5, across the Saugus River between Saugus and Lynn, Massachusetts. This deviation allows the bridge owner to open the bridge only three times each day for vessel traffic. This deviation is necessary to facilitate repairs to replace structural steel, floor beams and the wearing surface at the bridge.

DATES: This deviation is effective from January 3, 2000 to March 2, 2000.

FOR FURTHER INFORMATION CONTACT: Mr. John McDonald, Project Officer, First Coast Guard District, (617) 223-8364.

SUPPLEMENTARY INFORMATION: The Fox Hill SR107 Bridge has a vertical clearance of 6 feet at mean high water and 16 feet at mean low water.

The existing regulations for the Fox Hill SR107 Bridge in 33 CFR 117.618(c) require the bridge to open on signal;

except that, from October 1 through May 31, 7 p.m. to 5 a.m., daily, and all day on December 25 and January 1, the draw shall open as soon as possible, but not more than one one-hour, after notice is given to the drawtenders either at the bridge during the time the drawtenders are on duty or by calling the number posted at the bridge.

The bridge owner, Massachusetts Highway Department (MHD), asked the Coast Guard to allow the bridge to open on signal, only, at 6 a.m., 2 p.m., and 6 p.m., from January 3, 2000, through March 2, 2000.

The purpose of this temporary deviation is to facilitate necessary repairs to the bridge. Structural steel, floor beams, and the bridge wearing surface will be replaced during the 60 day repair period. The bridge can not open for vessel traffic during the replacement of the above components. Vessels that can pass under the bridge without an opening may do so at all times.

In accordance with 33 CFR 117.35(c), this work will be performed with all due speed in order to return the bridge to normal operation as soon as possible. This deviation is authorized under 33 CFR 117.35.

Dated: December 17, 1999.

R.M. Larrabee,
Rear Admiral, U.S. Coast Guard Commander,
First Coast Guard District.

[FR Doc. 00-257 Filed 1-5-00; 8:45 am]

BILLING CODE 4910-15-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Parts 154 and 155

[USCG-1998-3350]

Review of Cap Increases; Response Plans for Marine Transportation- Related (MTR) Facilities and Tank Vessels

AGENCY: Coast Guard, DOT.

ACTION: Notice of decision.

SUMMARY: Coast Guard response plan regulations contain requirements for on-water oil recovery capacity (referred to as caps). These caps were scheduled to increase by 25 percent on February 18, 1998, provided the Coast Guard completed a review of the cap increases. The Coast Guard has completed its review and the 25 percent increase for on-water mechanical recovery will take effect 90 days from the date of this notice. The Coast Guard will consider a 2003 cap for mechanical on-water

removal capability and requirements for other removal technologies in a subsequent notice of proposed rulemaking.

DATES: The scheduled cap increase for on-water mechanical recovery requirements will take effect on April 5, 2000.

ADDRESSES: The Docket Management Facility maintains the public docket for this notice (USCG-1998-3350). The Response Plan Equipment Cap Review (Cap Review) is part of the docket and is available for inspection or copying at room PL-401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC 20590-0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at <http://dms.dot.gov>. The Cap Review is also available for examination on the Vessel Response Plan Internet site at <http://www.uscg.mil/vrp>.

FOR FURTHER INFORMATION CONTACT: For questions on this notice, call Lieutenant Commander John Caplis, Office of Response (G-MOR), Coast Guard, telephone 202-267-6922 or by e-mail at JCaplis@comdt.uscg.mil. For questions on viewing materials in the docket, call Dorothy Walker, Chief, Dockets, Department of Transportation, telephone 202-366-9329.

SUPPLEMENTARY INFORMATION:

Regulatory History

In 1996, the Coast Guard published two final rules entitled "Vessel Response Plans" (61 FR 1052, January 12, 1996) and "Response Plans for Marine Transportation-Related Facilities" (61 FR 7890, February 29, 1996). Those rules finalized the 1993 interim rules (58 FR 7330, February 5, 1993, and 58 FR 7376, February 5, 1993, for Marine Transportation-Related Facilities and Vessels, respectively) and are located in the Code of Federal Regulations (CFR) in 33 CFR parts 154 and 155. 33 CFR 154.1045(m) and 155.1050(o) contain requirements for on-water oil recovery capacity (referred to as caps) that an owner or operator must ensure is available, through contract or other approved means, in planning for a worst case discharge. These caps were established taking into account 1993 technology, deployment capability, and availability of response resources.

The 1993 and 1996 rules established a 1998 cap, a 25 percent increase from the 1993 levels, as a target for increasing response capabilities. This increase was endorsed by the Vessel Response Plan Negotiated Rulemaking Committee as an incentive to expand response

capabilities within the United States to an obtainable and desirable level by 1998. The Coast Guard concurred with the recommendation from the Committee, adopted for both vessel and facility rules, to review the proposed cap increase before the increase would be implemented to determine if it remains practicable.

On January 27, 1998, we published a "Request for Comment" notice (63 FR 3861) with regard to the Cap Review and stated that the 1993 caps would remain in effect pending the results of that review and that the cap increases as originally scheduled would not be implemented until the review was complete.

On June 24, 1998, we published a Notice of Meetings (63 FR 34500) that announced three public workshops to solicit comments on the potential changes to the equipment requirements within the response plan regulations (33 CFR parts 154 and 155) for mechanical recovery, dispersants, and other spill removal technologies. These workshops were held in Oakland, CA, on July 24, 1998, with 55 attendees; in Houston, TX, on August 19, 1998, with 71 attendees; and in Washington, DC, on September 16, 1998, with 49 attendees. We completed the Response Plan Equipment Cap Review (Cap Review) in May 1999, placed it in the docket and made it available on-line on July 26, 1999. The Cap Review can be viewed on the Internet at the sites listed in the ADDRESSES section.

Discussion of Comments

The Coast Guard received 25 written comments in response to a "Request for Comment" published in the *Federal Register* on January 27, 1998 (63 FR 3861). In addition, we recorded 41 verbal comments regarding mechanical recovery caps in the summaries for three public workshops which were conducted in the summer of 1998. We received 37 letters in response to the workshops. These letters were placed in the public docket. In general, public comment regarding an increase in the mechanical recovery equipment is divided, with numerous comments received both for and against such an increase.

Current Equipment Inventories

Five comments stated that the cap increase is practicable since equipment inventories already exceed the increased cap requirements. We agree that equipment inventories are sufficient throughout the nation to support an increase in the equipment required to be ensured available by any individual

planholder. The Cap Review indicates that only a few port areas do not have aggregate equipment stockpiles significantly in excess of the increased cap requirements, and that from an availability standpoint, the caps are practicable.

Five comments suggested that the cap increase was not necessary because the additional mechanical recovery equipment already exists and is sufficient to respond to most anticipated spills. We disagree that the mere existence of surplus equipment in the regional response inventories negates the need for an increase in an individual planholder's equipment requirements. The Oil Pollution Act of 1990 (Pub. L. 101-380) (OPA 90) directed that response plans should prepare for, to the maximum extent possible, a response to a worst case discharge. Scheduled increases in recovery capability were intended and remain necessary to close the gap between the equipment required to be ensured available by a planholder and that amount which would be necessary to respond to a worst case discharge. The equipment requirements, however, should not be elevated to the entire worst case discharge amount simply because aggregate regional inventories are now available at those levels. This is because the capped amounts also attempt to discount for operational considerations, such as limitations regarding the effective deployment of equipment during the first 72 hours of the response. Total availability within regional equipment inventories is only one of many factors that must be considered in determining what is a practicable equipment cap.

Two comments stated that the cap increases are not necessary because free market forces have generated the large equipment inventories as a result of competition between the oil spill removal organizations (OSROs). We agree that competition between OSROs, who have individually acquired enough resources each to meet the cap requirements, has resulted in the accumulation of large aggregate equipment inventories in each regional and port area. We determined that these accumulations are suitable and necessary, as the caps rely on these excess stockpiles to come into play in the event of a catastrophic spill, such as a worst case discharge from a large tankship. The cap requirements reflect the limitations of a planholder's ability to deploy and effectively manage equipment during the initial phase of a response. As such, the capped equipment tiers are designed to ensure

an increasing availability of equipment during that first 72 hours of a response. If a worst case discharge were to occur from a large tank vessel or facility, however, the equipment needed to respond past that initial 72-hour period is likely to exceed the cap levels. As spill management team and incident command systems are firmly established, their ability to effectively deploy and manage equipment should also surpass the capped levels. The response will need to draw upon those aggregate inventories in excess of the caps to ensure the response can continue to expand in scope beyond that initial 72-hour period.

Five comments supported the cap increase, stating that the equipment has already been obtained in anticipation of the scheduled increase, and that a failure to implement the new requirements will result in additional equipment being sold off or put out of service. We agree that a failure to implement a cap increase may result in declining equipment inventories. If the equipment caps are not increased, economic pressures may force a sell-off of un-mandated equipment which may result in a lessening of our overall response capability.

Three comments stated that the evaluation of equipment stockpiles must account for the fact that tiered response requirements allow equipment to be brought in from other regions and that this "cascading" of equipment may strip the providing area of critical response capability. This was cited as a major concern where ports and stockpiles are separated by hundreds of miles. We acknowledge that the cascading of equipment out of a region may impact the ability of a particular OSRO or planholder to respond in that port. This possibility reinforces the need to maintain aggregate levels of response equipment within a port area that significantly exceed the cap requirements. These surplus inventories will ensure that a viable response capability is retained within one region when some of its resources are cascaded into another region in response to a discharge.

Four comments stated that the equipment required under the current cap has been sufficient to respond to all spills since the passage of OPA 90 and is also sufficient to respond to the current risk of spills. Two comments stated the Cap Review should evaluate responses to actual incidents in order to determine whether more response equipment is necessary or not. The Coast Guard has the responsibility for issuing regulations that require a

planholder to respond, to the maximum extent possible, a worst case discharge. The fact that a worst case discharge from a large tank vessel (such as an ultra-large crude carrier) or large tank facility has not occurred in the United States since the passage of OPA 90 does not mean that such a discharge could not happen. Nor does it change the intent of Congress that industry develop response plans that prepare for, to the maximum extent possible, a worst case discharge. While spill tendencies since the passage of OPA 90 do show a decline in large oil spill events, the risk of future spills still includes the contingency of a worst case discharge. Evaluating the cap increase with regard to the smaller incidents that have occurred since the passage of the OPA 90 does not satisfy the intent of Congress in preparing for a worst case discharge.

One comment stated that the cap increase must be based upon a determination that the resources currently required are not sufficient to remove a worst case discharge. One comment stated the caps should be increased because the current cap levels represent a very small percentage of the overall capability required to respond to a worst case discharge from a large tankship. The Cap Review evaluated the scheduled increase to determine if it required resources that exceeded the amount necessary to respond to a worst case discharge. This evaluation was based on the planning assumptions and calculations contained within 33 CFR part 154, Appendix C and 33 CFR part 155, Appendix B, and compared the increased caps against the worst case discharge volumes found within the Area Contingency Plans throughout the country. The comparison revealed that the increase is still far below the levels of equipment that would be necessary to respond to a worst case discharge (see Cap Review Tables 3-9, A-C for more information).

Regional, State, and Local Issues

Two comments stated that the caps should be consistent with State requirements. One comment stated that California has already mandated a 25 percent increase in State equipment caps. The State of California Office of Spill Prevention and Response (OSPR) commented that a 25 percent increase in the planning standards for on-water oil recovery volumes was both feasible and necessary to meet the best achievable protection of the California coast. The State of Alaska Department of Environmental Conservation (ADEC) has also commented that their State

requirements exceed the existing cap requirements and that the Federal caps should increase in order to strengthen and stabilize equipment inventories. Another comment stated that the U.S. Environmental Protection Agency (EPA) has already implemented the 25 percent increase in the caps for the OPA 90 response plans required under their regulations. We agree that response requirements should be as consistent as possible across Federal agency and State requirements. Increasing the national response standards for caps will promote consistency between EPA, Coast Guard, and State cap requirements. The State of California OSPR, Alaska ADEC and the EPA have all commented that the caps should increase, both for reasons of ensuring consistency, as well as for ensuring an adequate level of national preparedness. We will continue to work with the Federal and State agencies to ensure consistency and as much harmony between requirements as possible.

Three comments recommended that the mechanical recovery equipment caps should be flexible to accommodate local priorities and concerns and should be developed regionally. Another comment stated that the cap increases should not be applicable in areas shown to have lower levels of risk. We disagree. The equipment caps were designed to establish on a national level a minimum baseline for response equipment that would be ensured available for any given location. Similarly, the cap increase was designed to raise the baseline to provide consistency on a national basis. The use of a national standard does not impede the development of response inventories that are reflective of regional and local needs or risks. Market forces will shape a region's response equipment inventory irrespective of the regulatory baseline. The Gulf Coast region is an example where market forces have built a substantially larger stock of equipment than most other regions of the country. This larger equipment stockpile is also reflective of the higher regional risk of an oil spill. Conversely, the response plan rules allow for situations where market forces dictate that the sustainable level of response equipment in an area falls below the national baseline. Under these circumstances, planholders may request an alternative planning criteria from the Coast Guard.

One comment suggested that Area Committees should establish the equipment requirements for each region. We disagree. The National Contingency Plan charges Area Committees with many responsibilities as outlined in the

Section 311(j)(4) of the Federal Water Pollution Control Act (Pub. L. 92-500). These responsibilities include, but are not limited to, developing an area contingency plan, response strategies and procedures, joint contingency plans, agency responsibilities, and the identification of sensitive resources. Area Committee's do not have the responsibility for establishing response plan equipment requirements, nor have they been delegated that authority by the President under the Federal Water Pollution Control Act.

One comment stated that the Coast Guard should evaluate the net environmental benefit in each regional area to determine if any equipment increases are necessary. Before the adoption of the vessel and facility response plan requirements, we conducted a regulatory assessment that determined an acceptable level of benefits would result from an increase in the equipment caps as a national planning standard. In addition, the response plan rules charge the Coast Guard with conducting a review to determine whether an equipment cap increase is practicable. Our determination of practicability has included an evaluation of technological, operational, and economic feasibility. Net environmental benefit studies are better suited for evaluating area specific response strategies and are beyond the scope of the analysis needed to evaluate the cap increase as a national planning standard.

One comment stated that the Coast Guard should use the Preparedness for Response Exercise Program (PREP) as an evaluation tool in assessing the need for increased equipment caps at local and regional levels throughout the United States. We disagree. PREP was developed as a workable, voluntary program that would facilitate the planholders' compliance with the exercise requirements of OPA 90. PREP was designed to test preparedness of the Area, vessel, or facility level, but was not designed to establish regional or national equipment requirements. While government-led exercises do occasionally test an area contingency plan's worst case discharge scenario, the resultant tabletop exercise is not suitable for determining the baseline of equipment that should be ensured available by all planholders. A PREP exercise cannot test the adequacy of a national equipment cap in the isolation of a single simulated response. Nor would a series of such exercises held around the country be suitable for evaluating the sufficiency of an increased national planning standard.

High-rate Removal Technology

The Texas General Land Office stated that the addition of high-rate removal technologies is preferred to an increase in mechanical recovery systems, indicating that the surplus of mechanical equipment stationed on the Gulf Coast already exceeds the scheduled increase. We agree that mechanical stockpiles on the Gulf Coast already exceed the cap increase. However, the cap increase is necessary to raise the individual planholder's level of preparedness. The increase will raise the amount of equipment ensured available by an individual planholder, but will not necessarily raise the level of overall equipment located on the Gulf Coast. The Coast Guard acknowledges that high-rate removal technologies, such as dispersants, are valuable response options that should complement the existing mechanical recovery capabilities on the Gulf Coast. We are considering the addition of such technologies to the response plan requirements in a separate rulemaking.

Many comments suggested that high-rate removal technologies are more cost-effective and capacity-enhancing than additional mechanical recovery and advocated the inclusion of these high-rate removal technologies, rather than the addition of more mechanical recovery. Other comments suggested that the high-rate removal technologies should be included, but not at the expense of mechanical recovery capabilities. We disagree that the scheduled increases in mechanical recovery should be replaced by requirements for high-rate removal technologies. Each response technology is unique and the situations where these technologies provide an environmental benefit may vary considerably, dependant upon the circumstances of each response. The Coast Guard determined that high-rate removal technologies should augment and not necessarily replace required mechanical recovery capacities. We will consider requirements for high-rate removal technologies in a separate response cap rulemaking. A credit provision currently exists within the vessel and facility regulations for ensuring the availability of a dispersant capability (high-rate removal technology), which may be applied toward the total required recovery capacity a planholder must ensure available. Planholders may take advantage of this existing credit, as appropriate, to meet the scheduled cap increase. However, planholders should be aware that we are considering the removal of this credit from the

regulations as part of a separate rulemaking.

Recovery System Components

One comment suggested the caps review should take a "systems" approach to evaluating the need for an equipment cap increase. We agree. The Cap Review, in making its determination of the practicability of an increase, reviewed each of the components of a mechanical recovery system, including containment booms, skimming mechanisms, pumps, storage devices, and oil-water separators. The review revealed that improvements to the overall technology and operability of mechanical recovery systems support the practicability of an equipment increase.

One comment stated that the proposed increases should apply to all components of a mechanical recovery system, not just boom, skimmers, and storage devices. We agree. The cap increase as set out in 33 CFR 154.1045(m) and 33 CFR 155.1050(o) specifically addresses the requirements in 33 CFR part 154, Table 5 of Appendix C and 33 CFR part 155, Table 6 of Appendix B. These tables establish increased amounts for effective daily recovery capacity (EDRC) that must be ensured available. While EDRC is used to determine the required number of oil recovery devices (through calculations outlined in 33 CFR part 154, paragraph 6 of Appendix C and 33 CFR part 155, paragraph 6 of Appendix B), the increased EDRC values are also indirectly applied to the "system" of resources necessary to sustain those recovery devices. Title 33 CFR part 154, paragraph 9.2 of Appendix C, and 33 CFR part 155, paragraph 9.2 of Appendix B, both require that temporary storage for the recovered oil be ensured available in amounts equivalent to twice that of EDRC. Since the regulations establish a direct proportion between EDRC and temporary storage, an increase in EDRC requires that temporary storage amounts also increase by 25 percent. Title 33 CFR part 154, paragraph 9.1 of Appendix C, and 33 CFR part 155, paragraph 9.1 of Appendix B, also require that sufficient numbers of ancillary equipment (such as trained personnel, boats, spotting aircraft, sorbents, booms and other resources as necessary to support the oil recovery devices employed), are ensured available to achieve the required EDRC values. While specific amounts of such ancillary equipment are not required to be listed in the response plans, the levels of ancillary equipment should

increase as necessary to support the 25 percent increase in EDRC. It is the planholder's responsibility to ensure and certify that ancillary response resources are available to support the cap increase. We may amend the OSRO classification guidelines to include more detailed guidance concerning ancillary equipment necessary to support the cap increase in an effort to assist planholders and reviewers.

One comment stated that the cap increase should not be required for containment boom. We disagree. Title 33 CFR 154.1045(e)(3) and 33 CFR part 154, paragraph 5.6 of Appendix C (for facilities), and 33 CFR 155.1050(f)(3) and 33 CFR part 155, paragraph 5.6 of Appendix B (for vessels) indicate that sufficient amounts of containment and collection boom must be ensured available to recover the required EDRC volumes. If EDRC values increase as a result of the cap increase, then it is reasonable to assume that the amounts of containment and collection boom must increase proportionately. While specific amounts of containment and collection boom are not required to be listed in the response plans, the levels of boom ensured available should increase as necessary to support the increase in EDRC. We may amend the OSRO classification guidelines to include more detailed guidance concerning amounts of collection and containment boom necessary to support the cap increase.

Two comments stated that the cap increase should increase the amount of shoreline protection boom that must be ensured available. One comment stated that the cap increases should not apply to shoreline protection boom requirements. The cap increase, as set out in 33 CFR 154.1045(m) and 33 CFR 155.1050(o), applies specifically to the equipment requirements contained in 33 CFR part 154, Table 5 of Appendix C and 33 CFR part 155, Table 6 of Appendix B. Tables 5 and 6 do not contain any requirements to increase shoreline protection boom amounts. Therefore, the cap increase will not affect the amount of shoreline protection boom required to be ensured available. The regulatory requirements for shoreline protection boom will not increase and will remain as originally outlined in 1993 (see 33 CFR 155.1050(m) and 33 CFR part 155, Appendix B, Table 2 for vessel response plans, and by 33 CFR 154.1045(k) and 33 CFR part 154, Appendix C, paragraph 5.6 for facility response plans).

Deployment Ability

One comment stated that the Cap Review should consider the ability to deploy equipment when determining whether a cap increase is practicable. We agree. The cap requirements were originally designed in part to reflect the limitations of a planholder's ability to deploy and effectively manage equipment during the initial phase of a response. The Cap Review, in making its determination for practicability, evaluated the technological and operational feasibility of deploying increased amounts of equipment. Improvements in equipment technology and availability, as well as advances in the ability to track, deploy, and manage resources were all factors that indicate an increase is practicable.

One comment stated that training and exercising of response personnel and equipment has improved greatly since 1993 and has resulted in a far greater capability to operate and deploy such equipment effectively. We agree that personnel training and response exercises have improved the ability of today's responders to deploy and operate response equipment effectively. The improvements to personnel training and response exercises support the determination that it is practicable to increase the cap for mechanical recovery systems.

OSRO Classification

One comment stated that the 25 percent cap increase appears reasonable and should carry over to OSRO classification standards. We agree and the OSRO guidelines will be adjusted to reflect the increases in equipment required by the cap increase.

Seven comments stated the Cap Review should focus on the quality of equipment, rather than increasing the quantity. We agree that quality is a relevant issue, but one that will be addressed outside of the Cap Review process. Standards or guidelines that address the quality of response equipment would be better addressed as revisions to the OSRO classification guidelines. We will review the OSRO guidelines and consider the question of equipment quality during that process.

Two comments stated that the Coast Guard must revise the OSRO classification program before any cap increases are implemented. We disagree. Potential changes to the OSRO classification program are best addressed separately from the cap increase. Most OSRO-related issues of recent concern do not directly involve the cap increase and do not need to be addressed before the implementation of

the increase. The Coast Guard will be addressing the OSRO-related issues in workshops that are planned during the next year. The Coast Guard will announce the schedule and agenda for these workshops in a separate Federal Register document.

Response Database

One comment suggested that the government should capture information on personnel, vessels, and response equipment and store that information in a database that is universally available and frequently updated. We agree. Currently this information is maintained in the Response Resource Inventory (RRI). However, it is not universally available at this time. We are considering methods to improve or increase public accessibility to this database.

Costs

Two comments stated that the economic costs and benefits of all OPA 90 requirements should be considered when determining whether to increase the response caps. Four comments stated that a cap increase must consider the cost and benefits of such an increase, and is not practicable because the caps will increase costs without providing any benefits to the preparedness of a planholder to respond. And, an additional comment stated that OPA 90 prevention measures have lowered the risk of spills substantially, and the need for a cap increase should look at current risk rather than pre-OPA 90 risk.

We agree. The Coast Guard has determined that the treatment of equipment caps increases presented in the regulatory impact analysis for vessel response plans that was published in January of 1993 is legally sufficient to support actions enumerated in this notice of decision. We also agree that consideration of the economic costs and benefits of all the OPA 90 requirements, and therefore, consideration of current risk rather than pre-OPA 90 risk, is a valid approach. Accordingly, a risk analysis based on post-OPA 90 experience will be completed as part of a new economic analysis. The new economic analysis will in turn be used as a principal program decision tool for equipment caps decisions scheduled for the year 2003.

One comment stated that the Cap Review should consider the economic impacts of additional equipment requirements on OSROs. It stated that there are fewer OSROs today resulting in a reduction of the number of qualified and trained personnel

available for a major response. Additional cost burdens on the OSROs may result in OSROs going out of business. OPA 90 and resulting vessel response plan rules that were mandated by OPA 90, established a demand for response products and services as it established a captive market for them. Market-driven adjustments, such as "shakeouts" among providers that result from cost pressures, are a natural occurrence which we would expect. A threat to the availability of qualified and trained personnel does not necessarily follow. The federally established demand remains and prices are expected to be the incentive that results in a balance with the supply of qualified and trained personnel available for a major response.

One comment stated that the cap increase will force OSROs to purchase new equipment, which will reduce the amount of funds spent on training and exercises in the future. We disagree. The Cap Review has found by examination of public comment and independent research that most OSROs have already purchased the required equipment in anticipation of the scheduled increase. The majority of OSROs will not have to purchase new equipment to meet this cap increase. The Coast Guard has no evidence to suggest that funding normally spent on personnel training and response exercises will decrease as a result of equipment purchases driven by this cap increase.

Review Standard for Increase

Two comments stated that the Cap Review must show a scientific and economic justification for an increase. One comment stated that the Cap Review must prove that a net environmental benefit would result from an increase. Section 4202(a) of the OPA 90 states that response plans shall ensure the availability of private personnel and equipment necessary to remove, to the maximum extent practicable, a worst case discharge. The Cap Review evaluated the scheduled increase against the standard of practicability, as required by the statute. This evaluation included an assessment of the technological, operational, and economic feasibility, and found the increase to be practicable.

Public Resources

One comment stated that the equipment ensured available by industry should not increase, but should be augmented with public resources in order to meet the demands of a worst case discharge. We disagree. Section 4202(a) of OPA 90 states that response

plans must ensure, by contract or other means approved by the President, the availability of private personnel and equipment necessary to remove, to the maximum extent practicable, a worst case discharge. OPA 90 clearly states that the capability to respond to a worst case discharge should be provided by the private sector, to the maximum extent practicable. The Cap Review evaluated the scheduled increase

against the standard of practicability and found that it is practicable for the private sector to provide the increase.

Discussion of Decision

In accordance with 33 CFR 154.1045(n) and 155.1050(p), we have completed our review of the 25 percent cap increase for on-water mechanical recovery capacity, and have determined that the increase, as originally

scheduled for February 18, 1998, is practicable. This notice announces the results of the Cap Review and sets an implementation date for the scheduled increase listed in Table 1. The increase was originally scheduled for vessel response plans in 33 CFR part 155, Appendix B, Table 6, and for facility response plans in 33 CFR part 154, Appendix C, Table 5, to take effect on February 18, 1998.

TABLE 1.—1993 AND SCHEDULED INCREASES TO CAPABILITY LIMITS ON MECHANICAL RECOVERY EQUIPMENT FOR VESSELS AND FACILITIES

Geographic area	1993 Caps (BPD)			Scheduled Increase (BPD)		
	Tier I	Tier II	Tier III	Tier I	Tier II	Tier III
All except rivers and canals and Great Lakes	10,000	20,000	40,000	12,500	25,000	50,000
Great Lakes	5,000	10,000	20,000	6,250	12,500	25,000
Rivers and canals	1,500	3,000	6,000	1,875	3,750	7,500

Note: BPD, barrels per day. Table 1 corrects previously published typographical errors in Great Lakes Tier I and Tier II increases.

A team of policy and technical professionals prepared the Cap Review for the Coast Guard. This team had extensive experience in oil spill preparedness and response, USCG policy and regulatory development, and technical, operational, and policy considerations affecting mechanical recovery, dispersant, and in situ burn equipment and its use. The team examined peer-reviewed, scientific, and technical papers as well as government documents, including Federal Register documents, government reports, the USCG spill database (Marine Safety Information System (MSIS)), and comments to the docket regarding the proposed cap increase.

This Cap Review focused on the open-water removal of Groups I through IV oils as defined in 33 CFR 155.1020. Although the recovery of Group V oils has become a topic of interest in recent years, the recovery techniques and equipment for these oils are not well developed, and equipment caps have not been established for such oils under the current regulations (per 33 CFR 154.1047 and 33 CFR 155.1052).

In order to assess the practicability of the scheduled 25 percent increase in mechanical recovery equipment, the review evaluated the planholders' current capability to implement the oil recovery process as compared with that which existed in 1993. In doing so throughout the United States for each generic operating environment (oceans, inland, Great Lakes, rivers, and canals), primarily three important elements were considered: technological capability, commercial or market availability, and the availability of existing equipment

stocks to respond within the prescribed time limitations (Tiers I, II, and III response times).

Technological capability was assessed by reviewing advances in systems and equipment design, which have occurred over the past 5 years. This assessment evaluated improvements in oil spill tracking systems, booms and skimming devices, oil/water separation and emulsion-breaking systems, and modular, easily transported, temporary storage devices. The original caps were limited, in part, due to the difficulties in effectively tracking multiple response operations simultaneously. Visual observation by aircraft and the use of remote sensing systems enhance oil recovery by allowing more precise direction of oil removal response resources to the thickest portions of the spilled oil. Advances in aerial surveillance and other oil tracking systems have improved and, when used in conjunction with improved command and control systems, support the deployment of increased levels of response equipment effectively. Improvements in command and control, such as the increased use of an incident command system (ICS), and the establishment of a network of qualified individuals (QIs), and spill management teams (SMTs) also support the effective deployment and tracking of a greater number of response resources during the initial phases of a spill than was possible in 1993.

Conventional on-water mechanical recovery equipment, however, has not improved significantly since 1993 in terms of design efficiency or effectiveness. While improved storage

units are more readily available to support skimming units, actual recovery rates are still limited by skimmer mechanics and pump rates. Therefore, the increases in daily recovery capacity require that additional recovery equipment is ensured available. As the efficiency of most skimming devices has not improved significantly, increases in recovery capacity continue to require an additional increase in storage at the existing storage to EDRC ratio of two to one (2:1). While there has been some improvement in oil/water separation systems, this type of technology has not been widely procured and is not generally available in most recovery systems. In situations where large recovery units, such as large seagoing oil spill response vessels (OSRVs), have demonstrated that installed separation systems have improved their ability to store and recover oil, allowances have been granted through the OSRO classification program. Situations such as these, however, do not support a generic credit or offset for separator systems with respect EDRC or storage requirements.

Commercial or market availability was assessed by reviewing equipment currently on the market in terms of representative models and their intended applications as compared with that which was available 5 years ago. The primary references for this assessment were the fourth and sixth editions of the *World Catalog of Oil Spill Response Products* (Schulze, 1993, 1997). The assessment revealed that the number of models available for each of the components of an on-water recovery system has increased. Equipment is

widely available for purchase, and a healthy level of competition exists among manufacturers capable of maintaining a current and adequate stock of response equipment at increased levels. The overall availability of new oil spill response equipment in the commercial market has improved since 1993.

The availability of existing equipment stocks for deployment to spills was assessed by reviewing nationwide inventories of major items such as booms, skimmers, skimming vessels, and temporary storage devices. Primary data was compiled using the Coast Guard National Strike Force Coordination Center's (NSFCC) Response Resource Inventory (RRI). The resulting equipment distribution and the daily recovery capacity it represented were examined for each geographic region and operating environment. The comparison of the scheduled cap increase with the existing equipment stocks available to planholders clearly indicated that planning for a response is not equipment limited. The scheduled 25 percent cap increase can easily be accommodated with the existing stocks of equipment available to planholders for each geographical region and operating environment.

The assessments of technological capability, market availability, and regional availability of existing stocks, support the determination that the scheduled increase in caps is practicable. For a more detailed explanation of these findings, the Cap Review can be viewed on the Internet at the sites listed in the **ADDRESSES** section.

Other removal technologies. The Cap Review also evaluated the following topics:

a. Additional proposed increases for on-water mechanical removal capacity in 2003.

b. Advances in oil tracking technology.

c. Improvements in high-rate removal technologies such as dispersants or in situ burning.

The conclusions and recommendations of the Cap Review concerning these topics are contained within the Response Plan Equipment Cap Review document. This notice does not address these topics and makes no changes to existing regulations or policy. However, we intend to address any additional cap increases for mechanical recovery or other removal technologies in a subsequent rulemaking. The Cap Review recommendations regarding these other removal technologies should be viewed

as information only. We will consider them along with previously received public comments when formulating any subsequent rulemakings.

Dated: December 28, 1999.

Joseph J. Angelo,

Acting Assistant Commandant for Marine Safety and Environmental Protection.

[FR Doc. 00-31 Filed 1-5-00; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[FRL-6519-3]

RIN 2060-A173

Protection of Stratospheric Ozone: Allocation of Essential Use Allowances for Calendar Year 2000: Allocations for Metered-Dose Inhalers and the Space Shuttle and Titan Rockets

AGENCY: Environmental Protection Agency (EPA).

ACTION: Interim final rule.

SUMMARY: With this action, EPA is allocating essential-use allowances for calendar year 2000 for ozone depleting substances (ODS) for use in medical devices and for use in the Space Shuttle Rockets and Titan Rockets for the year 2000 control period. Production and import of ODS for laboratory and analytical applications will be addressed in a separate rulemaking. The United States nominated specific uses of controlled ozone-depleting substances as essential for calendar year 2000 under the Montreal Protocol on Substances that Deplete the Ozone Layer (Protocol). The Parties to the Protocol subsequently authorized specific quantities of ODS for calendar year 2000 for the uses nominated by the United States. EPA allocates essential use allowances to an applicant for exempted production or import of a specific quantity of controlled substances solely for the designated essential purpose. These essential use allowances permit a person to obtain controlled ODS as an exemption to the January 1, 1996, regulatory phaseout of production and import.

DATES: This action is effective January 6, 2000. EPA will consider all written comments received by February 7, 2000 to determine if any change to this action is necessary.

ADDRESSES: Those wishing to notify EPA of their intent to submit adverse comments on this action should contact Erin Birgfeld, U.S. Environmental

Protection Agency, Stratospheric Protection Division, Office of Air and Radiation (6205J), Ariel Rios Building, 1200 Pennsylvania Avenue, NW., Washington, DC, 20460; <birgfeld.erin@epa.gov>; (202) 564-9079 phone and (202) 565-2096 fax. Materials relevant to this rulemaking are contained in Docket No. A-92-13. The Docket phone is (202) 260-7548 and is located in room M-1500, First Floor, Waterside Mall 401 M Street, SW., Washington, DC 20460. The materials may be inspected from 8 a.m. until 4 p.m. Monday through Friday. A reasonable fee may be charged by EPA for copying docket materials.

FOR FURTHER INFORMATION CONTACT: The Stratospheric Ozone Protection Hotline at (800) 296-1996 or Erin Birgfeld, U.S. Environmental Protection Agency, Stratospheric Protection Division, Office of Air and Radiation (6205J), Ariel Rios Building, 1200 Pennsylvania Avenue, NW., Washington, DC, 20460; <birgfeld.erin@epa.gov>; (202) 564-9079 phone and (202) 565-2096 fax.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Background
- II. Allocation Process for the Calendar Year 2000
- III. Allocation of Essential Use Allowances for Calendar Year 2000
- IV. Response to Comments
- V. Administrative Requirements
- VI. Judiciary Review
- VII. Congressional Review

I. Background

Overview of the Notice of Proposed Rulemaking

The Notice of Proposed Rulemaking (NPRM) for allocating essential use allowances was published on November 2, 1999 (64 FR 59141). In the NPRM, EPA proposed allocating chlorofluorocarbon (CFCs) for use in metered dose inhalers (MDIs), and methyl chloroform for use in the Space Shuttle and Titan Rocket. EPA explained that because of additional requirements in the Clean Air Act that apply beginning in calendar year 2000, before allocating CFCs for use in MDIs, EPA must receive a determination from the Food and Drug Administration (FDA) indicating the amount of CFCs that are necessary for use in MDIs. The quantities of CFCs proposed to be allocated were the quantities that were agreed upon at the Eighth Meeting of the Parties to the Montreal Protocol. FDA's determination of the amount of CFCs that are necessary for use in MDIs, which EPA has subsequently received, is substantially lower than what was proposed in the NPRM. The allocations

in this action reflect these lowered amounts. Because stakeholders have not had a chance to comment on the lower amounts, today's action is being issued as an interim final rule effective January 6, 2000. This will allow essential use applicants access to necessary CFCs for continued production of MDIs, and at the same time will allow for further comment on and potential changes to the allocation.

In the NPRM, EPA also explained that due to requirements of the CAA that apply beginning in calendar year 2000, the essential use exemption for import and production of small amounts of high purity ozone depleting substances (ODS) for laboratory and analytical uses may not be available after January 1, 2000. Today's action does not address this issue. EPA will issue a separate final rule on the topic of laboratory essential uses.

Overview of the Essential Use Process

The Montreal Protocol on Substances that Deplete the Ozone Layer (Protocol) sets specific deadlines for the phaseout of production and importation of ozone depleting substances (ODS). At their Fourth Meeting in 1992, the Parties to the Protocol (the Parties) amended the Protocol to allow exemptions to the phaseout for uses agreed by the Parties to be essential. At the same Meeting, the Parties also adopted Decision IV/25, which established criteria for determining whether a specific use should be approved as essential, and the process for making such a determination.

The criteria for an essential use as set forth in Decision IV/25 are the following:

"(1) that a use of a controlled substance should qualify as 'essential' only if:

(i) it is necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects); and

(ii) there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health;

(2) that production and consumption, if any, of a controlled substance for essential uses should be permitted only if:

(i) all economically feasible steps have been taken to minimize the essential use and any associated emission of the controlled substance; and

(ii) the controlled substance is not available in sufficient quantity and quality from existing stocks of banked or

recycled controlled substances, also bearing in mind the developing countries' need for controlled substances."

The procedure set out by Decision IV/25 first calls for individual Parties to nominate essential uses. The Protocol's Technology and Economic Assessment Panel (TEAP or the Panel) evaluates the nominated essential uses and makes recommendations to the Protocol Parties. The Parties make the final decisions on essential use nominations at their annual meeting.

Persons requesting essential use exemptions submit applications which respond to the specific questions in the 1997 Handbook on Essential Use Nominations. This document may be obtained from the Stratospheric Protection Division, U.S. Environmental Protection Agency or the Ozone Secretariat of the Montreal Protocol in Nairobi. The Handbook can also be downloaded from the TEAP website at: http://www.teap.org/html/teap_reports.html.

What does EPA do with the information in the essential use applications?

The U.S. EPA carefully reviews all the information in each essential use application and enters the information into a tracking system which permits year by year comparison of quantities of ODS requested, quantities allocated, quantities of ODS received in previous years, and quantities of ODS used for the specific essential activity. The review of data enables EPA to assess whether entities are stockpiling ODS, whether there seem to be inflated requests relative to actual use, and whether there is possible double-counting between companies. For example, in 1998 we identified some double-counting in the requests for CFCs among companies. Our analysis also revealed that there were disparities between the total quantity of CFCs requested for MDIs and the actual quantity used to manufacture MDIs in previous years. To account for this inflation in the request for allocation, EPA reduced the total U.S. nomination for 1998 by 10 percent before forwarding the applications for consideration by the TEAP and the Parties to the Protocol.

Every year since 1994, EPA has reviewed applications for essential uses according to the above criteria and then forwarded the applications to the Parties. The Parties then review the recommendations by the TEAP and make final decisions on essential use nominations.

What are the essential uses that EPA has nominated in the past?

Decision IV/25 was implemented initially in the context of halons which were phased out of production at the end of 1993. At that time, nominations for halons were separated from those for other ozone-depleting substances. EPA issued a **Federal Register** notice requesting nominations for essential uses of halons (February 2, 1993; 58 FR 06786). In response, the Agency received over ten nominations, but was able to work with applicants to resolve their near-term requirements. As a result, the U.S. did not nominate any uses for continued halon production in 1994. About a dozen other nations put forth nominations which were reviewed by the Panel, which determined that in each case alternatives existed or that the existing supply of banked halons was adequate to meet near-term needs. The Panel, therefore, did not recommend approval for any of the nominations. In November of 1993, at the Fifth Meeting, the Parties unanimously adopted the Panel's recommendation not to approve any essential uses for production and consumption of halons in 1994.

EPA issued a second notice requesting applications for essential use applications for halons for the 1995 control period on October 18, 1993 (58 FR 53722). In response to this inquiry, EPA received no applications. The TEAP received only one nomination (from France) for essential use exemptions for halons for production and consumption of halons for an essential use in 1995. The TEAP did not recommend approval of this nomination.

In 1993, EPA issued a **Federal Register** notice requesting essential use applications for CFCs, methyl chloroform, carbon tetrachloride, and hydrobromofluorocarbons required beyond the 1996 phaseout of consumption and production of these class I substances (May 20, 1993, 58 FR 29410). EPA received 20 applications in response to this notice. For several of these applications, EPA determined that the criteria contained in Decision IV/25 had not been satisfied. For example, EPA rejected two applications seeking CFCs for use in servicing air-conditioning equipment on the basis that adequate supplies of banked and recycled CFCs were available. However, in rejecting these nominations, the United States noted that servicing existing air-conditioning and refrigeration equipment remains a major challenge to the successful transition from ODSs and that a future nomination in this area might be necessary if a

combination of retrofits, replacements, recycling, recovery at disposal, and banking do not adequately address these needs.

In 1993, the United States forwarded essential use nominations to the Protocol Secretariat for the following uses of CFCs: metered dose inhalers and other selected medical applications; rocket motor assembly for the Space Shuttle; aerosol wasp killers; limited use in a specified bonding agent and polymer application; and a generic application for laboratory uses under specified limitations. (Letter from Pomerance to the United Nations Environment Programme (UNEP), September 27, 1993).

The TEAP reviewed over 200 specific uses which were submitted to the Montreal Protocol Secretariat by the Parties to the Protocol. In March 1994, the Panel issued the "1994 Report of the Technology and Economic Assessment Panel," which included the Panel's recommendations for essential-use production and consumption exemptions. The Panel recommended that essential use exemptions be granted for nominations of: methyl chloroform in solvent bonding for the Space Shuttle; CFCs used in metered dose inhalers; and specific controlled substances needed for laboratory and analytical applications. For each of the other nominations submitted, the TEAP determined that one or more of the criteria for evaluating an essential use had not been satisfied. The Parties approved essential use exemptions for the uses recommended in the 1994 TEAP report. The U.S. has continued to request and receive exemptions for those same uses in subsequent years.

II. Allocation Process for the Calendar Year 2000

The domestic allocation process for this year differs from past allocations due to changes in the requirements under the Clean Air Act (CAA or the Act). The purpose of this section is to explain the legal background behind these changes, and to outline the procedures that EPA and the Food and Drug Administration (FDA) used to fulfill our obligations under the CAA in allocating ozone depleting substances for calendar year 2000.

Prior to the year 2000, EPA allocated essential use exemptions under the original phase-out schedule contained in section 604 of the Act. This schedule does not require the complete phaseout of any ODS prior to calendar year 2000. Under section 606 of the Act, EPA was obligated to create an accelerated phaseout through regulation to match

the accelerated phaseout under the Protocol. However, EPA had the flexibility to create exemptions to the regulatory phaseout, where such exemptions had been approved under the Montreal Protocol. Thus, for the past several years, EPA has been able to authorize production and import of ozone-depleting substances for essential uses allowed under the Protocol, without regard to whether the Act contains exceptions for those uses, as long as the total authorized production does not exceed the amount permitted by the Act. However, January 1, 2000, is the phaseout date under Section 604 of the Act for all class I substances with the exception of methyl chloroform and methyl bromide. The phaseout dates for methyl chloroform and methyl bromide are January 1, 2002 and January 1, 2005, respectively. After the phaseout date for a particular substance has passed, EPA will no longer be able to authorize production of that substance on the basis of the slower phaseout schedule under the Act. Because CFCs are to be phased-out by calendar year 2000 under the original phase-out schedule, EPA must now implement essential use exemptions for these chemicals as specified under the Act in section 604(d).

The phaseout date for methyl chloroform under the Act is January 1, 2002. Until that date, the Act permits production and import of methyl chloroform equivalent to 20% of baseline. The amount of methyl chloroform allocated for calendar year 2000 is well below this limit. Beginning in the year 2002, EPA will implement the exception for essential uses of methyl chloroform found in 604(d)(1) of the Act.

For calendar year 2000, the entities in Table I submitted applications requesting class I controlled substances for essential uses. The applications provided information in accordance with the criteria set forth in Decision IV/25 of the Protocol and the procedures outlined in the "1997 Handbook on Essential Use Nominations." The applications requested exemptions for the production and import of specific quantities of certain class I controlled substances after the phaseout. The EPA reviewed the applications and nominated these uses to the Protocol Secretariat for analysis by the TEAP and its Technical Option Committees (TOCs). The Parties to the Montreal Protocol approved the U.S. nominations for essential-use exemptions during the Tenth Meeting in 1998 (Decision IX/18). Today's action allocates essential-use allowances to U.S. entities as authorized

by the Parties to the Montreal Protocol and to the extent consistent with the CAA.

The Act provides for the following essential use exemptions to the ban on production and import. Section 604(d)(2) states that notwithstanding the phaseout, EPA shall, to the extent consistent with the Montreal Protocol, authorize production of limited quantities of class I substances for use in medical devices, if FDA, in consultation with EPA, determines that such production is necessary. Section 604(d)(3) states that EPA may, to the extent consistent with the Montreal Protocol, authorize production of limited quantities of halon-1211, halon-1301, and halon-2402 solely for the purpose of aviation safety, if the Federal Aviation Administration, in consultation with EPA, determines that no safe and effective substitute has been developed and that such authorization is necessary for aviation safety purposes. Section 604(d)(1) provides that during the period from January 1, 2002 to January 1, 2005, EPA may, to the extent consistent with the Montreal Protocol, authorize the production of limited quantities of methyl chloroform solely for use in essential applications for which no safe and effective substitute is available. Section 604(d)(4) states that EPA cannot use any of these three exemptions to authorize any person to produce a class I substance in annual quantities greater than 10 percent of that person's baseline year as defined in Section 601(2). Section 604(g)(3) of the Act provides that EPA may, to the extent consistent with the Montreal Protocol, authorize the production of limited quantities of halon-1211, halon-1301, and halon-2402 after December 31, 1999, and before December 31, 2004 for use in fire suppression and explosion prevention in association with domestic production of crude oil and natural gas energy supplies on the North Slope of Alaska, if it is determined that no safe and effective substitute has been developed and that such authorization is necessary for fire suppression or explosion prevention purposes. EPA cannot use this exemption to authorize any person to produce any of these halons in an amount greater than 3 percent of that person's baseline. Finally, section 604(f) states that the President may, to the extent consistent with the Montreal Protocol, provide an exemption for production of CFC -114, halon-1211, halon-1301, and halon-2402 as necessary to protect U.S. national security interests, if the President finds that adequate substitutes are not

available and that the production and use of the substance are necessary to protect national security interests.

Today's action allocating CFCs for use in MDIs requires EPA to implement the exception for medical devices found in section 604(d)(2) of the Clean Air Act. "Medical device" is defined in section 601(8) of the Clean Air Act as follows: [A]ny device (as defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321), diagnostic product, drug (as defined in the Federal Food, Drug, and Cosmetic Act), and drug delivery system—

(A) if such device, product, drug, or drug delivery system utilizes a class I or class II substance for which no safe and effective alternative has been developed, and where necessary, approved by the Commissioner [of FDA]; and

(B) if such device, product, drug, or drug delivery system, has, after notice and opportunity for public comment, been approved and determined to be essential by the Commissioner [of FDA] in consultation with the Administrator [of EPA].

The preamble to FDA's September 1, 1999, notice of proposed rulemaking on essential use determinations (64 FR 47735) discusses FDA's approach to determining whether "safe and effective alternative[s]" have been developed. It states that "A non-CFC product simply having the same active moiety as a CFC product is only one factor to be considered. Other factors, such as whether the non-CFC product has the same route of administration, the same indication, and can be used with approximately the same level of convenience, are important considerations. Additionally, FDA must consider whether patients who medically need the CFC product are adequately served by the non-CFC product. FDA's approval of a non-CFC product is a determination that the product is safe and effective, but it is not a determination that the product is a safe and effective alternative to any other product. That requires a separate and distinct analysis." FDA has not yet determined that any non-CFC product is a safe and effective alternative to any CFC MDI. Accordingly, part (A) of the definition of medical device has not affected today's allocation.

With respect to part (B) of the definition of medical device (section 601(8)(B)), and in particular the use of the word "essential" in that part of the definition, EPA is relying on current FDA regulations (21 CFR 2.125) which contain a list of uses of CFCs that FDA in consultation with EPA has found to be essential. This list includes, among

others, metered-dose steroids, metered-dose adrenergic bronchodilators, metered-dose cromolyn sodium, metered-dose ipratropium bromide, and metered-dose nedocromil sodium, all drugs for oral inhalation in humans. The companies for which EPA is granting essential use allowances produce CFC MDIs that contain these active moieties. Thus, the products for which EPA is granting essential use allowances are "determined to be essential" by FDA.

Also with respect to part (B) of the definition of "medical device", EPA and FDA considered how to interpret the language regarding approval by FDA of the "device, product, drug, or drug delivery system." The complete phrase reads as follows: "if such device, product, drug, or drug delivery system, has, after notice and opportunity for public comment, been approved and determined to be essential by the Commissioner in consultation with the Administrator." The decision was made to interpret this phrase as referring to FDA's approval of an essential use and not the approval of the specific product in question through approval of the New Drug Application (NDA) or Abbreviated New Drug Application (ANDA) for that product. This means that any MDI whose active moiety appears on FDA's essential use list is eligible to receive essential use allowances. This interpretation was taken for the following reasons. The term "approved" must be interpreted in light of the surrounding language. Section 601(8)(B) requires notice and comment rulemaking and refers to action by FDA, in consultation with EPA. Since approval of an NDA or ANDA under the FDCA involves unilateral action by FDA without notice-and-comment rulemaking, it is reasonable to conclude section 601(8)(B) does not refer to approval of an NDA or ANDA under the FDCA. Therefore, FDA and EPA are interpreting section 601(8)(B) to refer to FDA's approval of an essential use. This interpretation is consistent with the surrounding language, since FDA engages in notice-and-comment rulemaking in listing essential uses and since EPA has a strong interest in decisions about essential uses. This means that an MDI is "approved and determined to be essential" if the MDI contains an active moiety on FDA's essential use list. All of the MDIs for which we are allocating CFCs today meet this qualification.

Implementing the essential use exemption for MDIs under the Act required EPA to consult with FDA regarding the quantity of CFCs to be allocated. As stated earlier, section

604(d)(2) of the Act provides that EPA shall authorize production and import of limited quantities of class I substances for use in medical devices if FDA, in consultation with EPA, determines such authorization to be necessary. Administrator Carol Browner sent a letter to Dr. Jane Henney, Commissioner of FDA, dated October 28, 1999, requesting that FDA make a determination on the amount of CFCs that are "necessary" for the production of MDIs for calendar year 2000. A December 23, 1999, letter was sent in response from Commissioner Henney that contains FDA's determination.

EPA also collected additional information relevant to the allocation. The 1997 TEAP Handbook on Essential Use Nomination (Handbook), the guidance document for essential use exemption applications, does not request information regarding specific products for which the CFCs will be used. As a result, EPA sought more detailed information including which drug products would be produced using the allocated CFCs for calendar year 2000. EPA sent out letters to the essential use applicants (separate letters were sent to the International Pharmaceutical Aerosol Consortium (IPAC) member companies) for medical devices, requesting this additional information under section 114 of the Act. The responses to the letters included confidential business information on the types of drug products to be manufactured, as well as the quantity and the specific CFC chemical to be used in the manufacture of each product. EPA shared the responses to these letters with FDA to assist it in determining the amount of CFCs for use in medical devices that are "necessary."

Dr. Henney's letter in response to the Administrator dated December 23, 1999, provided FDA's analysis of the amounts of CFCs that FDA determined are necessary in calendar year 2000 for the production of medical devices as defined under the Clean Air Act. FDA determined that a total of 2737.3 metric tons are necessary for use in MDIs for calendar year 2000. In contrast, the total amount of CFCs proposed to be allocated in the NPRM (November 2, 1999 64 FR 59141) was 3735 metric tons. The rationale underlying FDA's determination is provided in Dr. Henney's December 23, 1999 letter:

"In listing the amounts we believe to be necessary for use in medical devices, we referred to historical use and have included an additional amount to allow for overage, for waste during manufacturing, for uncertainties in the

supply chain of CFCs since they are no longer produced in the United States, for changes in future market shares of specific products, as well as for unforeseen circumstances in the market. We also provided additional amounts based on our knowledge of certain manufacturing problems. In addition, we eliminated any double-counting we found and eliminated allocations for uses not considered essential by the parties to the Montreal Protocol, even if those uses are currently listed in our regulation at 21 CFR 2.125(e)." FDA also noted that they accounted for CFCs for use in the production of MDIs that would ultimately be exported to Canada.

FDA's determination that 2737.3 metric tons of CFCs are necessary for use in MDIs is consistent with EPA's data on historical use and import for MDIs. In order for companies to place an order for CFCs they must provide a letter from EPA which indicates the amount of CFC that they are allowed to purchase from chemical producers. Before issuing these letters, EPA asks companies if they still need the entire allocation of CFCs. In many cases, companies voluntarily give up part of their CFC allocation for various reasons. The net result is that the amount of CFCs actually purchased each year is substantially less than the amount of CFCs allocated each year. For example, in 1998, 4,363 tons of CFCs were allocated for use in medical devices. However, only 2,235.6 tons were actually imported or produced for MDIs in that year, and a total of 2,425.5 tons were actually used in the production of MDIs. Similarly in 1997, 4,656.0 tons of CFCs were allocated for use in MDIs while 2,032.3 tons were imported or produced, and 2,255.1 tons were used in MDI production (data from the EPA CFC accounting framework). Thus, the amount of CFCs that FDA has determined is "necessary" is about 300 metric tons higher than EPA's data on actual use of CFCs in MDIs for 1998. As stated in the letter from FDA, this additional amount will act as a safety factor accounting for any unplanned interruptions in CFC supply that could occur during the course of the year.

As mentioned above, section 604(d)(2) of the Act states that EPA's allocation must be consistent with the Montreal Protocol. Article 2A(4) of the Protocol states that Parties such as the United States may not produce or import CFCs after January 1, 1996, except that the Parties may decide collectively to permit a specified amount of production or import for uses that they agree to be essential. The Parties to the Protocol

approved the U.S. nominations for calendar year 2000 during their Tenth Meeting in 1998 (Decision IX/8). The quantities we are allocating today do not exceed the amounts approved by the Parties. Therefore, we believe that this action is consistent with the Protocol.

Can I Submit Comments on This Interim Final Rule?

In the interest of maintaining as open and transparent a process as possible, this year's allocation for medical devices and the space program is being issued as an interim final rule instead of a final rule. This will allow stakeholders to comment on the appropriateness and accuracy of the allocation while still allowing pharmaceutical companies access to CFCs in the near term for continued manufacture of MDIs. Today's action allocates 2737.3 tons of CFCs for use in medical devices instead of the 3735 metric tons proposed in the NPRM. EPA received no comments on the NPRM stating that the proposed allocation was insufficient for an applicant's needs. While we are accepting comment on the lowered allocation figures, EPA, under the terms of the Montreal Protocol cannot allocate CFCs in an amount higher than 3735 metric tons because no more than that amount has been approved for essential use by the Parties to the Montreal Protocol. Because we are issuing this action as an interim final rule, the following paragraphs explain the relevant procedures under the CAA and the Administrative Procedures Act (APA), as well as EPA's findings.

Section 307(d) of the CAA states that in the case of any rule to which section 307(d) applies, notice of proposed rulemaking must be published in the *Federal Register* (CAA 307(d)(3)). The promulgation or revision of regulations under title VI of the CAA is generally subject to section 307(d). However, section 307(d) does not apply to any rule referred to in subparagraphs (A) or (B) of section 553(b) of the Administrative Procedures Act (APA), 5 U.S.C. 551 *et seq.*

Section 553 of the Administrative Procedures Act, 5 U.S.C. 553(b)(B), provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, the agency may issue a rule without providing notice and opportunity for public comment. In its proposed rule, 64 FR 59141 (Nov. 2, 1999), EPA provided notice that the allocation of essential use allowances for MDIs for calendar year 2000 would

be made in accordance with CAA sections 601(8) and 604(d)(2). EPA also provided preliminary interpretations of the relevant statutory language and announced that the final allocation would be based on what FDA determined was "necessary" under section 604(d)(2) of the CAA. The proposed allocation reflected the quantities of CFCs that had been approved by the Parties to the Montreal Protocol for this use. Because the quantities that appear in today's allocation differ significantly from the quantities that appeared in the proposal, EPA has decided to provide an opportunity for post-promulgation comment on this allocation.

EPA has determined that there is good cause for making today's allocation final without prior notice of FDA's determination or an opportunity to comment on the allocation, as adjusted to reflect FDA's determination. The allocation of these essential-use allowances to the specified MDI manufacturers will allow for the pharmaceutical industry to continue to produce life-saving MDIs for the treatment of asthma and chronic obstructive pulmonary disease. Thus, prior notice and an opportunity to comment with regard to today's allocated quantities are impracticable and contrary to the public interest. EPA finds that this constitutes good cause under 5 U.S.C. 553(b)(B). Nonetheless, EPA is providing 30 days for submission of public comments following today's action. EPA will consider all written comments submitted in the allotted time period to determine if any change to this action is required.

Section 553(d) of the APA generally provides that rules may not take effect earlier than 30 days after they are published in the *Federal Register*. However, APA section 553(d) excepts from this provision any action that grants or recognizes an exemption or relieves a restriction. Since today's action grants an exemption to the phaseout of production and consumption of CFCs, EPA is making this action effective immediately to ensure the availability of CFCs for medical devices during the 2000 control period.

III. Allocation of Essential Use Allowances for Calendar Year 2000

What Is EPA's Proposed Essential Use Allocation for Calendar Year 2000?

In today's action, EPA is allocating essential use allowances for the year 2000 control period to entities listed in Table I for exempted production or import of the specific quantity of class

I controlled substances solely for the specified essential use. The final allocation for CFCs for use in MDIs

reflects FDA's determination of the amounts of CFCs that are necessary as

specified under section 604(d)(2) of the Act.

TABLE I.—ESSENTIAL USE ALLOCATION FOR CALENDAR YEAR 2000

Company	Chemical	Quantity (metric tons)
(i) Metered Dose Inhalers for Treatment of Asthma and Chronic Obstructive Pulmonary Disease		
International Pharmaceutical Aerosol Consortium (IPAC)—Medeva Americas, Inc., Boehringer Ingelheim Pharmaceuticals, Glaxo Wellcome, Rhone-Poulenc Rorer, 3M.	CFC-11	381.0
	CFC-12	1169.0
	CFC-114	89.0
Medisol Laboratories, Inc.	CFC-11	13.0
	CFC-12	29.0
	CFC-114	7.0
Schering Corporation	CFC-11	301.0
	CFC-12	747.0
	CFC-114	0.0
Sciarra Laboratories, Inc.	CFC-11	0.2
	CFC-12	0.7
	CFC-114	0.4
(ii) Cleaning, Bonding and Surface Activation Applications for the Space Shuttle Rockets and Titan Rockets		
National Aeronautics and Space Administration (NASA)/Thiokol Rocket	Methyl Chloroform	56.7
United States Air Force/Titan Rocket	Methyl Chloroform	3.4

The table above reflects FDA's determination of the quantities CFCs that are necessary for calendar year 2000 and breaks down the amount of CFC by molecule. However, in developing today's action, EPA has decided to allocate essential-use allowances in aggregate amounts in accordance with Decision X/6 of the Parties to the Montreal Protocol. Paragraph 2 of Decision X/6 states that the "levels of production and consumption necessary to satisfy essential uses of CFC-11, CFC-12, CFC-113, and CFC-114, for metered-dose inhalers for asthma and chronic obstructive pulmonary diseases * * * are authorized as specified in annex I to the report of the Tenth Meeting of the Parties." Paragraph 5 of Decision X/6 goes on to say that "the quantities approved under paragraph 2 above and all future approvals are for total CFC volumes with flexibility between CFCs within each group." EPA has determined that allocating essential-use allowances for CFCs for the manufacture of metered-dose inhalers in the aggregate instead of on a compound-by-compound basis will add flexibility for protecting patient health by allowing companies to better meet market demand for MDIs. Because CFC-11, CFC-12 and CFC-114 all have an ozone depleting potential of 1.0, allocating these substances in the aggregate will not cause any additional damage to the stratospheric ozone layer.

The International Pharmaceutical Aerosol Consortium (IPAC)

consolidated the essential use exemption requests of its member companies for administrative convenience. EPA will separately allocate the essential-use allowances that FDA has determined to be "necessary" to each of IPAC's member companies by means of a confidential letter.

Although the Montreal Protocol does allow for a global essential use exemption for small quantities of high quality Class I ODS for use in laboratory applications, the CAA does not contain an explicit exemption for this use. Therefore, import and production of CFCs and carbon tetrachloride for use in laboratory and analytical applications may no longer be available for this use. Today's action allocates CFCs for use in metered dose inhalers and methyl chloroform for use in the Space Shuttle and the Titan Rocket. Laboratory essential uses will not be addressed in today's rulemaking. A separate final rule addressing laboratory essential uses will be published at a later date.

What Reporting Requirements Relate to the Essential Uses of Ozone Depleting Substances?

Any person obtaining class I controlled substances after the phaseout under the essential use exemptions in today's action is subject to all the restrictions and requirements in other sections of 40 CFR part 82, subpart A. Holders of essential-use allowances or persons obtaining class I controlled

substances under the essential-use exemptions must comply with the record keeping and reporting requirements in 40 CFR 82.13.

IV. Response to Comments

EPA received comments from six organizations in response to the proposed rule. Three of these organizations commented on various aspects of the allocation of ODSs for medical devices, and three discussed the possibility of the lack of essential use exemptions for laboratory essential uses. Because a final rule addressing laboratory essential uses will be published separately at a later date, the only comments discussed in this section are those regarding the essential use allocation for medical devices.

One commenter stated that EPA may only authorize production and/or importation of CFCs for an MDI if EPA determines that there is no safe and effective alternative *propellant* to the CFCs used in the MDI. The commenter asserts that FDA approval of a product under the FDCA means that the alternative propellant in that product is safe and effective for purposes of the CAA. The effect of this interpretation would be limited, according to the commenter, because "it is only the CFC-containing product that contains the same active moiety and same labeled indications that no longer qualifies as a 'medical device.'"

We do not share the commenter's interpretation of the statutory language.

The first prong of the definition of "medical device" reads as follows: "The term "medical device" means any device * * *, diagnostic product, drug * * *, and drug delivery system * * * if such device, product, drug, or drug delivery system utilizes a class I or class II substance for which no safe and effective alternative has been developed, and where necessary, approved by the Commissioner." According to the commenter, the phrase "for which no safe and effective alternative has been developed" modifies "class I or class II substance," and not "device, product, drug, or drug delivery system." The difficulty with the commenter's interpretation is that FDA does not approve MDI propellants separately from drug products. Thus, it is impossible for FDA to approve an alternative to the class I or class II substance (i.e., the propellant) alone since FDA only approves MDIs under an ANDA or NDA as a whole unit and not by approving each of its components. For this reason, even if we were to agree with the commenter that the statutory language was clear on its face, this would be a situation where the literal meaning of the statutory text would produce absurd results. We believe that the overall purpose of the CAA language regarding medical devices is to ensure that EPA's mission of environmental protection does not conflict with FDA's mission of protecting the public health. Consistent with this purpose, we believe that in drafting this prong of the definition, Congress was focusing on the availability of alternative medical treatment for patients who rely on CFC MDIs. We are not the appropriate agency to decide whether such alternative medical treatment is available. We do not believe that Congress intended EPA to make decisions involving medical judgment. On such questions, we defer to FDA. Because FDA has not identified any "safe and effective alternative," as the phrase is used in the CAA, for any CFC MDI, the first prong of the definition of "medical device" has not affected today's allocation.

One commenter asserted that "the CAA contemplates a product-by-product determination of essentiality at the time a particular product is approved," and that this principle applies to generic drugs as well as brand-name drugs. We do not believe that the statutory language requires each product's essentiality to be determined in a vacuum, as if no other products of that type existed. The definition of medical device states that a device, product, drug, or drug delivery system is a

medical device if the first prong of the definition is satisfied and "if such device, product, drug, or drug delivery system, has, after notice and opportunity for public comment, been approved and determined to be essential by the Commissioner in consultation with the Administrator." This language does not prevent FDA from grouping together particular types of products containing the same active moiety and determining that all products using a given active moiety are essential. Our understanding is that FDA has always added uses to its essential use list through notice and comment rulemaking. Because FDA's list of essential uses is determined by active moiety and makes no reference as to whether a drug product is generic or branded, we believe all MDIs for which we are allocating CFCs are covered by 21 CFR 2.125, regardless of whether they were or will be approved under an NDA or ANDA.

This commenter also objects to EPA's use of FDA's pre-1990 determinations of essentiality in deciding whether an MDI qualifies as a "medical device" for purposes of the 1990 CAA Amendments. The commenter states that EPA cannot allocate essential use allowances for particular MDIs until FDA finalizes the proposed revisions to its essential use regulations or engages in a separate rulemaking to determine whether those MDIs are essential.

While we are aware that FDA is currently engaged in rulemaking to revise its essential use regulations, we are relying on FDA's current essential use list at 21 CFR 2.125 for purposes of today's action. That list contains all of FDA's determinations regarding "essentiality" to date. The statute does not specify a particular time at which FDA must make such a determination or invalidate determinations made prior to the date of the 1990 CAA Amendments. Additionally, the 1990 Amendments to the Clean Air Act use language consistent with FDA's regulations at 21 CFR 2.125. We presume that Congress was aware of FDA's regulations when it passed the 1990 Amendments to the CAA. Therefore, we believe that the current essential use list remains valid. If FDA revises its regulations, we will take the revised list into account in future allocation decisions.

We received several comments on the meaning of the word "approved" in section 601(8)(B). In the preamble to the proposed rule, we stated that EPA and FDA were discussing how best to interpret this term, and that there were at least two possible interpretations. One such interpretation was that FDA

had to approve the specific product under the FDCA. The second interpretation was that FDA had to have approved either that product or another product that contained the same active moiety. Several commentors stated that the second interpretation would be contrary to the plain meaning of the statute.

Section 601(8)(B) refers to approval as occurring "after notice and opportunity for comment." FDA has informed us that approvals of drug products under the FDCA are issued without notice and comment. For this reason, FDA has concluded that in using the word "approved," Congress cannot have been referring to approval of the drug product under the FDCA. We agree with this conclusion. We also note that the statutory language refers to actions taken by FDA, *in consultation with EPA*. FDA does not consult with EPA prior to approving drug products under the FDCA. Furthermore, FDA points out that it has provided notice and opportunity for comment prior to adding categories of drug products to the essential use list in 40 CFR 2.125. (FDA has also informally consulted with EPA in the course of such actions.) Therefore, FDA interprets the phrase "approved and determined to be essential" as referring to FDA's action in approving the use of CFCs in MDIs containing a particular active moiety as an essential use. As a result, FDA regards all MDIs containing an active moiety that appears on its essential use list as "approved" for purposes of 601(8)(B). According to this interpretation, an MDI that has not yet received approval of its ANDA or NDA under the FDCA is considered to be approved as an essential use if it contains an active moiety that appears on the essential use list.

Two commentors stated that section 601(8)(B) requires FDA approval of the "medical device" itself and that an active moiety cannot be a "medical device". We would like to clarify that the term "device" and the phrase "medical device" have two separate and distinct definitions. "Medical device" is defined under 601(8) of the CAA. "Device" is defined under the FDCA. Furthermore, we are not stating that the active moiety in an MDI is a "medical device" under the CAA. Rather, FDA and EPA are interpreting section 601(8)(B) to allow MDIs to be "approved and determined to be essential" by active moiety. That is, if FDA, in consultation with EPA, has listed MDIs containing a particular active moiety as essential, then a separate determination is not necessary for each MDI that

contains that active moiety. FDA has listed MDIs with reference to the active moiety. Therefore, an MDI that contains an active moiety that appears on FDA's essential use list has been "approved and determined to be essential."

One commentator stated that according to principles of statutory construction, the term "approved" should be interpreted the same way in section 601(8)(A) and section 601(8)(B). We believe that the term "approved" must be interpreted in light of the surrounding language in each instance. Section 601(8)(B) requires notice-and-comment rulemaking and refers to action by FDA, in consultation with EPA. Since approval under the FDCA involves unilateral action by FDA without notice-and-comment rulemaking, it is reasonable to conclude that section 601(8)(B) does not refer to approval of an NDA or ANDA under the FDCA. Instead, we interpret the phrase "approved and determined to be essential" as referring to any MDI that contains an active moiety appearing on FDA's essential use list. This interpretation is consistent with the surrounding language, as FDA adds uses to its list through notice-and-comment rulemaking, and EPA has a clear interest in being consulted regarding the listing of essential uses of ODS.

In regard to section 601(8)(A), we interpret this section as requiring a determination by FDA that there is a "safe and effective alternative" to a CFC MDI. Approval under the FDCA may be a prerequisite to such a determination. (We note that the statutory language calls for approval "where necessary.") Because section 601(8)(A) does not refer to notice and comment rulemaking or consultation with EPA, it is reasonable to interpret the reference to "approval" as a reference to approval under the FDCA. However, neither EPA nor FDA views FDA approval of a non-CFC product under the FDCA as constituting a determination that the product is a "safe and effective alternative" to any CFC MDI. That determination would require a separate analysis. FDA has described some of the factors that would enter into such an analysis in the preamble to its September 1, 1999 notice of proposed rulemaking on essential use determinations (64 FR 47735), and we refer the reader to that notice for further details.

This commentator also stated that the term "approved" as used in section 601(8)(B) should be interpreted as it is interpreted under the FDCA, to refer to the entire drug product rather than simply the active ingredients. For the reasons stated above, we have

concluded that the word "approved" in section 601(8)(B) does not refer to approval under the FDCA.

One commentator stated that EPA had not meaningfully addressed the requirements of section 604(d)(2) of the CAA, the exception for medical devices. This commentator stated that EPA must provide information on "current market demand for the use of CFCs in particular MDIs, what quantities of CFCs were requested by particular companies in their annual applications for each particular active moiety and how the essential use allowances are "necessary" or "limited", and how the applicant met its burden of demonstrating that it qualifies for CFCs under the essential use criteria set out in the Act."

Section 604(d)(2) of the CAA states that "the Administrator, after notice and opportunity for public comment, shall, to the extent such action is consistent with the Montreal Protocol, authorize the production of limited quantities of class I substances solely for use in medical devices if such authorization is determined by the Commissioner, in consultation with the Administrator, to be necessary for use in medical devices." As described in Section II of this preamble, EPA and FDA have consulted on whether the limited quantities contained in the proposed rule were "necessary" for use in medical devices, and FDA has determined that 2737.3 tons of the proposed amount are "necessary." Accordingly, in this interim final rule, EPA is allocating 2737.3 tons for use in medical devices.

With regard to the commentator's request for information, the letter from FDA states the following: ". . . we [FDA] have examined the table in your [EPA] proposed rule that lists the essential use amounts requested by sponsors for production of medical devices (64 FR 59143, Table 1). We have also examined the information you obtained from individual sponsors regarding their intended use of CFCs in specific products. We compared this information to the information filed with us by sponsors in their annual reports." FDA goes on to say "In listing the amounts we believe to be necessary for use in medical devices, we referred to historical use and have included an additional amount to allow for overage, for waste during manufacturing, for uncertainties in the supply chain of CFCs since they are no longer produced in the United States, for changes in future market shares of specific products, as well as for unforeseen circumstances in the market. We also

provided additional amounts based on our knowledge of certain manufacturing problems. In addition, we eliminated any double-counting we found and eliminated allocations for uses not considered essential by the parties to the Montreal Protocol, even if those uses are currently listed in our regulation at 21 CFR 2.125(e)." FDA also noted that they accounted for CFCs for use in the production of MDIs that would ultimately be exported to Canada. It should be noted that much of the data that FDA used in their analysis were confidential business information and cannot be shared publicly. These confidential data included each applicant's response to EPA's request for information on the quantity of each CFC to be used in the manufacture of specific products in calendar year 2000, EPA's historical data on yearly import and actual use of CFCs for each company, and information filed with FDA by drug sponsors in their annual reports.

The commentator further stated that in order to achieve the congressional objective of reducing and eliminating production and use of ODS "as expeditiously as possible," "EPA and FDA must conclude that new MDIs are not 'necessary' where FDA has approved or issued an 'apposable' letter for a CFC-free alternative involving the same active moiety and overlapping labeling as that in the CFC-containing MDI." The commentator also states that if EPA nonetheless finds that CFCs are necessary for these MDIs, EPA must limit the quantities allocated to those that are necessary until the CFC-free alternative is approved. The commentator goes on to describe this stance as a "policy."

Under section 604(d)(2) of the CAA, FDA (in consultation with EPA) determines whether production or import of CFCs for MDIs is necessary. EPA does not independently make such a determination, as the comment appears to suggest. We defer to FDA on the wisdom of adopting the policy urged by the commentator. The commentator has not demonstrated that this policy is compelled by the statutory language. For purposes of today's action, we are relying on FDA's determination that the quantities allocated in the final rule are "necessary."

One commentator stated that EPA must ensure that its allocation is consistent with the decisions and recommendations of the Parties to the Montreal Protocol. The commentator refers to two existing decisions: Decision IV/25, which provides criteria for assessing essential uses for purposes

of the Protocol's control measures, and Decision VIII/10, which addresses the transition away from CFC-based MDIs.

Decision IV/25 contemplates that Parties nominating essential uses will apply the stated criteria at the time of nomination, and that the Protocol's Technology and Economic Assessment Panel will apply these criteria in developing its recommendations on whether the Parties should approve the nominated uses and quantities at their yearly meeting. Thus, these criteria drive the essential use process at the international level. The uses to which we are allocating CFCs in today's action were approved at the Tenth Meeting of the Parties, after nomination by the U.S. and evaluation by the Technology and Economic Assessment Panel. Therefore, we believe today's allocation is consistent with the Protocol. In addition, the commenter has not identified any respect in which these uses fail to meet the criteria in Decision IV/25.

Decision VIII/10 describes a variety of actions that Parties are to request MDI companies to undertake. For example, Parties are to "request companies applying for MDI essential-use exemptions to demonstrate that they are undertaking individual or collaborative industry efforts, in consultation with the medical community, to educate health-care professionals and patients about other treatment options and the transition to non-CFC alternatives." (Decision VIII/10(2)) The TEAP Handbook on Essential Use Nominations was revised in 1997 to incorporate requests relevant to Decision VIII/10. For example, question B.2. of the form entitled "Nomination of the Aerosol Metered Dose Inhaler (MDI) as an Essential Use," in Appendix D of the TEAP Handbook on Essential Use Nominations, requests applicants to "List and describe in detail the education efforts, individual and/or collaborative, being undertaken to advise patients and health care professionals about treatment options and the transition to non-CFC alternatives." EPA requests companies applying for MDI essential-use exemptions to submit the information specified in the TEAP Handbook, including the information relevant to Decision VIII/10. Nevertheless, we do not view Decision VIII/10 as imposing barriers to allocation. The Decision does not attach any consequences to the company's failure to comply with any of the requests. The commenter incorrectly describes Decision VIII/10 as "requiring" manufacturers of CFC MDIs to take the specified actions. By its own

terms, the Decision simply states that Parties "will request" companies to take these actions.

One commenter stated that under the CAA EPA cannot allocate CFCs to Medisol Laboratories for use in their generic albuterol MDI because this product does not fall within the definition of a "medical device" under the statute. For reasons stated above, EPA considers the generic albuterol MDI to be a medical device as defined by the statute and thus eligible to receive essential use allowances. While we are aware that FDA has approved a CFC-free albuterol product, FDA has not determined that this product is a "safe and effective alternative" to the Medisol generic albuterol MDI. In addition, albuterol is an adrenergic bronchodilator. FDA continues to regard the use of CFCs in "[m]etered-dose adrenergic bronchodilator human drugs for oral inhalation" as essential (21 CFR 2.125(e)(3)). Because FDA's list of essential uses makes no reference as to whether a drug product is generic or branded, we believe all MDIs for which we are allocating CFCs are covered under 21 CFR 2.125 regardless of whether they were or will be approved under an NDA or ANDA. Therefore, we believe that CFC albuterol MDIs are "medical devices." Finally, we have based our allocation of 49 tons of CFCs to Medisol on FDA's determination that this quantity is "necessary" under CAA section 604(d)(2).

One commenter stated that Sciarra's application for essential use allowances for production of albuterol, epinephrine hydrochloride, ipratropium bromide, triamcinalone acetonide, beclomethasone dipropionate, and cromolyn sodium MDIs should be denied because these products do not satisfy many, if not all of the requirements set by the CAA. According to the commenter, an albuterol MDI should not qualify as a "medical device" under the CAA because there is a "safe and effective alternative propellant" (HFC-134a), that is, a safe and effective alternative to the CFCs used in albuterol MDIs. Additionally, the commenter stated that FDA has not determined that the generic products listed above are essential after notice and opportunity for public comment. The commenter also noted that FDA has issued appposable letters for CFC-free versions of all the above moieties except epinephrine and ipratropium, and concluded that even if these products qualify as "medical devices," the allocation of CFCs is not "necessary." Additionally, the commenter stated that Sciarra's application provided

inadequate information in its response to the Protocol criteria. Specifically, Sciarra did not provide information about the availability of alternatives to CFC MDIs or information on its plans for implementation of these alternatives. The commenter did note that Sciarra had stated that it would develop its own non-CFC products after receiving approval for its CFC-containing products.

As stated before, while FDA has approved a CFC-free albuterol product, FDA has not determined that this product is a "safe and effective alternative" to any other albuterol product. In addition, albuterol is an adrenergic bronchodilator. FDA continues to regard the use of CFCs in "[m]etered-dose adrenergic bronchodilator human drugs for oral inhalation" as essential (21 CFR 2.125(e)(3)). Therefore, we believe that CFC albuterol MDIs are "medical devices." Our understanding is that FDA has always added uses to its essential use list through notice and comment rulemaking. Because FDA's list of essential uses makes no reference as to whether a drug product is generic or branded, we believe all MDIs for which we are allocating CFCs are covered under 21 CFR 2.125 regardless of whether they were or will be approved under an NDA or ANDA. In Sciarra's response to the CAA section 114 letter that EPA sent to MDI manufacturers on October 13, 1999, Sciarra provided a refined list of moieties for the MDIs for which it is requesting CFCs. The use of any of these moieties in an MDI is essential under 21 CFR 2.125(e). With the regard to the issue of whether CFCs are "necessary" for the Sciarra MDIs, we are relying on FDA's determination. FDA, in its analysis of the amount of CFCs necessary for the production of MDIs, determined that much of the quantity we had proposed to allocate to Sciarra was not "necessary" because at present, Sciarra does not have any currently approved CFC MDIs. The essential use allocation for Sciarra was reduced accordingly in this interim final rule.

The TEAP Handbook contains several questions relating to the availability of alternatives. As we noted earlier, many of the questions in the current TEAP Handbook derive from Decision VIII/10. This Decision directs the Parties to request certain information from companies applying for MDI essential-use exemptions. However, it does not attach specific consequences to a company's failure to provide information, nor does it state what constitutes an adequate response.

One commenter stated that the application for CFCs from Schering should be denied only if EPA also denies CFC applications for albuterol MDIs for all other companies marketing such products. The commenter identified Schering as the company that markets the non-CFC albuterol MDI. For the reasons stated above, EPA is allocating CFCs to manufacturers of CFC albuterol MDIs, including Schering.

One commenter stated that the public version of the application for the International Pharmaceutical Aerosol Consortium (IPAC) did not provide information about the specific products that would be manufactured using the essential use allowances. The commenter noted that Medeva Americas is one of the companies identified in the IPAC proposal, and stated that this company markets a generic CFC albuterol MDI. The commenter further stated that another IPAC company, Glaxo Wellcome, markets a CFC albuterol MDI. According to the commenter, neither of these companies should receive CFC allocations for these products.

IPAC completed the application for essential use allowances in accordance with the TEAP Handbook. EPA requested information about the specific products for which the allowances would be used from IPAC's member companies in a letter issued pursuant to section 114 of the CAA on October 13, 1999. The responses to these letters are considered confidential business information and are therefore not available in the public docket. As stated earlier FDA used this information in its analysis of what quantities of CFCs are necessary for the production of medical devices as defined in the Act. Each of the products for which FDA determined a quantity of CFCs to be necessary is "essential" under 21 CFR 2.125(e). Since the commenter specifically mentions albuterol, we note again that albuterol is an adrenergic bronchodilator. FDA continues to regard the use of CFCs in "[m]etered-dose adrenergic bronchodilator human drugs for oral inhalation" as essential (21 CFR 2.125(e)(3)). Our understanding is that FDA has always added uses to its essential use list through notice and comment rulemaking. Because FDA's list of essential uses makes no reference as to whether a drug product is generic or branded, we believe all MDIs for which we are allocating CFCs are covered under 21 CFR 2.125 regardless of whether they were or will be approved under an NDA or ANDA. Furthermore, as stated before, while FDA has approved a CFC-free albuterol

product, FDA has not determined that this product is a "safe and effective alternative" to any other albuterol product. Therefore, we believe that CFC albuterol MDIs are "medical devices."

One commenter stated that EPA determines the safety and efficacy of alternatives to CFCs under the Significant New Alternatives Policy (SNAP) program (section 612 of the CAA). The commenter further stated that EPA relies upon FDA's approval of medical products containing alternative propellants as a determination that the alternative propellant has no adverse human health effects. The commenter concluded that "when FDA approves a product containing an alternative propellant as safe and effective under the FDCA, EPA concludes that the non-CFC propellant in that product is safe and effective for the purposes of the CAA."

Under section 612 of the CAA, EPA determines whether substitutes for ozone-depleting substances may present adverse effects to human health or the environment. In the SNAP rule published in the *Federal Register* on March 18, 1994 (59 FR 13044), EPA stated: "Some medical devices * * * currently contain class I or class II compounds. The Agency has determined that such products are exempt from further review for human health effects under the SNAP program where FDA approval of such effects is required before a product can be introduced into commerce. EPA will rely in its SNAP determination on FDA's conclusions regarding health effects. The Agency believes this exemption is justified because of the higher burden of proof placed on submitters under the FDCA. However, the Agency will continue to evaluate all other environmental effects of the proposed substitute, and will consult with the FDA to determine the appropriate course of action." (59 FR 130660).

The quoted language simply indicates that EPA will conclude that a substitute does not present adverse health effects if FDA approves, under the FDCA, a product containing the substitute. It does not say that EPA will treat the product approval as a determination that the substitute is a "safe and effective alternative" to the ODS for purposes of section 601(8)(A). FDA approval of a CFC-free MDI under the FDCA does not constitute approval of the non-CFC propellant as safe and effective. Such approval relates to the product in its entirety, not to the propellant. Therefore, it would be inappropriate for the EPA to conclude

from FDA's approval of a non-CFC MDI that the non-CFC propellant had been approved for use in MDIs generally. In listing acceptable alternatives under the SNAP program, EPA does not intend to preempt FDA's role in approving individual products or in deciding whether a particular product is a safe and effective alternative for another.

V. Administrative Requirements

A. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector.

Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Section 204 of the UMRA requires the Agency to develop a process to allow elected state, local, and tribal government officials to provide input in the development of any proposal containing a significant Federal intergovernmental mandate.

Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local, or tribal governments or the private sector. Because this rule imposes no enforceable duty on any State, local or tribal government it is not subject to the requirements of sections 202 and 205 of the UMRA. EPA has also determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments; therefore, EPA is not required to develop a plan with regard to small governments under section 203. Finally, because this rule does not contain a significant intergovernmental mandate, the Agency is not required to develop a process to obtain input from elected state, local, and tribal officials under section 204.

B. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether this regulatory action is "significant" and therefore subject to OMB review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

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

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

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

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. It has been determined by OMB and EPA that this action is not a "significant regulatory action" under the terms of Executive Order 12866 and is therefore not subject to OMB review under the Executive Order.

C. Paperwork Reduction Act

This action does not add any information collection requirements or increase burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* The Office of Management and Budget (OMB) previously approved the information collection requirements contained in the final rule promulgated on May 10, 1995, and assigned OMB

control number 2060-0170 (EPA ICR No. 1432.16).

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR Part 9 and 48 CFR Chapter 15.

D. Executive Order 13084: Consultation and Coordination With Indian Tribal Governments

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities." Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the

requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

E. Regulatory Flexibility

After considering the economic impacts of today's final rule on small entities, EPA has determined that it is not necessary to prepare a regulatory flexibility analysis in connection with this final rule. EPA has also determined that this action will not have a significant economic impact on a substantial number of small entities. This rule does not have a significant impact on a substantial number of small entities. The only entities that are directly affected by this allocation are those to which CFCs and other ODSs are being allocated. There are only ten entities which are affected by this rulemaking (see table 1 above). This rule does not have an adverse economic impact on any entity because it grants exceptions to a pre-existing ban.

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

Executive Order 13045: "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997) applies to any rule that (1) is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health and safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency. EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5-501 of the Order has the potential to influence the regulation. This rule is not subject to Executive Order 13045 because it implements the phaseout schedule and exemptions established by Congress in Title VI of the Clean Air Act.

G. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 ("NTTAA"), Public Law No. 104-113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be

inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This rule does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

H. Executive Order 13132 (Federalism)

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." Under Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

If EPA complies by consulting, Executive Order 13132 requires EPA to provide to the Office of Management and Budget (OMB), in a separately identified section of the preamble to the

rule, a federalism summary impact statement (FSIS). The FSIS must include a description of the extent of EPA's prior consultation with State and local officials, a summary of the nature of their concerns and the agency's position supporting the need to issue the regulation, and a statement of the extent to which the concerns of State and local officials have been met. Also, when EPA transmits a draft final rule with federalism implications to OMB for review pursuant to Executive Order 12866, EPA must include a certification from the agency's Federalism Official stating that EPA has met the requirements of Executive Order 13132 in a meaningful and timely manner. This interim final rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. This interim final rule will affect only the ability of private entities and the national government to request production of controlled ozone-depleting substances. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

VI. Judicial Review

Under Section 307(b)(1) of the Act, EPA finds that these regulations are of national applicability. Accordingly, judicial review of this action is available only by the filing of a petition for review in the United States Court of Appeals for the District of Columbia Circuit within sixty days of publication of this action in the *Federal Register*. Under Section 307(b)(2), the requirements of this rule may not be challenged later in judicial proceedings brought to enforce those requirements.

VII. Congressional Review

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 rule effective sooner than otherwise provided by the CRA if the agency makes 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 January 6, 2000. 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).

List of Subjects in 40 CFR Part 82

Environmental protection, Administrative practice and procedure, Air pollution control, Chemicals, Chlorofluorocarbons, Exports, Hydrochlorofluorocarbons, Imports, Ozone layer, Reporting and recordkeeping requirements.

Dated: December 30, 1999.

Carol M. Browner,
Administrator.

40 CFR Part 82 is amended as follows:

PART 82—PROTECTION OF STRATOSPHERIC OZONE

1. The authority citation for part 82 continues to read as follows:

Authority: 42 U.S.C. 7414, 7601, 7671–7671q.

Subpart A—Production and Consumption Controls

2. Section 82.4(t)(2) is amended by revising the table to read as follows:

§ 82.4 Prohibitions.

*	*	*	*	*	*
(t)	*	*	*		
(2)	*	*	*		

TABLE I.—ESSENTIAL USE ALLOCATION FOR CALENDAR YEAR 2000

Company	Chemical	Quantity (metric tons)
(i) Metered Dose Inhalers for Treatment of Asthma and Chronic Obstructive Pulmonary Disease (in metric tons)		
International Pharmaceutical Aerosol Consortium (IPAC)—Medeva Americas, Inc., Boehringer Ingelheim Pharmaceuticals, Glaxo Wellcome, Rhone-Poulenc Rorer, 3M.	CFC-11 or CFC-12 or CFC-114	1639.0
Medisol Laboratories, Inc.	CFC-11 or CFC-12 or CFC-114	49.0
Schering Corporation	CFC-11 or CFC-12 or CFC-114	1048.0
Sciarra Laboratories, Inc.	CFC-11 or CFC-12 or CFC-114	1.3
(2)(ii) Cleaning, Bonding and Surface Activation Applications for the Space Shuttle Rockets and Titan Rockets		
National Aeronautics and Space Administration (NASA)/Thiokol Rocket	Methyl Chloroform	56.7
United States Air Force/Titan Rocket	Methyl Chloroform	3.4

* * * * *

[FR Doc. 00-273 Filed 1-5-00; 8:45 am]

BILLING CODE 6560-60-P

Proposed Rules

Federal Register

Vol. 65, No. 4.

Thursday, January 6, 2000

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99-CE-72-AD]

RIN 2120-AA64

Airworthiness Directives; British Aerospace Jetstream Model 3201 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to adopt a new airworthiness directive (AD) that would apply to all British Aerospace Jetstream Model 3201 airplanes. The proposed AD would require inspecting the fuel quantity indication system for damage to the insulation of the wiring within the fuel tanks. Damage is defined as corrosion (indicated by a dark stain), cuts, or nicks. The proposed AD would also require replacing or repairing any damaged wiring. The proposed AD is the result of mandatory continuing airworthiness information (MCAI) issued by the airworthiness authority for the United Kingdom. The actions specified by the proposed AD are intended to detect damage to the insulation of the wiring within the fuel tanks of the fuel quantity indication system, which could result in a malfunction in the cockpit indicators and/or electrical sparking inside the fuel tank with consequent fire or explosion.

DATES: Comments must be received on or before February 9, 2000.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 99-CE-72-AD, 901 Locust, Room 506, Kansas City, Missouri 64106. Comments may be inspected at this location between 8 a.m. and 4 p.m., Monday through Friday, holidays excepted.

Service information that applies to the proposed AD may be obtained from British Aerospace Regional Aircraft, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland; telephone: (01292) 672345; facsimile: (01292) 671625. This information also may be examined at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Mr. S.M. Nagarajan, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 506, Kansas City, Missouri 64106; telephone: (816) 329-4145; facsimile: (816) 329-3091.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed 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 proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 99-CE-72-AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 99-CE-72-AD, 901 Locust, Room 506, Kansas City, Missouri 64106.

Discussion

The Civil Airworthiness Authority (CAA), which is the airworthiness authority for the United Kingdom, recently notified the FAA that an unsafe condition may exist on all British Aerospace Jetstream Model 3201 airplanes. The CAA reports that, during a routine inspection, damage to the insulation of the wiring within the wing fuel tanks of the fuel quantity indication system on two of the affected airplanes was revealed. Further investigation shows that the damage to the insulation occurred during factory installation.

This condition, if not detected and corrected in a timely manner, could result in a malfunction in the cockpit indicators and/or electrical sparking inside the fuel tank with consequent fire or explosion.

Relevant Service Information

British Aerospace has issued Jetstream Alert Service Bulletin 28-A-JA990841, Original Issue: September 8, 1999; and Jetstream Alert Service Bulletin 28-A-JA990841 Revision No. 1: November 12, 1999. These documents include procedures for inspecting the fuel quantity indication system for damage to the insulation of the wiring within the fuel tanks, and replacing or repairing any damaged wiring.

The CAA classified these service bulletins as mandatory and issued British AD 003-09-99, dated September 13, 1999, in order to assure the continued airworthiness of these airplanes in the United Kingdom.

The FAA's Determination

This airplane model is manufactured in the United Kingdom and is type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the CAA has kept the FAA informed of the situation described above.

The FAA has examined the findings of the CAA; reviewed all available information, including the service information referenced above; and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Explanation of the Provisions of the Proposed AD

Since an unsafe condition has been identified that is likely to exist or develop in other British Aerospace Jetstream Model 3201 airplanes of the same type design registered in the United States, the FAA is proposing AD action. The proposed AD would require inspecting the fuel quantity indication system for damage to the insulation of the wiring within the fuel tanks. Damage is defined as corrosion (indicated by a dark stain), cuts, or nicks. The proposed AD would also require replacing or repairing any damaged wiring. Accomplishment of the proposed actions would be required in accordance with the service information previously discussed.

Compliance Time Criteria of the Proposed AD

The compliance time of this AD is presented in both calendar time and hours time-in-service (TIS). Damage to the insulation of the wires in the fuel quantity indicator system could result in corrosion in the core conductor. Corrosion damage can then develop regardless of whether the airplane is in flight, and may not develop until a later time. Therefore, in order to assure that any damage does not go undetected, a compliance time of both hours TIS and calendar time (the prevalent one being that which occurs first) is proposed.

Cost Impact

The FAA estimates that 115 airplanes in the U.S. registry would be affected by the proposed AD, that it would take approximately 60 workhours per airplane to accomplish the proposed inspection, and that the average labor rate is approximately \$60 an hour. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be \$414,000, or \$3,600 per airplane.

Regulatory Impact

The regulations proposed herein would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this proposed rule would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this action (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if

promulgated, 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 copy of the draft regulatory evaluation prepared for this action has been placed in the Rules Docket. A copy of it may be obtained by contacting 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.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 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 a new airworthiness directive (AD) to read as follows:

British Aerospace: Docket No. 99-CE-72-AD.

Applicability: Jetstream Model 3201 airplanes, all serial numbers, 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 in the body of this AD, unless already accomplished.

To detect damage to the insulation of the wiring within the fuel tanks of the fuel quantity indication system, which could result in a malfunction in the cockpit indicators and/or electrical sparking inside the fuel tank with consequent fire or explosion, accomplish the following:

(a) Within the next 100 hours time-in-service (TIS) after the effective date of this AD or within the next 60 calendar days after the effective date of this AD, whichever occurs first, inspect the fuel quantity

indication system for damage to the insulation of the wiring within the fuel tanks. Damage is defined as corrosion (indicated by a dark stain), cuts, or nicks. Prior to further flight, replace or repair any damaged wiring. Accomplish these actions in accordance with one of the following:

(1) British Aerospace Jetstream Alert Service Bulletin 28-A-JA990841, Original Issue: September 8, 1999; or

(2) British Aerospace Jetstream Alert Service Bulletin 28-A-JA990841, Original Issue: September 8, 1999; Revision No. 1: November 12, 1999.

(b) Special flight permits may be issued in accordance with sections 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.

(c) An alternative method of compliance or adjustment of the compliance times that provides an equivalent level of safety may be approved by the Manager, Small Airplane Directorate, Aircraft Certification Service, 901 Locust, Room 301, Kansas City, Missouri 64106. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Small Airplane Directorate.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Small Airplane Directorate.

(d) Questions or technical information related to the service information referenced in this document should be directed to British Aerospace Regional Aircraft, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland; telephone: (01292) 672345; facsimile: (01292) 671625. This service information may be examined at the FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106.

Note 3: The subject of this AD is addressed in British AD 003-09-99, dated September 13, 1999.

Issued in Kansas City, Missouri, on December 29, 1999.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 00-241 Filed 1-5-00; 8:45 am]

BILLING CODE 4910-13-U

DEPARTMENT OF COMMERCE

International Trade Administration

DEPARTMENT OF THE INTERIOR

Office of Insular Affairs

15 CFR Part 303

[Docket No. 991228350-9350-01]

RIN 0625-AA55

Proposed Changes in Watch, Watch Movement and Jewelry Program for the U.S. Insular Possessions

AGENCIES: Import Administration, International Trade Administration, Department of Commerce; Office of Insular Affairs, Department of the Interior.

ACTION: Notice of proposed rulemaking and request for comments.

SUMMARY: The Departments invite public comment on a proposal to amend the regulations governing duty-exemption allocations for watch producers and duty-refund benefits for watch and jewelry producers in the United States insular possessions (the U.S. Virgin Islands, Guam, American Samoa and the Commonwealth of the Northern Mariana Islands ("CNMI")). The proposal would amend Subpart A of Title 15 CFR Part 303 by establishing the total quantity and respective territorial shares of insular watches and watch movements which would be allowed to enter the United States free of duty during calendar year 2000 and by clarifying the definition of a new firm for watches. The proposal would also amend Subparts A and B of 15 CFR 303 by establishing a permanent formula for the creditable wage ceiling.

DATES: Written comments must be received on or before February 7, 2000.

ADDRESSES: Address written comments to Faye Robinson, Program Manager, Statutory Import Programs Staff, Room 4211, U.S. Department of Commerce, Washington, D.C. 20230.

FOR FURTHER INFORMATION CONTACT: Faye Robinson, (202) 482-3526, same address as above.

SUPPLEMENTARY INFORMATION: The insular possessions watch industry provision in Sec. 110 of Pub. L. No. 97-446 (96 Stat. 2331) (1983), as amended by Sec. 602 of Pub. L. No. 103-465 (108 Stat. 4991) (1994); additional U.S. Note 5 to chapter 91 of the Harmonized Tariff Schedule of the United States ("HTSUS"), as amended by Pub. L. 94-241 (90 Stat 263) (1976) requires the Secretary of Commerce and the Secretary of the Interior, acting jointly,

to establish a limit on the quantity of watches and watch movements which may be entered free of duty during each calendar year. The law also requires the Secretaries to establish the shares of watches and watch movements which may be entered from the Virgin Islands, Guam, American Samoa and the CNMI. Regulations on the establishment of these quantities and shares are contained in Sec. 303.3 and 303.4 of Title 15, Code of Federal Regulations (15 CFR 303.3 and 303.4). The Departments propose amending Sec. 303.14(e) to establish for calendar year 2000 a total quantity of 3,366,000 units and respective territorial shares as shown in the following table:

Virgin Islands	1,866,000
Guam	500,000
American Samoa	500,000
CNMI	500,000

Compared to the total quantity established for 1999 (63 FR 49666; September 17, 1998), this amount would be a decrease of 374,000 units. The proposed Virgin Islands territorial share would be reduced by 374,000 units and the shares for Guam, American Samoa and the CNMI would not change. The amount we propose for the Virgin Islands is more than sufficient for the anticipated needs of all the existing producers.

The enactment of Pub. L. 106-36 amended additional U.S. notes to chapter 71 of the Harmonized Tariff Schedule of the United States to provide a duty-refund benefit for any article of jewelry within heading 7113 which is a product of the Virgin Islands, Guam, American Samoa or the CNMI in accordance with the new provisions of the note in chapter 71 and additional U.S. note 5 to chapter 91. The Departments published a final rule on December 1, 1999 (64 FR 67149) which amended the regulations by changing Title 15 CFR Part 303 to include jewelry and creating a Subpart A for the insular watch and watch movement regulations and a Subpart B for the new regulations pertaining to jewelry duty-refund benefits authorized by Pub. L. 106-36. When we requested comments on the proposed jewelry regulations, we received a comment regarding the requirement that a new firm be "completely separate from and not associated with, by way of ownership or control" with other jewelry program participants in the territory. In the final jewelry rule, we revised the language using new terminology borrowed from existing fair trade law to clarify the language. To ensure consistency and clarity, we propose amending Sec.

303.2(a)(5) to include the new terminology in Subpart A as well.

We also propose establishing a permanent formula for the creditable wage ceiling for watches and jewelry by amending Sec. 303.2(a)(13), Sec. 303.14(a)(1)(i) and Sec. 303.16(a)(9), respectively. The creditable wage ceiling is used in the calculation of the value of the production incentive certificate (duty refund). We propose establishing an annual wage ceiling up to an amount equal to 65% of the contribution and benefit base for Social Security as defined in Sec. 230(c) of the Social Security Act, as amended (42 U.S.C. 430). Until 1976, the Departments credited wages up to the contribution and benefit base for Social Security. In that year, the Departments adopted an independent ceiling lower than the contribution and benefit base in order to increase the incentive for the employment and training of territorial residents in skilled jobs. (see 40 FR 54274 (1975)) Since 1983, the Departments have revised the ceiling upwards several times to keep pace with inflation. We now believe that establishing a new ceiling in the form of a fixed percentage of the contribution and benefit base for Social Security would serve the public interest. It would assist producers in better planning expenditures and calculating potential profits and benefits. This change would also eliminate the need for periodic rulemaking to adjust the ceiling, provide an annual incremental increase consistent with the Departments' past policy objectives, *id.*, and create transparency in the calculation of the ceiling.

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, the Chief Counsel for Regulation at the Department of Commerce has certified to the Chief Counsel for Advocacy, Small Business Administration, that the proposed rule, if promulgated as final, will not have a significant economic impact on a substantial number of small entities. There are currently five watch companies, all of which are located in the Virgin Islands. Although a reduction of the 2000 Virgin Islands territorial share of duty-exemption is being proposed, the reduced amount would still represent more than twice the amount of duty-exemption used in 1998. The statute does not permit a lower amount in the year 2000. Similarly, clarifying new entrant affiliation language and updating the creditable wage ceiling with a permanent annual mechanism will not impose any cost or have any other

adverse economic effect on the producers.

Paperwork Reduction Act

This proposed rulemaking involves no new collection-of-information requirements subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. Collection activities are currently approved by the Office of Management and Budget under control numbers 0625-0040 and 0625-0134 and the amendments will not increase the information burden on the public.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information unless it displays a currently valid OMB Control Number.

E.O. 12866.

It has been determined that the proposed rulemaking is not significant for purposes of Executive Order 12866.

List of Subjects in 15 CFR Part 303

Administrative practice and procedure, American Samoa, Customs duties and inspection, Guam, Imports, Marketing quotas, Northern Mariana Islands, Reporting and record keeping requirements, Virgin Islands, Watches and jewelry.

For reasons set forth above, The Departments propose to amend 15 CFR Part 303 as follows:

PART 303—WATCHES, WATCH MOVEMENTS AND JEWELRY PROGRAM

1. The authority citation for 15 CFR Part 303 reads as follows:

Authority: Pub. L. 97-446, 96 Stat. 2331 (19 U.S.C. 1202, note); Pub. L. 103-465, 108 Stat. 4991; Pub. L. 94-241, 90 Stat. 263 (48 U.S.C. 1681, note); Pub. L. 106-36, 113 Stat. 127, 167.

2. Section 303.2(a)(5) is revised to read as follows:

§ 303.2 Definitions and forms.

(a) *Definitions.* Unless the context indicates otherwise:

* * * * *

(5) *New firm* is a watch firm which may not be affiliated through ownership or control with any other watch duty-refund recipient. In assessing whether persons or parties are affiliated, the Secretaries will consider the following factors, among others: stock ownership; corporate or family groupings; franchise or joint venture agreements; debt financing; and close supplier

relationships. The Secretaries may not find that control exists on the basis of these factors unless the relationship has the potential to affect decisions concerning production, pricing, or cost. Also, no watch duty-refund recipient may own or control more than one jewelry duty-refund recipient. A *new entrant* is a new watch firm which has received an allocation.

* * * * *

3. The first sentence of § 303.2(a)(13) is amended by removing "up to the amount per person shown in § 303.14(a)(1)(i)" and adding "up to an amount equal to 65% of the contribution and benefit base for Social Security as defined in the Social Security Act for the year in which the wages were earned" in its place.

§ 303.14 [Amended]

4. Section 303.14(a)(1)(i) is amended by removing ", up to a maximum of \$38,650 per person," and adding ", up to an amount equal to 65% of the contribution and benefit base for Social Security as defined in the Social Security Act for the year in which the wages were earned," in its place.

5. Section 303.14(e) is amended by removing "2,240,000" and adding "1,866,000" in its place.

§ 303.16 [Amended]

6. The first sentence of § 303.16(a)(9) is amended by removing "up to the amount per person of \$38,650" and adding "up to an amount equal to 65% of the contribution and benefit base for Social Security as defined in the Social Security Act for the year in which the wages were earned" in its place.

Richard W. Moreland,

Acting Assistant Secretary for Import Administration, Department of Commerce.

Sandra King,

Acting Director, Office of Insular Affairs, Department of the Interior.

[FR Doc. 00-287 Filed 1-5-00; 8:45 am]

BILLING CODE 3510-DS-P; 4310-93-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA-172-0205A; FRL-6519-2]

Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision South Coast Air Quality Management District; Extension of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; extension of the comment period.

SUMMARY: EPA is extending the comment period for a proposed rule published December 17, 1999 (64 FR 70652). On December 17, 1999, EPA proposed a disapproval of revisions to the California State Implementation Plan concerning federal recognition of variances in the South Coast Air Quality Management District. In response to requests from the South Coast Air Quality Management District, the San Diego Air Pollution Control District, and the Regulatory Flexibility Group, EPA is extending the comment period for 14 days.

DATES: The comment period is extended until January 17, 2000.

ADDRESSES: Comments should be submitted to: Ginger Vagenas, Permits Office (AIR-3), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105-3901.

FOR FURTHER INFORMATION CONTACT: Ginger Vagenas at (415) 744-1252.

Dated: December 21, 1999.

Felicia Marcus,

Regional Administrator, Region IX.

[FR Doc. 00-272 Filed 1-5-00; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

49 CFR Part 1244

[STB Ex Parte No. 385 (Sub-No. 4)]

Modification of the Carload Waybill Sample and Public Use File Regulations

AGENCY: Surface Transportation Board, Transportation.

ACTION: Notice of proposed rulemaking.

SUMMARY: Modifications to the existing regulations are proposed that would require all railroads to identify contract movements in the annual carload waybill sample. A 30-year limit on the confidentiality of the "Waybill Sample" is also proposed.

DATES: Comments are due February 21, 2000.

ADDRESSES: Send comments (an original and 10 copies) referring to STB Ex Parte No. 385 (Sub-No. 4) to: Surface Transportation Board, Office of the Secretary, Case Control Branch, 1925 K Street, NW, Washington, D.C. 20423-0001.

FOR FURTHER INFORMATION CONTACT: Paul A. Aguiar, (202) 565-1527 or H. Jeff

Warren, (202) 525-1533. [Assistance for the hearing impaired is available through TDD services (202) 565-1695.]

SUPPLEMENTARY INFORMATION: Railroads that annually terminate 4,500 or more carloads (or 5 percent of the carloads in any State) are required to report data, including revenues, on individual movements drawn from a sampling of their traffic. This "Waybill Sample" is used for a variety of purposes by the Board, by parties appearing before the agency, by other Federal and State agencies, and by the public in general. Because of the current widespread use of confidential transportation contracts in the railroad industry,¹ the Waybill Sample reporting requirements must be revised to ensure that accurate and representative data on contract movements are reported.² At the same time, confidentiality must be maintained and the reporting burden held to a minimum.

In an Advance Notice of Proposed Rulemaking (ANPR), served May 17, 1999, we solicited comments on modifications to the existing regulations at 49 CFR Part 1244 to enhance the usefulness of the Waybill Sample and to conform to requirements of the National Archives and Records Administration (Archives) for storing historical records. We specifically requested comments on requiring all railroads to identify (flag) those shipments in the Waybill Sample that are governed by transportation contracts and to report the actual revenues for each such contract shipment. We explained that, to maintain the confidentiality of the contract rate information, we would substitute an average revenue value for the actual revenues in the version of the Waybill Sample that is made publicly available. We suggested that these changes would fulfill our need for more complete contract data, while protecting sensitive commercial contract rate information, and would allow others to conduct accurate, broad-based economic studies. Finally, we requested comments on limiting the confidentiality of the Waybill Sample records to 20 years.

We received comments from AAR, the U.S. Department of Transportation (DOT), the Western Coal Traffic League

(WCTL), David L. Hall (Hall), and Escalation Consultants, Inc (EC).

1. Identification of Contract Shipments

AAR objects to mandatory flagging and suggests that the decision to identify contract movements should be left to the carriers. AAR questions the need to identify contract movements and argues that the flagging requirement would impose added administrative and cost burdens on the railroads.

DOT supports requiring the railroads to identify contract shipments. DOT states that this change will bring greater consistency to the Waybill Sample and improve the Board's capacity to monitor and analyze the rail industry. WCTL and Hall also support requiring railroads to identify contract shipments in the Waybill Sample, suggesting that it will increase the accuracy of the data and the sample's usefulness.

We agree that we need accurate information on the rail industry for monitoring and regulating that industry. Inaccurate information on the amount and nature of traffic moving under contract (and thus beyond our regulatory control) could affect our assessment of the potential impact of our decisions on rail transportation issues.

The collection of this contract data should place little additional burden on the industry. The proposed rule will have no impact on those carriers already flagging contract movements and, judging from the willingness of many railroads to do so voluntarily, should place only a relatively minor burden on those not currently flagging contracts.

2. Masking of Contract Revenues

Under current procedures each carrier that flags contract shipments is permitted to encrypt (mask) the revenues associated with such shipments so long as it provides us with the necessary information to develop the actual contract revenues. In an attempt to provide a more useful method of masking all revenue information in the Waybill Sample, we suggested developing an average revenue per ton-mile by Standard Transportation Commodity Code within broad geographic areas that we would substitute for actual revenues in the publicly available Waybill Sample. The commenting parties uniformly oppose this proposal. AAR is concerned that the submission of unmasked contract revenues (even though the revenues would be masked prior to any public release) would increase the risk of inadvertent release of confidential information. DOT, EC, WCTL and Hall are concerned that the use of broad

geographic aggregations would result in worse, rather than better, information being available. Given the parties' universal opposition to this proposal, we will not pursue it further.

Under the proposed regulations, railroads will be allowed to continue to develop their own procedures to mask contract revenues, provided that those procedures are disclosed to us. However, if carriers do not want to develop their own masking procedures, we will, upon request, mask the revenues once the waybill information is submitted or provide a masking procedure for the carriers to apply.

3. Waybill Confidentiality Time Limit

Finally, to conform to requirements for storage of the Waybill Sample by the Archives, the ANPR requested comment on limiting the confidential treatment of contract revenue information contained in the Waybill Sample to a 20-year period. We selected 20 years because most rail contracts do not exceed a 20-year term. Thus, we believed this period would be adequate to protect commercially sensitive shipper and railroad data.

AAR argues that the confidential information should never be made public and should be destroyed at the end of the period for which the Board normally maintains these records. WCTL and Hall support the proposed 20-year confidentiality limit, while EC regards the 20-year period as excessive and suggests a time limit of no more than 5 to 7 years.

The Archives, however, has concluded that the Waybill Sample is a permanent Board record and, as such, must be retained.³ Therefore, our task here is not to determine whether the Waybill Sample should be kept, but rather how long it should remain confidential. We are concerned about the premature release of information that continues to have proprietary commercial value. For that reason, we now propose a confidentiality period of 30 years, a period significantly longer than the term of any rail contract of which we are aware. We also propose that the Waybill Sample be sent to the Archives as we maintain it—the contract flags will be included, but the contract revenue will remain masked.

³ In accordance with the National Archives and Records Administrations Act of 1984, Pub. L. 98-497, 44 U.S.C. 101 note, the Waybill Sample was appraised by the Archives and determined to be a permanent record of the Board (Request to Transfer, Approval, and Receipt of Records to National Archives of the United States Job Number NN3-134-094-001). Permanent records must be transferred to the Archives under 44 U.S.C. 2107.

¹ The Association of American Railroads (AAR) recently advised the General Accounting Office that 70% of rail traffic moves under contract. *Railroad Regulation: Changes in Railroad Rates and Service Quality Since 1990* (GAO/RCED-99-93, Apr. 1999), p.23.

² Most class I railroads identify contract movements in the Waybill Sample. Some carriers, however, do not, and as a result, the accuracy and representativeness of Waybill Sample suffers.

This action will not significantly affect either the quality of the human environment or energy conservation.

Pursuant to 5 U.S.C. 605(b), we conclude preliminarily that our action will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act.

List of Subjects in 49 CFR Part 1244

Railroads, Reporting and recordkeeping requirements.

Authority: 49 U.S.C. 11145.

Decided: December 27, 1999.

By the Board, Chairman Morgan, Vice Chairman Clyburn, and Commissioner Burkes.

Vernon A. Williams,
Secretary.

For the reasons set forth in the preamble, title 49, part 1244 of the Code

of Federal Regulations is proposed to be amended as follows:

1. The authority citation for Part 1244 continues to read as follows:

Authority: 49 U.S.C. 721, 10707, 11144, 11145.

2. Redesignate §§ 1244.3 through 1244.8 as §§ 1244.4 through 1244.9.

3. Add new § 1244.3 to read as follows:

§ 1244.3 Reporting contract shipment waybills.

(a) All railroads shall identify (flag) contract shipment waybills.

(b) The revenue associated with contract shipments may be encrypted (masked) to safeguard the confidentiality of the contract rates.

(1) Upon written request, the Board will provide a masking procedure for a railroad's use or will mask the contract revenues when the waybill sample is filed with the Board.

(2) When a railroad intends to use its own proprietary masking procedure, those procedures, and any changes in those procedures, must be approved by the Board thirty (30) days prior to their use.

(3) All railroads that use a proprietary masking procedure, and intend to continue to use the same procedure, must certify, by letter to the Board, prior to January 31 each year, that the contract revenue masking procedures are unchanged.

(4) All correspondence and certifications concerning masking procedures should be addressed to: Director, Office of Economics, Environmental Analysis, and Administration, Surface Transportation Board, Washington, D.C. 20423-0001, ATTN: Waybill Coordinator.

[FR Doc. 00-209 Filed 1-5-00; 8:45 am]

BILLING CODE 4915-00-P

Notices

Federal Register

Vol. 65, No. 4

Thursday, January 6, 2000

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF COMMERCE

International Trade Administration

Final Results of Full Sunset Review: Brass Sheet and Strip From the Netherlands

[A-421-701]

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of final results of full sunset review: Brass sheet and strip from the Netherlands.

SUMMARY: On August 26, 1999, the Department of Commerce ("the Department") published a notice of preliminary results of the full sunset review of the antidumping duty order on brass sheet and strip from the Netherlands (64 FR 46637) pursuant to section 751(c) of the Tariff Act of 1930, as amended ("the Act"). We provided interested parties an opportunity to comment on our preliminary results. We received comments from both domestic and respondent interested parties. As a result of this review, the Department finds that revocation of this order would be likely to lead to continuation or recurrence of dumping at the levels indicated in the Final Results of Review section of this notice.

FOR FURTHER INFORMATION CONTACT: Eun W. Cho or Melissa G. Skinner, Office of Policy for Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, D.C. 20230; telephone: (202) 482-1698 or (202) 482-1560, respectively.

EFFECTIVE DATE: January 6, 2000.

Statute and Regulations

This review was conducted pursuant to sections 751(c) and 752(c) of the Act. The Department's procedures for the conduct of sunset reviews are set forth in Procedures for Conducting Five-Year

("Sunset") Reviews of Antidumping and Countervailing duty Orders, 63 FR 13516 (March 20, 1998) ("Sunset Regulations") and 19 CFR Part 351 (1999) in general. Guidance on methodological or analytical issues relevant to the Department's conduct of sunset reviews is set forth in the Department's Policy Bulletin 98:3—Policies Regarding the Conduct of Five-Year ("Sunset") Reviews of Antidumping and Countervailing Duty Orders; Policy Bulletin, 63 FR 18871 (April 16, 1998) ("Sunset Policy Bulletin").

Scope

Imports covered by this order are brass sheet and strip, other than leaded and tin brass sheet and strip, from the Netherlands. The chemical composition of the products under order is currently defined in the Copper Development Association ("CDA") 200 Series or the Unified Numbering System ("UNS") C20000 series. This order does not cover products the chemical composition of which are defined by other CDA or UNS series. The physical dimensions of the products covered by this order are brass sheet and strip of solid rectangular cross section over 0.006 inch (0.15 millimeter) through 0.188 inch (4.8 millimeters) in gauge, regardless of width. Coiled, wound-on-reels (traverse-wound), and cut-to-length products are included. The merchandise subject to this order is currently classifiable under items numbers 7409.21.00 and 7409.29.20 of the Harmonized Tariff Schedule of the United States ("HTSUS"). Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise subject to this order is dispositive.

History of the Order

The antidumping duty order on brass sheet and strip ("BSS") from the Netherlands was published in the Federal Register on August 12, 1988 (53 FR 30455).¹ In that order, the Department determined that weighted-average dumping margins for the Metallverken Nederland B.V. and all others were 16.99 percent.²

¹ See Antidumping Duty Order of Sales at Less Than Fair Value: Brass Sheet and Strip From the Netherlands, 53 FR 30455 (August 12, 1988).

² In the original investigation, Outokumpu Copper Strip, B.V. ("OBV") was doing business under the name, Metallverken Nederland B.V. (See March 4, 1999, Substantive Response of OBV at 5 (footnote

The Department has conducted several administrative reviews since that time.³ The order remains in effect for all producers and exporters of BSS from the Netherlands. We note that the Department has not conducted any investigation with respect to duty absorption regarding the exports of the subject merchandise.

Background

On August 26, 1999, the Department published the preliminary results of the sunset review on BSS from the Netherlands.⁴ Notwithstanding a finding of a significant decline in the import volumes of the subject merchandise after the issuance of the order, the Department preliminarily determined that revocation of the order would not be likely to lead to continuation or recurrence of dumping. The Department stated that although import volumes of the subject merchandise declined significantly after the issuance of the order, since the two most recent administrative reviews indicate that dumping of the subject merchandise has been eliminated, and since Outokumpu Copper Strip, B.V. ("OBV") presents effective other relevant information and arguments explaining why it is unlikely that OBV would resume dumping in the United States, the Department preliminarily determines that

4); see also March 3, 1999, Substantive Response of the domestic interested parties at 24.)

³ See Brass Sheet and Strip From the Netherlands: Final Results of Antidumping Duty Administrative Reviews (Corrections), 57 FR 11352 (April 2, 1992); Brass Sheet and Strip From the Netherlands: Final Results of Antidumping Administrative Reviews, 57 FR 9534 (March 19, 1992) (this review consolidated first and second reviews); Brass Sheet and Strip From the Netherlands: Final Results of Antidumping Duty Administrative Review, 61 FR 1324 (January 19, 1996); Brass Sheet and Strip From the Netherlands: Amendment to Final Results of Antidumping Duty Administrative Review, 62 FR 33395 (June 19, 1997); Brass Sheet and Strip From the Netherlands: Final Results of Antidumping Duty Administrative Review, 61 FR 1324 (January 19, 1996); Brass Sheet and Strip From the Netherlands: Final Results of Antidumping Duty Administrative Review, 62 FR 51449 (October 1, 1997); and Brass Sheet and Strip From the Netherlands: Final Results of Antidumping Duty Administrative Review, 63 FR 49544 (September 16, 1998). See also the final results of the latest administrative review, covering the period 1997-1998, which should be published concurrently with this publication.

⁴ See Preliminary Results of Full Sunset Review: Brass Sheet and Strip From the Netherlands, 64 FR 46637 (August 26, 1999).

recurrence of dumping is not likely if the order were revoked.

On October 13, 1999, both the domestic and respondent interested parties submitted additional information.⁵ Also, on October 25, 1999, we received case briefs from the domestic interested parties and OBV.⁶ On November 1, 1999, within the deadline specified in the Department's memorandum,⁷ both domestic and respondent parties submitted reply briefs. The Department held a public hearing on November 3, 1999. As a result of the aforementioned additional documents and comments, we have changed our determination.

Department's Determination

Based upon arguments raised by interested parties in case and rebuttal briefs, we have re-examined the facts and statements on the record in this case and determined that revocation of the antidumping duty order on brass sheet and strip from the Netherlands pursuant to section 751(c) of the Act would be likely to lead to recurrence of sales of subject merchandise at less than fair value.

In its *Sunset Policy Bulletin*, the Department established that it will normally determine that revocation of an antidumping duty order would be likely to lead to continuation or recurrence of sales of the subject merchandise at less than fair value where: (a) Dumping continued at any level above *de minimis* after the issuance of the order; (b) imports of the subject merchandise ceased after the issuance of the order; or (c) dumping was eliminated after the issuance of the

order and import volumes for the subject merchandise declined significantly (see section II.A.3).

In this case, consistent with section 752(c) of the Act, the Department considered whether dumping continued at any level above *de minimis* after the issuance of the antidumping duty order; whether the imports ceased after the issuance of the order; and whether dumping was eliminated and import volumes declined significantly after the issuance of the order. We found that dumping of the subject merchandise continued after the issuance of the order, through the first, second and third administrative reviews.⁸ We also found that OBV's imports of subject merchandise ceased after the issuance of the order for four administrative review periods,⁹ but resumed in 1995. Further, we found that OBV did not dump subject merchandise, at a level above *de minimis*, during the periods 1995-1996 and 1996-1997 (last two administrative review periods).

With respect to import volumes of the subject merchandise, the data reported by both OBV and the domestic interested parties in this case indicate that, since the imposition of the order, import volumes of subject merchandise have declined significantly. In addition, data in the United States Customs Census Bureau IM-146s and import data from the U.S. International Trade Commission indicate that imports of subject merchandise have declined over the life of the order. No party in this case disputes that import volumes of subject merchandise declined significantly since the issuance of the order. Rather, the parties have argued over the significance of the acquisition of the U.S. producer, American Brass, by OBV's parent company, and the corporate decision to have American Brass play the primary role in supplying subject merchandise to the U.S. market.

In the preliminary results, we agreed with OBV that the acquisition of American Brass makes OBV's position in the U.S. market rather unique because it appeared that OBV no longer had to dump subject merchandise in order to supply the U.S. market, and because American Brass had more than adequate capacity to meet the demand in the U.S. market for BSS. Given these apparent facts, we preliminarily found persuasive OBV's argument that it would not make sense for OBV to jeopardize the economic well being of American Brass by undercutting the prices of its U.S.-produced BSS by resumption of dumping. Because we

preliminarily found that American Brass was to bear the primary responsibility of satisfying U.S. customers' needs for BSS, we preliminarily determined that, despite the significant decline in import volumes of subject merchandise after the issuance of the order, the two most recent reviews were probative of the behavior of the company absent the discipline of the order.

As noted in the SAA, at 883, the determination called for in this type of review is inherently predictive and speculative. Therefore, we have established a policy of relying on past behavior as a predictor of future behavior. In light of OBV's announced resumption of import volumes at pre-order levels, we now find that the company's behavior during the most recent administrative reviews can no longer be considered probative of OBV's behavior absent the discipline of the order.¹⁰ In the two most recent administrative reviews, OBV's import volumes were abnormally small by any measure.¹¹ If the transfer of production and sales of subject radiator strip to American Brass were permanent, then these small import volumes could be considered normal for the company and the margins for the two recent reviews could be reflective of the company's future behavior. By contrast, where, as here, a company will resume imports of the subject merchandise at levels expected to exceed nearly 65 times the import volumes in the two most recent reviews, the Department is compelled to conclude that the company's pricing behavior during these previous periods in which import volumes were small has little or no probative value. Due to the transfer of production and sales of subject radiator strip back to OBV, the company will import subject merchandise in volumes that equal or exceed the volume of imports during the pre-order period. Accordingly, we determine that, consistent with established policy, the margin likely to prevail must be measured based on the company's behavior at the time of the original investigation. Therefore, we determine that revocation of the antidumping duty order on brass sheet and strip from the Netherlands under section 751(c) would be likely to lead to recurrence of sales of subject merchandise at less than fair value. We have addressed the comments received below.

¹⁰ See Sales Verification Report at 39.

¹¹ See Comment 1 below.

⁵ Following the Department's publication of its preliminary results of the instant sunset review, on October 5, 1999, counsel to the domestic interested parties, submitted a letter requesting the Department to allow the domestic interested parties to augment the existing record with additional information. The Department allowed both domestic and respondent interested parties to submit relevant information until October 13, 1999. (See the Department's memorandum to Mr. Jeffrey S. Beckington.) The domestic interested parties submitted Mr. Baker's affidavit and three different portions of the Department's Sales Verification Report ("Verification Report") which was completed in the concurrent administrative review of the order. Also, OBV submitted two portions of the Verification Report. Consequently, Mr. Baker's affidavit and the portions of the Verification Report submitted by interested parties are now on the record in this review.

⁶ On September 27, 1999, while requesting a public hearing, the domestic interested parties requested extensions of the deadlines for the case and rebuttal briefs and a postponement of the hearing. The Department extended the deadlines for case brief and rebuttal brief until and not later than October 25, 1999, and November 1, 1999, respectively. Also, at the same time, the Department postponed the hearing to November 3, 1999.

⁷ See footnote 6, *supra*.

⁸ See footnote 3.

⁹ *Id.*

Likelihood of Continuation or Recurrence of Dumping

Comment 1: The domestic interested parties contend that the factual premises underlying the Department's preliminary results are in error; namely, OBV was dumping during the most recent administrative review. The domestic interested parties claim that had the Department not allowed OBV the start-up adjustment and quarterly (instead of yearly) calculation of its cost, OBV would have been found to be dumping during 1997-1998 review period. Assuming, *arguendo*, OBV was not dumping, the domestic interested parties further argue that because such a finding was based on a small, unrepresentative volume of sales when compared to: (1) OBV's pre-order exports of the subject merchandise; (2) the current size of the U.S. market for the subject merchandise; (3) OBV's shipments of non-subject merchandise; (4) OBV's shipments in its home market; (5) OBV's shipments to other countries; or (6) OBV's projected volume of shipments to the United States, those few sales should not serve as the basis for a finding that dumping is not likely to occur in the future. (See the domestic interested parties' brief at 2 and 8-27, and the hearing transcript at 10-49 and 97-108.)

OBV argues that the start-up cost adjustment is a relatively new concept and, as a result, there have not been many applications of the adjustment. However, OBV contends that the rarity alone should not be considered as a determining factor in finding whether the adjustment is warranted. OBV further argues that a potential distortive effect of metal prices on margin calculation was recognized by the Department from the beginning (in the original investigation) and, therefore, allowing a cost calculation based on quarterly data is not unusual at all. (See OBV's reply brief at 24-26, and brief transcript at 56-97.)

OBV contends that its export volumes of the subject merchandise were low during the last three administrative review periods due to the acquisition of American Brass. OBV asserts that it never stated that the order was even a reason for stopping shipments. In other words, OBV claims that it could have sold a substantial amount of subject merchandise with the discipline of the order in place had OYJ not purchased American Brass. OBV further argues that, at any rate, the Department determined, in its most recent preliminary results of administrative review, that the import volumes in the recent administrative reviews constitute

commercial quantities. In addition, OBV asserts that the comparison between pre-order and post-order volumes is meaningless because OBV will never return to pre-order levels on account of American Brass's presence in the U.S. market. OBV basically dismisses the domestic interested parties' various comparisons of OBV's post-order export volumes of the subject merchandise as meaningless by resorting to the fact that the much larger American Brass's production replaced OBV's exports of the subject merchandise to the United States. Furthermore, OBV argues that its recent shipment levels are not aberrational or abnormally small in the first place, and to the extent they are deemed small, they are due to OYJ's purchase of American Brass. (See OBV's reply brief at 2 and 24-40.)

Department's Position: With respect to arguments raised regarding the results of the administrative review, we refer interested parties to the final results of the administrative review.¹²

Further, in light of the arguments raised in this sunset review, we do not agree with OBV that the comparison between OBV's pre-and post-order import volumes of the subject merchandise to the United States is meaningless. The Act, the SAA, the House Report, the Senate Report, the *Department's Regulations*, and the *Sunset Policy Bulletin* provide that, in making its determinations of likelihood of continuation or recurrence of dumping, the Department compare the import volumes of the subject merchandise for the period before and the period after the issuance of the order. In our preliminary results we compared the import volumes for the period before and the period after the issuance of the order and found, on the basis of uncontroverted evidence, that there was a significant decline in the volume of imports of the subject merchandise after the issuance of the order. However, as noted above, on the basis of additional information and argument provided by OBV, we preliminarily determined that the elimination of dumping in recent administrative reviews was, nonetheless, probative of the behavior of OBV without the discipline of the order. For the purposes of these final results we have reconsidered the weight to be accorded the more recently calculated margins and have determined, in light of OBV's stated intent to begin importing subject merchandise into the United States at pre-order levels once the order is revoked, that the more recently calculated margins are not

probative of the behavior of OBV were the order revoked.

Comment 2: The domestic interested parties insist that OYJ's ownership of American Brass is by no means unique; rather, such acquisition is a standard practice for foreign respondents to avoid the dumping laws. Essentially, the domestic interested parties claim that OYJ's acquisition of American Brass does not mean that OBV is not likely to dump. The domestic interested parties further note that the purchase of American Brass never demonstrated that OBV stopped dumping. (See the domestic interested parties brief at 3 and 29-30, and the hearing transcript at 10-49 and 97-108.)

OBV contends that the domestic interested parties misunderstood the rationale with respect to OBV's uniqueness argument. Specifically, OBV contends that its unique position is derived from the fact that: (1) OBV is the sole producer of the subject merchandise in the Netherlands; (2) the ownership of American Brass by OBV's parent company; (3) the size of American Brass *vis-à-vis* OBV; and (4) the relative roles of OBV and American Brass in the OYJ Group. In any case, OBV argues that the cases cited by the domestic interested parties were based on sparse, limited facts available and that the Department never addressed a uniqueness issue in these cases. (See OBV's reply brief at 3 and 40-50, and the hearing transcript at 56-97.)

Department's Position: The Department's preliminary results that the recently calculated margins were, despite the significant decrease between pre- and post-order import volumes, nonetheless probative of OBV's behavior without the discipline of the order was based on OBV's representation that the acquisition of American Brass enabled American Brass to meet the U.S. demand for BSS, thereby replacing OBV's exports of the subject merchandise to the United States. In part on this basis, we stated in our preliminary results that the cessation of imports from OBV after the purchase "buttresses the notion that American Brass basically took over OBV's exports of the subject merchandise."¹³

Once it became evident that OBV will take over the entire production of radiator strip from American Brass and export that subject merchandise to the United States from the Netherlands, OBV undermined its uniqueness contention. With the proposed production shift from American Brass to OBV, OBV's contention that the purchase of American Brass and

¹² See footnote 3, *supra*.

¹³ See footnote 4, 64 FR at 46641, *supra*.

subsequent presence of American Brass in the U.S. market eliminated any likelihood of future dumping is diminished (i.e., the existence of American Brass no longer has any bearing on whether the more recently calculated margins are probative of the behavior of OBV without the discipline of the order OBV and whether OBV would be likely to resume dumping subject merchandise, in general,¹⁴ and radiator strip, in particular).

Therefore, for purposes of these final results, we agree¹⁵ with the domestic interested parties that OYJ's purchase of American Brass after the imposition of the order, no longer provides sufficient reason and/or evidence to negate the presumption expressed in the *Sunset Policy Bulletin* and the SAA that the elimination of dumping coupled with a significant decrease in the volume of imports may be probative of the fact that producers/exporters may need to dump in order to maintain market share in the United States. Therefore, for the final results of this sunset review we have considered OBV's past histories pertaining to import volumes and weighted-average dumping margins.

With respect to import volumes of the subject merchandise, the data supplied by both OBV and the domestic interested parties indicate that, since the imposition of the order, import volumes of the subject merchandise have declined significantly. Moreover, data in United States Census Bureau IM146s and import data from the United States Commission clearly indicate that imports of the subject merchandise have declined over the life of the order. In 1986 (a year prior to the initiation of the original investigation), import volumes

of brass sheet and strip exceeded 15 million pounds; whereas, in 1998 import volumes have been well under 1 million pounds. In addition, OBV does not negate the statistics which show that OBV's import volumes of the subject merchandise decreased significantly after the issuance of the order. Consequently, we determine that the import volumes of the subject merchandise declined substantially after the issuance of the order.

In conclusion, although the three most recent reviews indicate that dumping of the subject merchandise has been eliminated,¹⁶ since import volumes of the subject merchandise declined significantly, we determine that recurrence of dumping of subject merchandise from the Netherlands is likely if the order were revoked.

Comment 3: The domestic interested parties assert that the Department's preliminary results reflect a marked departure from the standards established in the statute, the SAA, and the *Sunset Policy Bulletin*, based on which the Department determines whether continuation or recurrence of dumping is likely should the order be revoked. Specifically, the domestic interested parties contend that, in its preliminary results, the Department ignored the facts that dumping continued at levels above *de minimis* after the issuance of the order and that the import volumes of the subject merchandise ceased and declined substantially when dumping was eliminated. The domestic interested parties further argue that the Department should rely upon what OBV did in conjunction with the order and not upon what OBV says it will do in the future if the order were revoked. (See October 26, 1999, the domestic interested parties' case brief at 1 and 4-7, and the hearing transcript at 10-49 and 97-108.)

OBV claims that the Department's preliminary decision is fully consistent with and supported by a plain reading of the statute, the *Department's Regulations*, and the *Sunset Policy Bulletin*. OBV contends that the Department's ultimate mandate in a sunset review is to determine whether revocation of an order is likely to lead to a continuation or recurrence of dumping, and as such, the Department is free to consider all record evidence in carrying out its ultimate mandate in a sunset review. OBV claims that the Department stated that it makes no sense to conclude that Outokumpu is going to permit OBV to dump the subject merchandise in the United

States. (See November 1, 1999, OBV's reply brief at 1 and 4-17, and the hearing transcript at 56-97.)

Department's Position: We do not agree with the domestic interested parties' characterization that the Department ignored the facts that dumping continued at levels above *de minimis* and that the import volumes of the subject merchandise declined substantially after the issuance of the order. In the preliminary results, the Department noted that dumping continued for a period after the issuance of the order and further, that the import volumes of the subject merchandise decreased significantly after the issuance of the order.

As noted by OBV, in a sunset review, consistent with our regulations, interested parties are invited to submit any other relevant information or arguments that the party would like the Department to consider. (See section 351.218(d)(3)(iv)(B) of the *Sunset Regulation*.) In this review, OBV submitted additional information and argument to support its assertion that the significant decrease in the post-order volume of imports was not dispositive of the likelihood issue. We agree with OBV that the Department has the discretion to consider these arguments in the course of determining whether to deviate from the general policy. Specifically, our *Sunset Policy Bulletin* enunciates that, with a given set of facts, the Department normally will determine whether revocation of the order is likely to lead to continuation. (See section II.A.3 of the *Sunset Policy Bulletin*.) Nowhere do we state that the Department will always find that dumping is likely to continue or recur when dumping has been eliminated and there has been a significant decline in the volume of imports.

Comment 4: The domestic interested parties state that the Department erred in basing its preliminary results, without invoking good cause, on OBV's unsolicited, unilateral, uninvestigated, and self-serving representations regarding matters which would more properly fall within the purview of the sunset analysis of the International Trade Commission ("Commission"). The domestic interested parties argue that OBV's claims pertaining to the role it will play in the U.S. market (in terms of volumes and nature of the products it will supply, and the price it will charge) and pertaining to the competitive conditions of the U.S. market of the subject merchandise, were unsolicited, not subject to follow-up questioning, and not subject to verification by the Department. Since the Department did not have an

¹⁴As it is proposed to do with radiator strip, OYJ can shift production of any other type of BSS from American Brass to OBV and start dumping that subject merchandise without necessarily competing with American Brass.

¹⁵As noted in the previous paragraphs, however, we agree with the domestic interested parties for different reasons. The domestic interested parties cite five cases in their case brief (at 21-29). In *Brass Sheet and Strip From Germany; Final Results of Antidumping Duty Administrative Review and Determination Not To Revoke in Part*, 61 FR 49727 (September 23, 1996), the Department rejected Wieland's attempt to make a relevant issue out of its purchase of a U.S. production facility because the U.S. facility used imports of the subject merchandise as a feed product. The Department determined that had the order not been in place, Wieland would have used its dumped subject merchandise rather than U.S. produced domestic like product as its raw material; hence, Wieland's purchase of a U.S. production facility can be distinguished from the instant case. In the other four cited cases, also, the ownership of U.S. production facilities by foreign respondent interested parties was never an issue. In other words, the domestic interested parties reliance on the above-referenced cases to discredit OBV's uniqueness argument is misplaced.

¹⁶See footnote 3, *supra*.

affirmative showing of good cause, as required by the statute, the domestic interested parties conclude that the Department should exclude the aforementioned other factors and make its final determination based solely on the three-pronged test set forth in its *Sunset Policy Bulletin*. (See the domestic interested parties brief at 1 and 8-12, and the hearing transcript at 10-49 and 97-108.)

OBV notes that since OBV filed its substantive response on March 3, 1999, the domestic interested parties have had an ample opportunity to request follow-up questions, but did not do so. OBV claims that its substantive response is basically a questionnaire response; that there is nothing improper about the Department revoking an order prior to the Commission's decision; and that the factors considered are identical to the factors typically considered by the Commission in making its injury determination. (See OBV's reply brief at 13-17 and the hearing transcript at 56-97.)

Department's Position: We disagree with the domestic interested parties' argument that the Department erred in basing our preliminary results on unsolicited, unilateral, un-investigated, and self-serving representations made by OBV pertaining to the competitive conditions of the U.S. market. Consistent with the *Sunset Regulations* (section 351.218(d)(3)(iv)(B)), a party may submit in its substantive response other information or argument the party would like the Secretary to consider. Other parties (that filed substantive responses) may then rebut those arguments and information. Nothing precludes the Department from considering the type of information OBV submitted in its substantive response and the Department properly considered this information and the domestic interested parties' rebuttals thereto in its preliminary results.

Comment 5: The domestic interested parties note that the Department's finding that American Brass would bear the primary responsibility of satisfying the U.S. customers of radiator strip is contrary to OBV's acknowledgment that OBV will eventually assume the primary responsibility of satisfying its U.S.-based customers by exporting more than 15.8 million pounds of subject radiator strip in the future. Specifically, the domestic interested parties point out inconsistent claims by OBV: on one hand, OBV states that it never will return to pre-order export level while, on the other hand, OBV stipulates that it will eventually take over American Brass' entire production of radiator strip, which will result in OBV

exporting the subject merchandise to the United States at levels greater than pre-order export volumes of the subject merchandise to the United States.

The domestic interested parties assert that since OBV readily changed its position (production shift from OBV to American Brass and then back to OBV), nothing precludes the parent company of OBV, OYJ, from changing its mind again in the near future. Namely, the domestic interested parties claim that it is possible for OBV to start shipping other subject merchandise to the United States—and this production shift can rather easily be accomplished with only minor adjustment in OBV's current production process. According to the domestic interested parties, this possibility is looming especially large in light of shrinking radiator strip market. Domestic interested parties point out that OBV may start shipping electrostrip products, and that OBV can do this without competing with American Brass by utilizing a creative product mix. Inasmuch as the instant review covers all subject merchandise (not just radiator strip), the domestic interested parties further contend that should the order be revoked, OYJ can easily have OBV export other subject merchandise, besides radiator strip, to the United States. (See the domestic interested parties brief at 2 and 27-30, and the hearing transcript at 10-49 and 97-108.)

OBV argues that it informed the Department of OBV's plans to gradually increase shipments of subject radiator strip in its March 3, 1999, response to the notice of initiation in the instant review. OBV claims that the Department clearly contemplated that OBV will continue to ship the subject radiator strip and that the fact that the tonnage is not mentioned is by no means evidence that the Department was unaware of, or did not consider, this fact in reaching its preliminary results. OBV notes that the proposed shift of production of the radiator strip is only a minor portion of American Brass' 1998 production capacity and of American Brass' 1998 shipments within the United States. (See OBV's reply brief at 3, 45-50, and 52, and the hearing transcript at 96-97.)

Department's Position: We agree with the domestic interested parties that there is conflicting information on the record regarding OBV's intent to export subject merchandise to the United States. Although OBV states that American Brass permanently replaced OBV's exports of BSS to the United States, OBV also expresses its intention of resuming significant exports to the United States when and if the order were revoked (see OBV's substantive

response, Exhibit 1 (LECG Report at 41-42)). Therefore, for the purposes of the final results of this review, as noted above, we consider the planned resumption of imports at pre-order volumes to be probative of the behavior of OBV without the discipline of the order.

Comment 6: The domestic interested parties further note that when OBV was selling substantial volumes of the subject merchandise to the United States, the Department found margins at levels above *de minimis*. In other words, the domestic interested parties claim, according to facts of record, that OBV always dumped when shipping commercial quantities of the subject merchandise to the United States. Knowing that OBV has been an aggressive and a significant supplier of connector products in the European market and that the U.S. radiator-strip market is highly competitive, the domestic interested parties assert that OBV's self-imposed moratorium of not exporting other subject merchandise to the United States will not continue in the future. While arguing that OBV is likely to dump in the United States where it imports a large volume and a wide range of products to the United States if the order were revoked, the domestic interested parties try to illustrate its contention with the fact that OBV did not provide to the Department American Brass's price data regarding the domestic like product. The domestic interested parties also claim that in certain instances, the prices of some non-subject merchandise, which are more costly to produce than subject merchandise, were lower than the prices of the subject merchandise. The domestic interested parties also suggest that the Department postpone revocation until a later administrative review because revocation would result in serious prejudice to the domestic industry; whereas, the postponement would not prejudice OBV because its current cash deposit rate is zero, and if such is the finding in the instant review, OBV will not only be absolved from any duty liability, but will remain eligible for revocation; *i.e.*, OBV's ability to obtain revocation would in no way be prejudiced by delaying revocation. (See the domestic interested parties case brief at 3 and 30-36 and, the hearing transcript at 10-49 and 97-108.)

OBV indicates that in the last three administrative reviews, the Department found that OBV has shipped in commercial quantities without dumping. OBV claims that its sponsored LECG Report indicated that OBV would not resume dumping if the order were revoked. OBV contends that its future

exports of the subject merchandise will be limited to brass radiator strip. OBV claims that, as a matter of law, the Department cannot delay revocation in this sunset review just to determine whether OBV would dump in the next five years. OBV states that the Department did not request OBV to provide American Brass pricing data in this review, and thus it cannot be accused of not supplying something when not asked to do so. Further, OBV argues that unlike a small, "stand alone" company, OBV is not forced into dumping the subject merchandise for its own survival. OBV indicates that, even with antidumping duty orders in effect on the subject merchandise from numerous countries, the domestic interested parties, so far, do not find it profitable to manufacture radiator strip. Stated differently, based on the fact that OBV will not have any domestic competition in the radiator strip market, OBV forecasts that there will be no downward pricing pressure exerted on OBV by the domestic industries. Thus, OBV concludes that it is unlikely to resume dumping in the near future. (See OBV's reply brief at 4, 50-61, and 64-83, and the hearing transcript at 56-97.)

Department's Comment: We agree with the domestic interested parties that OBV has never attained a zero or *de minimis* margin when ever it exported more than a small amount of subject merchandise to the United States.¹⁷ However, we disagree with the domestic interested parties' contention that a postponement of revocation, where revocation is appropriate, would not prejudice OBV. We agree with OBV that the Department is required to revoke the order if, based on the record of the proceeding, the Department determines that dumping is not likely to recur.

As to the pricing data from American Brass, because we have determined that revocation of the order would be likely to result in the continuation or recurrence of dumping, this issue is moot. Further, because the scope of the order includes merchandise other than radiator strip and our determination is

based on OBV's historical behavior at a time when it exported significant volumes of subject merchandise to the United States, OBV's assertions with respect to the lack of domestic competition and downward pricing pressure are also moot.

Finally, with respect to OBV's contention that in three administrative reviews, the Department has found that OBV has shipped in commercial quantities without dumping, we refer interested parties to the notice of final results of the most recent administrative review, issued concurrently with this notice, in which the Department determined that OBV did not sell in commercial quantities for any of the three consecutive reviews that formed the basis of OBV's revocation request in that proceeding.

Comment 7: The domestic interested parties urge the Department not to revoke the order without first performing a verification because the Department made its preliminary findings based on other relevant information and arguments OBV has submitted. They further argue that a verification is mandated by statute and the Department's Regulation; thus, the phrase, "only where needed," in the Sunset Policy Bulletin is questionable since it is contrary to statute and regulations (782(i) of the Act and section 351.307(b) of the Department's Regulations). The domestic interested parties insist that the Department cannot rely on the verification report that was issued in the concurrent administrative review of the order because the verification report did not involve the relevant facts upon which the agency is relying in this case. The domestic interested parties list factors, based on which the Department purportedly made its preliminary determination yet to which the verification did not address: the historical nature of OBV's and American Brass's sales of the subject merchandise in the United States and the reasons therefor; the prices at which OBV is likely to sell radiator strip as compared to the prices charged by American Brass; the capacity of American Brass; the size of and competition in the U.S. radiator strip market; and the corporate relationship between OBV and American Brass and the effects thereof upon their future business and sales operations. The domestic interested parties further claim that OBV itself discredited the findings of the verification report in the concurrent administrative review. In conclusion, the domestic interested parties argue that the Department should not rely on the voluntary and self-serving

representations made by the OBV. Instead, domestic interested parties insist, the Department should issue a questionnaire and a supplemental questionnaire to elicit relevant information, and verify the information thereof so long as the Department continues to rely upon any of the factual representations proffered by OBV. (See the domestic interested parties' brief at 3 and 12-18, and the hearing transcript at 10-49 and 97-108.)

OBV asserts that a verification is unnecessary in the instant review. OBV claims that, first, the Department based its preliminary results upon, *inter alia*, the dumping margins in the most recently completed administrative reviews. OBV argues that, second, where the Department recently verified OBV's data, which included information supporting revocation of the dumping order and which was placed on the record of this review, the current situation would fall under the "other situations" in which the Department need not conduct a verification (see Sunset Regulations, 63 FR at 13519) because standards for two reviews are basically the same. OBV claims that many items which the domestic interested parties request the Department verify were either verified by the Department during the 1997-1998 administrative review or were not relied upon by the Department in making its preliminary results in this sunset review. OBV denies that it alleged the verification report issued in the administrative review is meaningless or challenged the accuracy of the numbers. OBV indicates, nonetheless, that it opposes unjustified extrapolation of numbers or leaps of logic based upon those numbers. Given the vast amounts of verified information already on the record in this review, an additional verification would be unnecessary and of little value to the Department in this review. (See OBV's reply brief at 17-24, the hearing transcript at 69-97.)

Department's Position: Because we have determined that dumping is likely to continue or recur were the order revoked, the issue of verification is moot.

Magnitude of the Margin

Because the magnitude of likely-to-prevail margin was not discussed in the preliminary results of this review, we incorporate interested parties' arguments in our determination as follows.

Comment 1: The domestic interested parties, in their substantive response and in the hearing transcript, simply state that the Department should select

¹⁷ The lowest weighted-average dumping margin associated with a significant import volume (2,284 metric tons) was 2.03 percent for August 1990-July 1991. When OBV was assessed with zero (0) percent or *de minimis* dumping margin for the last three administrative reviews, its imports of subject merchandise were significantly lower. Thus, we agree with the domestic interested parties that when OBV was exporting substantial volumes of the subject merchandise to the United States, it was dumping. This is especially true in light of the final results of the most recent administrative review, in which the Department found that the import volumes of the subject merchandise associated with OBV's zero or *de minimis* weighted-average dumping margins did not constitute commercial quantities. (See footnote 4, *supra*.)

a margin from the investigation according to the principle set forth in the SAA at 890 and the Sunset Policy Bulletin, 63 FR at 18873. (See the domestic interested parties' March 3, 1999 substantive response of at 45-46, March 12, 1999, rebuttal response at 25-26, and the hearing transcript at 10.) The domestic interested parties note that the margin from the original investigation is the only calculated rate that reflects the behavior of OBV without the discipline of the order. Therefore, the domestic interested parties argue that the Department should abide by its stated policy and provide to the Commission the rate set forth in the original investigation, which is 16.99 percent. *Id.*

Citing the same policy, but with a different emphasis, OBV argues that the Department can, and should, exercise its discretion, as allowed by the SAA.¹⁸ (See OBV's substantive response at 39.) OBV urges that the Department determine the margin likely to prevail if the order were revoked to be zero percent, which is the margin determined for sales by OBV in the last two administrative reviews, or, in the alternative, 2.03 percent, which is the margin from the third administrative review that is associated with a sales volume that is larger than the sales volume examined by the Department during the original investigation.

OBV further states that it came forth with data which support the selection of a margin other than the margin in the original investigation. OBV argues that the weighted-average dumping margin assigned to OBV in the original investigation is the least probative of the magnitude of the dumping margin likely to prevail were the order revoked. OBV bases its argument on the assertions that the margin from the original investigation is inherently unreliable and does not reflect the current circumstances surrounding the order. Specifically, the margin from the original investigation as well as those from the first two administrative reviews are skewed in OBV's view because the Department employed an old, and since-discarded, method in deriving such margins.¹⁹ OBV argues that the Exporter's Sales Price (now

called Constructed Export Price, CEP) used in the original investigation was deflated because some sales of the subject merchandise were made to an OBV affiliated U.S. company at a lower price. *Id.* at 41-45.²⁰ Therefore, OBV contends, the Department should reject the margins from original investigation and from the final results of the first two reviews because weighted-average margins therefrom are unreliable indicators of the magnitude of the margin that would be likely to prevail if the order were revoked. Instead, OBV argues that the Department should report to the Commission a zero or, at the most, a 2.03 percent as the likely-to-prevail margin were the order revoked.

In its rebuttal, OBV reiterates its arguments that there is no justification for the Department to use the margin from the original investigation because that margin is the least probative and inherently unreliable. Also, OBV states that it no longer has the capacity to and, in any case, will not further process the subject merchandise in the United States, thereby eliminating the adjustment for further-manufacturing, which OBV perceives resulted in an upward distortion of dumping margin.²¹

Department's Position: In the Sunset Policy Bulletin, the Department stated that it will normally provide to the Commission the margin that was determined in the final determination in the original investigation because that is the only margin that reflects the behavior of producers/exporters without the discipline of the order in place. Further, for companies not specifically investigated or for companies that did not begin shipping until after the order was issued, the Department normally will provide a margin based on the all-others rate from the investigation. (See section II.B.1 of the Sunset Policy Bulletin.) Exceptions to this policy include the use of a more recently calculated margin, where appropriate, and consideration of duty absorption determinations. (See sections II.B.2 and 3 of the Sunset Policy Bulletin.)

²⁰ During the original investigation, OBV had an affiliated U.S. company, Outokumpu Metallverken ("MINC"), which bought the subject merchandise at a bargain price and further processed it according to U.S. customers' specification. OBV implies that, in the process of calculating dumping margins, the cost associated with the process done by MINC was inflated, consequently further lowering OBV's export price to MINC.

²¹ OBV is indicating that it no longer has an affiliated U.S. company which further processes the subject merchandise on behalf of OBV, see footnote 30, *supra*. Also, due to the OYJ's purchase of American Brass, OBV feels that further processing of the subject merchandise in the United States is no long necessary. (See OBV's reply brief at 55-59.)

We note that, to date, the Department has not issued any duty absorption findings in this case.

The SAA at 890-891 and House Report at 63, provide that declining (or no) dumping margins accompanied by steady or increasing import volumes of the subject merchandise may be indicative of a situation in which respondent interested parties do not have to dump in order to maintain market share in the United States and that dumping is less likely to recur. To appropriately reflect such situation, the Department may, in response to argument from an interested party, provide to the Commission a more recently calculated margin in cases where: (1) The dumping margin was reduced or eliminated after the issuance of the order and (2) import volumes remained steady or increased. (See section II.B.2 of Sunset Policy Bulletin.)

However, in the instant review, as discussed above, immediately after the imposition of the order, import volumes of the subject merchandise fell substantially and ceased altogether for a period. Furthermore, for the last five years (1994-1998), the import volumes of the subject merchandise have remained at levels that can be characterized as negligible vis a vis pre-order volumes. These facts coupled with OBV's statement that it plans to resume exports from the Netherlands at pre-order volumes²² leads us to determine that the use of a more recently calculated margin is inappropriate. Therefore, we disagree with OBV's argument that we should report to the Commission a more recently calculated margin. Instead, because it is the only rate which reflects the behavior of producers/exporters without the discipline of the order, the Department determines that the margin from the original investigation is probative of the behavior of OBV without the discipline of the order and will provide to the Commission the weighted-average margin from the original investigation.

Final Results of Review

As a result of this review, the Department finds that revocation of the antidumping duty order would be likely to lead to continuation or recurrence of dumping at the margins listed below:

Manufacturer/exporter	Margin (percent)
OBV	16.99
All Others	16.99

²² See OBV Substantive Response at Exhibits 1 (at 41-42), 8, and 15.

¹⁸ OBV infers this discretion from the word "normally." (See Substantive Response of OBV at 39.)

¹⁹ The original investigation was based on the U.S. sale price compared to a weighted-average foreign market value. In investigations, the Department now employs an average-to-average method—a comparison of the weighted-average of the normal values with the weighted-average of the export prices (and constructed export prices) for comparable merchandise. (See 19 CFR 351.414(b) and (c).)

This notice serves as the only reminder to parties subject to administrative protective order ("APO") of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305 of the Department's regulations. Timely notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This five-year ("sunset") review and notice are in accordance with sections 751(c), 752, and 777(i)(1) of the Act.

Dated: December 28, 1999.

Holy Kuga,

Acting Assistant Secretary for Import Administration.

[FR Doc. 00-285 Filed 1-5-00; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

(A-421-701)

Notice of Final Results of Antidumping Duty Administrative Review and Determination Not To Revoke the Antidumping Duty Order: Brass Sheet and Strip From the Netherlands

AGENCY: Import Administration, International Trade Administration, Department of Commerce

SUMMARY: On September 8, 1999, the Department of Commerce (the Department) published the preliminary results of its administrative review of the antidumping duty order on brass sheet and strip from the Netherlands and its notice of intent to revoke the antidumping duty order. We gave interested parties an opportunity to comment on the preliminary results. We have analyzed the comments received and have made certain changes for the final results.

This review covers shipments by one respondent during the period August 1, 1997, through July 31, 1998. For our final results, we have found that sales of the subject merchandise have not been made below normal value. We will instruct the Customs Service not to assess antidumping duties on the subject merchandise exported by this company. Furthermore, we are not revoking the antidumping duty order given that shipments of subject merchandise to the United States by Outokumpu Copper Strip B.V. (OBV), the sole producer and exporter of subject merchandise from the

Netherlands, have not been made in commercial quantities for each of the three consecutive review periods that formed the basis of the revocation request. See *Determination Not To Revoke Order* section of this notice.

EFFECTIVE DATE: January 6, 2000.

FOR FURTHER INFORMATION CONTACT: John Brinkmann or Jarrod Goldfeder, Office of AD/CVD Enforcement VI, Group II, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230; telephone: (202) 482-4126 or (202) 482-2305, respectively.

SUPPLEMENTARY INFORMATION:

Applicable Statute and Regulations

Unless otherwise indicated, all citations to the statute are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Tariff Act of 1930 (the Act), by the Uruguay Round Agreements Act (URAA). In addition, unless otherwise indicated, all citations to the Department's regulations refer to the regulations codified at 19 CFR part 351 (1999).

Case History

This review covers OBV, the sole manufacturer/exporter of merchandise subject to the antidumping duty order on brass sheet and strip from the Netherlands.

On September 8, 1999, the Department published the preliminary results of this review. See *Notice of Preliminary Results of Antidumping Duty Administrative Review and Intent To Revoke Order: Brass Sheet and Strip from the Netherlands*, 64 FR 48760 (*Preliminary Results*). On October 20, 1999, we received case briefs from OBV and the petitioners. We received rebuttal briefs from OBV and the petitioners on October 29, 1999. A public hearing was held on November 2, 1999.

Scope of Review

Imports covered by this review are brass sheet and strip, other than leaded and tin brass sheet and strip, from the Netherlands. The chemical composition of the products under review is currently defined in the Copper Development Association (CDA) 200 Series or the Unified Numbering System (UNS) C2000 series. This review does not cover products the chemical compositions of which are defined by other CDA or UNS series. The physical dimensions of the products covered by this review are brass sheet and strip of

solid rectangular cross section over 0.006 inch (0.15 millimeter) through 0.188 inch (4.3 millimeters) in gauge, regardless of width. Included in the scope are coiled, wound-on-reels (traverse wound), and cut-to-length products. The merchandise under investigation is currently classifiable under item 7409.21.00 and 7409.29.20 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the merchandise under investigation is dispositive.

Determination Not To Revoke Order

The Department "may revoke, in whole or in part" an antidumping duty order upon completion of a review under section 751 of the Act. While Congress has not specified the procedures that the Department must follow in revoking an order, the Department has developed a procedure for revocation that is described in 19 CFR 351.222. This regulation requires, *inter alia*, that a company requesting revocation must submit the following: (1) A certification that the company has sold the subject merchandise at not less than normal value (NV) in the current review period and that the company will not sell at less than NV in the future; and (2) a certification that the company sold the subject merchandise in each of the three years forming the basis of the request in commercial quantities. See 19 CFR 351.222(e)(1). Upon receipt of such a request, the Department may revoke an order if it concludes that each exporter and producer covered at the time of revocation: (1) sold subject merchandise at not less than NV for a period of at least three consecutive years; and (2) is not likely in the future to sell the subject merchandise at less than NV; see 19 CFR 351.222(b)(1); 19 CFR 351.222(b)(2); see, e.g., *Final Results of Antidumping Duty Administrative Review and Determination Not To Revoke Order in Part: Pure Magnesium from Canada (Pure Magnesium from Canada)*, 64 FR 12977, 12982 (March 16, 1999).

In our *Preliminary Results*, we preliminarily determined that OBV sold in commercial quantities during the period of review (POR) and that it is not likely that OBV will sell at less than NV in the future (see *Preliminary Results*, 64 FR at 48765-48766). However, upon review of the criteria outlined at section 351.222(b) of the Department's regulations, the comments of the parties, and the evidence on the record, we have determined that the Department's requirements for revocation have not

been met. Based on the final results in this review and the final results of the two preceding reviews, OBV has demonstrated three consecutive years of sales at not less than NV. However, we find that OBV's aggregate sales to the United States have not been made in commercial quantities during each of the three review periods that formed the basis of OBV's revocation request. See Comment 5 for a discussion of the basis for this decision. The abnormally low level of sales activity does not provide a reasonable basis for determining that the discipline of the antidumping duty order is no longer necessary. Consequently, we find that OBV does not qualify for revocation of the order on brass sheet and strip under 19 CFR 351.222(e)(1)(ii).

Comparisons

We calculated export price (EP) and NV based on the same methodology used in the *Preliminary Results*.

Cost of Production

As discussed in the *Preliminary Results*, we conducted an investigation to determine whether OBV made home market sales of the foreign like product during the POR at prices below its cost of production (COP) within the meaning of section 773(b)(1) of the Act.

We found 20 percent or more of OBV's sales of a given product during the 12 month period were at prices less than the weighted-average COP for the POR and thus determined that these below cost sales were made in "substantial quantities" within an extended period of time, and that such sales were not made at prices which would permit recovery of all costs within a reasonable period of time, in accordance with section 773(b)(2) (B), (C), and (D) of the Act. Therefore, for purposes of these final results, we disregarded the below-cost sales and used the remaining sales as the basis for determining NV, pursuant to section 773(b)(1) of the Act.

We calculated the COP for these final results following the same methodology as in the preliminary results, with the following exceptions:

A. OBV had claimed a nine-month startup period for January 1998 through September 1998 for its new continuous strip casting mill. For the final results, we have allowed OBV the startup adjustment. However, we found that the startup period ended on May 31, 1998 and not September 30, 1998. As a result, we decreased the amount of OBV's startup adjustment. In addition, we amortized the capitalized startup costs and included a portion of the amortized

costs in the calculation of COP. See Comment 1.

B. We have calculated weighted-average monthly metal costs based on metal fix prices, which were confirmed at verification. See Cost Verification Exhibit (CVE) 18. For fabrication costs, we have used weighted-average annual costs based on the data reported in the COP and constructed value (CV) data files. See Comment 2.

C. OBV purchased major inputs from an affiliate and used the transfer prices in the calculation of its COP and CV. For the final results, we have increased the transfer prices to the affiliate's COP in calculating OBV's cost of manufacture. See Comment 3.

Analysis of Comments Received

We gave interested parties an opportunity to comment on the preliminary results. As noted above, we received comments and rebuttal comments from OBV and the petitioners.

Comment 1: Startup Adjustment

The petitioners contend that the Department should deny OBV's request for a startup adjustment because it is not eligible for such an adjustment. To be eligible for a startup adjustment, the petitioners state that a respondent must either be starting up a completely new production facility, retooling an existing facility, or producing a new product. The petitioners argue, however, that OBV's new strip caster does not meet any of these eligibility requirements because the company merely installed an expensive piece of equipment used in a single stage of the manufacturing process. In such situations, the petitioners claim that the Department has typically found that replacing or rebuilding only part of an operation, despite a substantial level of investment, does not result in a new facility and does not warrant a startup adjustment to cost. To support this claim, the petitioners cite to several recent cases in which the Department has denied similar requests. For example, the petitioners cite *Final Results of Antidumping Administrative Reviews: Certain Cold Rolled and Corrosion Resistant Carbon Steel Flat Products From Korea*, 64 FR 12927, 12950 (March 16, 1999) (*Flat Products from Korea*); *Final Determination of Sales at Less Than Fair Value: Stainless Steel Wire Rod from Spain*, 63 FR 40391, 40401 (July 29, 1998) (*SSWR from Spain*); *Final Determination of Sales at Less Than Fair Value: Certain Preserved Mushrooms from Chile*, 63 FR 56613, 56618 (October 22, 1998) (*Mushrooms from Chile*); *Final Results*

of Antidumping Duty Administrative Review: Small Diameter Circular Seamless Carbon and Alloy Steel Standard, Line and Pressure Pipe from Germany, 63 FR 13217, 13220 (March 18, 1998) (*Pressure Pipe from Germany*); and *Final Determination of Sales at Less Than Fair Value: Certain Preserved Mushrooms from India*, 63 FR 72246, 72253 (December 31, 1998) (*Mushrooms from India*). In each of these cases, the petitioners contend, the Department disallowed the startup adjustment because the applicants failed to undergo "substantially complete retooling" or the improvements did not result in a "near new facility."

To further their position that the Department should disallow OBV's startup adjustment, the petitioners also assert that the respondent has not met the Department's burden of proof requirements for receiving such an adjustment. Citing *Mushrooms from Chile*, the petitioners claim that the Department normally denies the startup adjustment when the respondent has not sufficiently supported its claim for such an adjustment. In this case, the petitioners claim OBV failed to adequately provide, completely omitted, or miscalculated the following information in their startup request.

First, according to the petitioners, OBV's investment in the new strip caster was not significant in comparison to its total property, plant, and equipment value. Moreover, the petitioners argue that OBV overstated the relative investment made in the strip caster mill by relying on historical, rather than inflation-adjusted costs, to calculate its reported investment percentages. As a result, the analysis provided by the respondent leads to the erroneous conclusion that the amount invested was significant. The petitioners contend that without a significant investment, OBV does not qualify for a startup adjustment.

Second, according to the petitioners, the Department should disallow OBV's startup claim because the company's data demonstrates that technical factors related to the new strip caster did not constrain the company's production levels. The petitioners contend that the production limitations that existed during the POR were the result of the company's conscious decision to run both the old and new casters simultaneously. This, according to the petitioners, is not a technical problem. More importantly, the petitioners claim, OBV's production volume approached maximum capacity during the POR. Thus, the petitioners conclude that OBV experienced no reduction in its production levels while installing the

new strip caster and, therefore, consistent with its determination in *Mushrooms from India*, the Department must disallow the adjustment. In addition, the petitioners point out that an analysis of OBV's yield data also demonstrates that technical factors did not hinder its production levels.

Third, the petitioners argue that OBV did not provide complete information concerning technical difficulties. According to the petitioners, OBV failed to provide sufficient information on the types and frequency of technical problems that the industry generally incurs in operating casting equipment. In other words, the company should have distinguished between normal repairs and technical difficulties related to startup. Without this information, the petitioners argue that it is impossible for the Department to draw a meaningful comparison between the operation of the ring caster and the strip caster. In prior determinations, the petitioners claim that the Department has relied upon this type of failure as sufficient grounds to deny a startup adjustment (see, e.g., *Mushrooms from Chile*).

Finally, according to the petitioners, OBV's reported costs after the startup adjustment were not consistent with common industry knowledge. Specifically, the petitioners contend that the startup adjustment distorts costs because it shifts costs away from thinner gauged merchandise.

If for some reason the Department determines that it should adjust OBV's production costs, the petitioners claim that the Department should account for the adjustment as a non-recurring cost adjustment. Moreover, in making such an adjustment, the petitioners believe that the Department should specifically limit the adjustment only to non-recurring variable costs (i.e., direct labor and variable overhead).

OBV, on the other hand, believes that it is entitled to a startup adjustment. OBV explains that the Department normally grants this adjustment when a producer is using a new production facility and the production levels are limited by technical factors associated with the initial phase of commercial production. According to OBV, the company's new continuous strip caster meets these qualifications because it qualifies as a new production facility and evidence on the record demonstrates that production levels were limited by technical factors associated with the initial phase of commercial production.

On the issue of whether a separate facility is required by law, OBV counters that the statute does not require that a respondent's new

production facility encompass all the steps in the production process (see, e.g., *Notice of Final Determination of Sales at Less Than Fair Value: Static Random Access Memory Semiconductors From Taiwan*, 63 FR 8909 (February 23, 1998) (*SRAMs from Taiwan*)). Instead, OBV claims, the statute only directs that the startup adjustment not be the result of making an "on-going" or "mere improvement" to an existing facility. To support its claim that its new casting facility is more than just an improvement, OBV notes that the evidence provided demonstrates that the new continuous strip casting mill constitutes a wholesale replacement of the old ring casting mill. To complete this replacement, OBV states that the new facility required significant investment and was a substantial undertaking. OBV emphasizes that it had to invest in an entirely new technology which required the installation of new equipment. Furthermore, the company had to construct a new building to house the operation.

In addition, OBV, in its rebuttal brief, specifically addresses each of the petitioners' arguments for disallowing the startup adjustment, as follows:

First, OBV states that it realizes that the burden of demonstrating the entitlement to a startup adjustment rests with the party making the claim (see, e.g., *SSWR from Spain*). OBV further notes that the standard of proof for a start-up adjustment is no greater than that for any other adjustment claimed by respondent. In this case, OBV states that it has met this requirement by providing evidence which demonstrates that the new mill meets the statutory criteria for a startup adjustment.

Second, OBV refutes the petitioners' contention that the level of investment was not significant by countering that it has not overstated the size of its investment in the new caster. According to OBV, the record in this case demonstrates that it has substantially increased the value of its property, plant, and equipment base. OBV further notes that the level of investment is significant whether one measures the investment using historical or inflation-adjusted costs.

Third, regarding production levels, OBV argues that they were limited by technical factors and that the company's overall output used in the petitioners' analysis is not the appropriate benchmark for determining limitations. OBV claims that the critical factor in measuring commercial quantities and determining the length of the startup period is the number of units processed, i.e., "production throughput" of the

strip caster. On this measure, the record demonstrates that the startup period continued at least through September 1998. In addition, OBV argues that the company's decision to operate its new and old caster at the same time was based on sound business reasons that does not result in an overstatement of the company's startup adjustment.

Fourth, OBV asserts that the strip caster had lower production volumes in the beginning of commercial production because specific categories of technical difficulties caused production delays and interruptions. Moreover, the respondent states that it provided all the necessary information to allow the Department to evaluate these specific categories of technical difficulties. OBV further claims that the type of difficulties relied upon to support its claim are distinct from the company's ordinary repairs. According to OBV, production personnel tracked and recorded these difficulties as they occurred in an effort to resolve the problems quickly and to continually develop procedures to avoid similar difficulties in the future.

Finally, OBV believes that the Department should adjust OBV's production costs related to the new caster as "startup" and not as a "non-recurring" cost adjustment. If the Department were to treat the adjustment as a non-recurring cost, OBV believes that the startup adjustment should not be limited to non-recurring variable costs. According to OBV, the Statement of Administrative Action (SAA) section describing non-recurring costs does not state that only variable cost should be adjusted.

DOC Position: We agree with OBV and have determined that the company's new continuous strip casting mill is eligible for a startup adjustment in accordance with section 773(f)(1)(C)(ii) of the Act. As for the appropriate startup period, however, we have determined that the period ended in May 1998, rather than September 1998, as claimed by OBV. Specifically, section 773(f)(1)(C)(ii) of the Act states that the Department will make an adjustment for startup costs where the following two conditions are met: (1) A producer is using new production facilities or producing a new product that requires substantial additional investment, and (2) the production levels are limited by technical factors associated with the initial phase of commercial production. We have examined OBV's claim and determined that the criteria for granting a startup adjustment have been satisfied in this case.

During the POR, OBV completed construction and began operating its strip caster, which consists of a caster and a heavy gauge rolling line. The caster melts copper and zinc into brass, and the heavy gauge rolling line rolls the resulting molten brass into master coils. This new casting line, which is based on new technology, allows the company to continuously cast and roll master coils (a semi-finished product). In contrast, the old ring caster required several more production steps because OBV first had to cast large brass rings (i.e., ingots). The company would then heat and roll these ingots into master coils. After fabricating the master coil, OBV then re-rolls and slits the semi-finished coil to make a finished product. To complete the new strip casting line, OBV also constructed a new building to house the new equipment. During part of the POR, OBV ran the old and new casting lines simultaneously. OBV eventually shut down the ring caster, but after the POR. For the instant proceeding, OBV claimed a startup adjustment to costs pursuant to section 773(f)(1)(C)(ii) of the Act for its new continuous strip casting line because it experienced abnormally high costs for output produced on the strip caster. OBV's proposed startup adjustment covered a nine-month startup period from January 1998 through September 1998.

In this case, under section 773(f)(1)(C)(ii) of the Act, we have determined that OBV has satisfied the first condition of the test in that it is using a new production facility. Specifically, OBV replaced its old ring caster and began using its new strip casting facility which was a wholesale replacement of the company's essential casting production facility. The Department has recognized that a company may satisfy the requirement for using new production facilities without completing a top-to-bottom reconstruction. See, e.g., *Notice of Final Determination of Sales at Less Than Fair Value: Foam Extruded PVC and Polystyrene Framing Stock From the United Kingdom*, 61 FR 51412, 51419 (October 2, 1996). Moreover, our determination that the strip casting facility in this instance is a new production facility is consistent with past Department determinations. See *Preliminary Results of Antidumping Duty Administrative Reviews and Intent To Revoke in-Part: Certain Corrosion-Resistant Carbon Steel Flat Products and Certain Cut-to-Length Carbon Steel Plate From Canada*, 63 FR 37320, 37325

(July 10, 1998).¹ In that case, the Department determined that the construction of the respondent's new Electric Arc Furnace (EAF) facility, which is similar to the caster in this case, constituted a new production facility under section 773(f)(1)(C)(ii) of the Act.

As noted by the petitioners, the Department has disallowed some startup adjustments in the past because we found that they resulted from either making mere improvements to an existing facility or did not entail the replacement (or rebuilding) of nearly all of the respondent's production machinery in its claimed new facilities (see, e.g., *Flat Products from Korea*, 64 FR at 12950; *Pressure Pipe from Germany*, 63 FR at 13220). We find, however, that OBV's startup situation differs from the determinations cited by the petitioners because OBV documented that its new casting and rolling facility was more than a "mere" or "on-going" improvement to the company's manufacturing facility. The information on the record shows that the new continuous strip casting mill was the result of a significant undertaking and substantial investment. For an example of the significant undertaking involved, OBV showed that its new continuous strip casting mill constituted a wholesale replacement of the old ring casting mill. Although not determinative, we further note that this wholesale replacement required OBV to structurally modify its production facility by constructing a new building and installing new casting and heavy rolling equipment. See OBV's February 2, 1999 Startup Memorandum, at Exhibit 4 (containing before and after plant diagrams that identify the physical magnitude of the new facility). As for substantial investment, record evidence of the fixed asset expenditures in this case demonstrates that to construct the new strip casting facility, OBV committed a significant amount of investment capital as part of the renovation project. For example, OBV showed that it purchased new equipment and that the final cost of the strip casting facility makes up a sizable percentage of the company's total fixed assets value.² See OBV's February 2,

¹ This preliminary determination was upheld in the final results. See *Final Results of Antidumping Duty Administrative Reviews and Determination To Revoke in Part Certain Corrosion-Resistant Carbon Steel Flat Products and Certain Cut-to-Length Carbon Steel Plate From Canada*, 64 FR 2173, 2176 (January 13, 1999) (*Certain Corrosion-Resistant Carbon Steel Flat Products from Canada*). The Department denied the startup adjustment on other grounds.

² To perform this analysis, we excluded the ring-caster investment from the total fixed asset amount

1999 Startup Memorandum, at Exhibit 6A (containing a schedule identifying the original cost basis of all of the fixed assets owned by OBV as reported on the audited financial statements); Exhibit 20 of the Supplemental D Questionnaire Response (containing a schedule identifying the level of investment on a constant dollar basis); and CVEs 25 and 27 (containing sample source documents that support the purchase of new equipment casting and rolling equipment).

As for meeting the second condition of limited production due to technical factors under section 773(f)(1)(C)(ii) of the Act, we found that OBV's production levels were indeed limited by technical factors associated with bringing the new facility online. See the proprietary Memorandum from Stan Bowen to the File, "Analysis of Technical Factors Related to Startup Adjustment," dated December 21, 1999. OBV identified the number of occurrences of production starts and provided detailed descriptions on the technical restraints and problems that limited the strip caster's production volumes. We cannot identify these technical factors here due to their proprietary nature, see OBV's February 2, 1999 Startup Memorandum, at 14-21 (containing detailed descriptions and identifies the number of occurrences). At verification, we reviewed these items with production personnel and found no reason to consider them ordinary repairs and maintenance (see Cost Verification Report, at 33). Based upon the information on the record, we disagree with the petitioners that production levels were not limited by technical factors; nor do we agree that OBV failed to provide complete information concerning the types and frequency of technical difficulties. Specifically, we found that the information on the record does not lead to the conclusion that OBV's low production volumes resulted from factors unrelated to startup (e.g., seasonal demand, business cycle, etc). In fact, to meet its customers' demands during the startup period, OBV continued to operate its old ring caster while working out the technical problems which limited production at the new strip caster facility. OBV actually maintained production levels in total that were consistent with its past experience. During this period, OBV incurred the extra cost of operating two casters simultaneously. However, in

reported on the financial statement. See the proprietary Memorandum from Stan Bowen to the File, "Analysis of Investment," dated December 21, 1999.

evaluating OBV's startup adjustment, we focused upon when the new caster achieved commercial production quantities and the operational cost of this facility.

To determine when the new caster achieved commercial production levels, we reviewed the number of units processed (*i.e.*, starts) at the facility from January 1998 through October 1998. The SAA directs the Department to examine the units processed in determining the claimed startup period. See SAA at 836. In *SRAMs from Taiwan*, we stated "our determination of the startup period was based, in large part, on a review of the wafer starts at the new facility during the POI, which represents the best measure of the facility's ability to produce at commercial production levels." 63 FR at 8930. Consistent with the SAA and the Department's practice, we continue to apply production starts as the best measure of a facility's capability to produce at commercial production levels. From this analysis, we find that the OBV had worked out the majority of technical problems that had initially restricted its production by May 1998 (see business proprietary information contained in Exhibit 19 of the section D supplemental questionnaire response and Cost Verification Exhibit 1). Thus, we identified May 1998 as the month in which OBV significantly increased the number of caster starts. The decision to significantly increase the number of caster starts is indicative of OBV's resolution of technical problems that had initially restricted production.

As for the petitioners' concern that OBV's reported costs were not consistent with common industry averages due to the startup adjustment, we disagree. After review of the record, we found that the startup cost adjustment does not affect the costs incurred by the company at the finished rolling and slitting stages which determine cost differences for width and thickness. In fact, OBV separated its casting costs from the costs that it incurred for finished rolling, slitting, and other brass fabrication processes. Then, OBV isolated only the fabrication costs associated with the new strip caster during the startup period and applied the startup adjustment to only the CONNUMs processed on the new caster. As for the costs OBV used to compute its startup adjustment, we found that the company appropriately used the type of unit production costs referenced in section 773(f)(1)(C)(iii) of the Act (*e.g.*, depreciation of equipment and plant, labor costs, insurance, rent, lease expenses, material costs, and overhead). Likewise, we found that OBV

correctly excluded non-allowable costs (*e.g.*, sales expenses, other non-production costs, and up-front research and development costs) that the Act states are ineligible for a startup adjustment.

Since we have accepted OBV's startup adjustment, we find the arguments on accounting for the startup adjustment as a section 773(f)(1)(B) non-recurring cost adjustment to be moot.

Comment 2: Using Monthly or Quarterly Raw Material Costs Instead of an Annual Weighted-Average

The petitioners argue that the Department should deny OBV's request that raw material costs (*i.e.*, metal costs) be calculated on a quarterly or monthly basis. According to the petitioners, the Department's standard practice is to calculate POR weighted-average costs and OBV has provided no basis for deviating from this practice in this review. For the Department to deviate, OBV would have to show that the price declines it incurred were unusually significant and consistent. The petitioners claim that the facts in this proceeding, however, do not identify such a decline. Instead, the petitioners characterize the changes in price as mere short-term fluctuations that typically occur in the normal course of business. Since the Department can characterize the price fluctuations as typical, the petitioners conclude that the calculation of an annual weighted-average cost adequately mitigates the effect of price changes because it is a weighted-average of high and low prices.

The petitioners provide additional reasons as to why monthly or quarterly costs should not be used. The petitioners claim that OBV has not demonstrated that calculating costs on a quarterly basis would more accurately portray OBV's total costs recorded during the POR. In fact, the petitioners contend, given that OBV fixes the metal price at a much earlier time than it actually records its metal cost, the use of quarterly costs would distort the results of the Department's sales-below-cost test. Specifically, the petitioners claim that a quarterly cost methodology generates fictitious profits on some metal transactions that would distort the Department's sales below cost analysis. The petitioners further explain that OBV can realize these fictitious profits on certain sales because the higher metal values reflected on the sales invoice (fixed at a time prior to the date of sale) will often be matched with a non-contemporaneous lower quarterly weighted-average metal acquisition cost. Thus, the petitioners claim OBV would

realize a profit where none should exist because metal costs are passed through to the customers. In addition, the petitioners argue that the record does not support a truly contemporaneous comparison on a quarterly basis because a number of OBV's home market sales have metal fix dates outside the POR. In order to make proper comparisons, the petitioners claim that the Department would need quarterly costs that occurred before and after the POR. However, the petitioners note that OBV has failed to provide this information. Likewise, the petitioners claim that the use of monthly weighted-average costs will result in similar comparisons of non-contemporaneous metal costs and metal prices. Since OBV only provided monthly costs for the POR, rather than monthly costs outside the POR, the information necessary to make contemporaneous comparisons was not provided.

Furthermore, the petitioners argue that the declining metal costs were not the only cause for declining sales prices in OBV's home market. According to the petitioners, fabrication costs also declined. Thus, the petitioners believe that associating the decline in home market sales prices with metal fluctuations is inappropriate. The petitioners additionally argue that OBV failed to provide monthly or quarterly fabrication costs for comparison purposes. For these reasons, the petitioners argue that the Department should deny OBV's request to use monthly or quarterly costs for metal charges.

OBV counters that a POR weighted-average metal cost will not counter the sharp decline in metal prices the company realized and that the Department should instead use either monthly or quarterly metal value costs. According to OBV, the Department has commonly used monthly or quarterly costs in instances where there have been significant and consistent price declines throughout a period of investigation or review. In fact, OBV states, the Department has used this methodology in several previous brass sheet proceedings due to the distortive effects that metal price fluctuations would have had on the margin calculations. For example, OBV states that in the original investigation the Department made an adjustment for metal value by dividing the period of investigation (POI) into three separate periods. According to OBV, the Department selected three periods because, within each period, metal prices were relatively stable (see *Final Determination of Sales at Less than Fair Value: Brass Sheet and Strip From Netherlands*, 53 FR 23431, 23432

(June 22, 1988) ("*Brass Sheet and Strip from the Netherlands*"). In an Italian brass sheet proceeding, OBV claims that the Department used monthly costs to resolve the distortive effects the fluctuating metal prices had on the margin calculations (see *Final Results of Antidumping Administrative Review: Brass Sheet and Strip from Italy*, 52 FR 9235, 9236 (March 17, 1992) ("*Brass Sheet and Strip from Italy*").

As for a preference toward using quarterly or monthly weighted-average costs, OBV suggests that the Department use monthly metal costs in this proceeding because they provide the most accurate reflection of metal costs for the POR. According to OBV, customers purchase metals at a market price on a specific date (*i.e.*, metal fix date) prior to fabrication and, therefore, the metal price is a direct pass-through to the customer. OBV further notes that it maintains the information that identifies each transaction-specific metal cost in its accounting records and even submitted this information to Department. Thus, OBV believes that the Department has the necessary data to accurately measure the metal costs of any single sales transaction based on the metal fix date. Moreover, and contrary to the petitioners' claims, OBV states that this information (*i.e.*, metal fix date and monthly metal weighted-average costs since 1996) is on the record for all U.S. and home market sales made during the POR.

If the Department does not wish to use monthly weighted-average costs, then OBV suggests that quarterly weighted-average costs would provide a reasonable basis for determining sales below cost. At a minimum, OBV believes that this method is more appropriate than annual costs. OBV also states that the Department should not be influenced by the petitioners' position on the perceived time lag between metal fix and invoice dates. OBV explains that its affiliated supplier ships metals on a first-in, first-out basis. As a result of this practice, the metal ordered in one month is not delivered to OBV until sometime in the following months. According to OBV, it records the cost of metal in its inventory ledgers when the metal is received. Thus, OBV claims that any lag between the metal fix date and the invoice date is mitigated by lag time between the metal fix date and the date on which OBV recorded the cost of that metal in its books and records (*i.e.*, the date used by OBV to compute direct materials costs on a quarterly basis). In any event, if the petitioners are truly concerned about contemporaneity, OBV claims that they should support its

position that the Department use monthly average costs in this review.

In addition and contrary to the petitioners' position, OBV states that the decline of metal prices during the POR was significant and consistent.

According to OBV, the cost of metal can fluctuate widely depending on market conditions. In this case, OBV contends that prices decreased dramatically for the first five months of, and declined consistently throughout, the POR. To demonstrate this decline, OBV states that the variation between the average review period metal prices and the metal prices at the beginning and end of the review period are dramatic. Furthermore, OBV notes that these declines were not mere short-term fluctuations because the metal prices never recovered.

OBV also disagrees with the petitioners' contention that its fabrication costs declined significantly and consistently throughout the POR and should be accounted for in the same manner as metal costs. According to OBV, analysis of its fabrication costs shows that these amounts remained stable throughout the POR. Therefore, OBV argues that reporting quarterly or monthly fabrication costs are not necessary.

DOC Position: We agree with OBV that monthly weighted-average metal costs should be used in the instant review for the calculation of COP and CV. In the ordinary course of business, OBV accounts for metal as a pass-through item. Specifically, OBV requires customers to purchase the metals before it will fabricate the product. As a service to its customers, OBV purchases the metals on the customer's behalf and then bills the customer for the cost of metals, the terms of which are set forth on the finished brass sales invoice. The parties determine the price of the metals at a metal fix date, which occurs prior to the invoice dates of finished brass. Since OBV purchases the metal and then passes on the cost of the metal to the customer, the company must record and recognize the cost of this purchased metal in its accounting system.

The metal cost included in OBV's audited financial statements reflects the cost at the metal fix date of metal consumed to produce the sold items. Rather than reporting the cost of the metals consumed, OBV used the average quarterly metal cost at the metal fix date for metals received. As a result, for any given month, the average metal cost of metal physically received reflects a mix of metal prices from differing time periods depending on how far in advance of receipt the metals were purchased (in certain instances, this

range varies from less than one month to up to six months). We calculated an adjustment factor to account for the differences between the reported purchase cost and the consumption cost.

As for the costs of metals (*i.e.*, copper and zinc) in this review, we have found and verified that OBV's reported metal costs make up a significant portion of the total cost of manufacturing brass sheet and strip. See CVE 12 (identifying the portion metal costs make up of the total cost of manufacturing). Moreover, after reviewing the information on the record, we found that the market values of these inputs sharply and consistently decreased from the beginning to the end of the POR. Specifically, we reviewed monthly London Metal Exchange (LME)³ prices, which we verified as being the basis for OBV's metal cost. We found that the drop in metal prices did not affect OBV's brass fabrication business as a result of the pass through of the cost of metals to its customers. However, the drop in price does affect the margin calculations because the Department normally calculates direct material costs as a POR weighted-average. As a result of using the normal POR average cost methodology, the decline in metal prices would tend to create below-cost sales when the LME metal purchase price falls below the weighted-average LME POR price. See, *e.g.*, OBV's August 11, 1999 Letter (identifying OBV's sales that are above and below costs). Hence, in this review, the method of calculating metal costs does have an impact on the comparisons used in the margin calculations. For example, and as noted by the petitioner, the normal cost methodology could create fictitious profits (or losses) on home market sales.

Our normal practice for a respondent in a country that is not experiencing high inflation is to calculate a single weighted-average cost for the entire POR except in unusual cases where this preferred method would not yield an appropriate comparison. See, *e.g.*, *Brass Sheet and Strip from the Netherlands* (dividing POI into three periods because of the effect metal price fluctuations had on the margin calculations and finding that metal portion of price was a pass through); *Brass Sheet and Strip Italy* (using monthly costs to resolve the distortive effects the fluctuating metal prices had on the margin calculations); *Final Determination of Sales at Less Than Fair Value: Stainless Steel Sheet and Strip in Coils from the Republic of*

³ The London Metal Exchange is an international commodity, futures and options exchange that specializes in non-ferrous metals.

Korea, 64 FR 30664, 30676 (June 8, 1999) (concluding that weighted-average costs for two periods were permissible where major declines in currency valuations distorted the margin calculations); *Final Determination of Sales at Less than Fair Value: Static Random Access Memory Semiconductors from Taiwan*, 63 FR 8909, 8925 (February 23, 1998) (the Department will utilize shorter cost periods if markets experience significant and consistent price declines); *Final Determination of Sales at Less than Fair Value: Dynamic Random Access Memory Semiconductors of One Megabit and Above from the Republic of Korea*, 58 FR 15467, 15476 (March 23, 1993) (determining that the Department may use weighted-average costs of shorter periods where there exists a consistent downward trend in both U.S. and home market prices during the period); *Final Determination of Sales at Less than Fair Value: Erasable Programmable Read Only Memories from Japan*, 51 FR 39680, 39682 (October 30, 1986) (finding that significant changes in the COP during a short period of time due to technological advancements and changes in production process justified the use of weighted-average costs of less than a year).

In applying these criteria to this case, we have reviewed the information on the record and note that both OBV's sales prices for the subject merchandise and the cost of metal used in the manufacture of this merchandise correspondingly and consistently declined during the POR. Specifically, our analysis of data from the LME identifies a significant drop in metal values. In this case, we have determined that computing a single POR weighted-average cost would distort the results of the cost test because: (1) the cost of copper and zinc are treated as pass-through items when brass is sold to customers; (2) these metal costs represent a significant percentage of the total cost of producing brass sheet and strip; and (3) the cost of the metal dropped consistently and significantly throughout the POR. To avoid this distortion, we have relied upon monthly weighted-average costs rather than calculating quarterly or a single weighted-average POR cost for metal. Moreover, the use of monthly costs for a pass-through item is consistent with *Brass Sheet and Strip from Italy*, 52 FR 9235, 9236; *Brass Sheet and Strip from the Netherlands*, 53 FR 23431, 23432; and *Final Results of Administrative Review: Brass Sheet and Strip from Canada*, 56 FR 57317, 57318 (November 8, 1991) (using monthly metal costs to

calculate differences in merchandise adjustments).

We find that using monthly weighted-average metal costs is the most appropriate method in this proceeding for several reasons. First, the record indicates that the monthly changes in selling prices and input metal costs are significant. See the proprietary memorandum from Geoffrey Craig to John Brinkmann, "Analysis of Metal Costs," dated December 28, 1999. In addition, we have the information on the record to determine accurate monthly metal costs that reasonably correspond to the amounts paid by the customer, which makes the petitioners' concerns with quarterly costs moot. We also note that using monthly metal costs calculated from the company's metal fix prices conforms with the company's normal accounting records which are kept in accordance with home market generally accepted accounting principles (GAAP). Finally, by using weighted-average monthly price fixed metal cost, we are able to make a contemporaneous comparison of metal values which results in a more accurate calculation of the margin of dumping in this case than using either the reported quarterly or POR weighted average costs.

We also agree with the respondent that calculating fabrication costs on a monthly basis is unnecessary. After reviewing the information on the record, we found no significant fluctuations in OBV's fabrication costs that would require averaging periods of less than a year.

For the final results, we recalculated OBV's COP and CV. Specifically, we calculated monthly metal costs using metal fix date information (see CVE 18) and calculated annual fabrication costs using the reported costs in the section D data file.

Comment 3: Affiliated Purchases and the Major Input Rule

The petitioners state that the Department should adjust OBV's costs for metals (i.e., copper and zinc) obtained from affiliated suppliers to reflect the highest of market price, cost of production or transfer price.

OBV believes that the Department should not make this adjustment. According to OBV, the petitioners' argument reflects a lack of understanding of the verified data on the record. OBV states that the small differences between market price, cost of production and transfer prices are not the result of non-arms length transactions, but simply the result of timing differences and differences in purchase terms. To make a proper

comparison, the company argues that the timing differences and the difference in purchase terms would have to be accounted for. More important, OBV claims that the Department should continue to use OBV's metal costs as reported since the differences are slight.

DOC position: We agree with the petitioners. OBV submitted a schedule which shows that, on average, its POR purchases of zinc and copper from an affiliated party were made at prices lower than the cost of production. We have adjusted the cost of metals to reflect the affiliate's higher cost of production in accordance with section 773(f)(3) of the Act because the information provided by OBV supports the conclusion that the purchases from the affiliated party were made below the affiliate's cost. See CVE 28. We are unable to address OBV's claim that timing differences and the differences in purchase terms may account for the difference between the reported transfer price and the affiliate's cost of production, since OBV did not submit any information to support its contention.

Comment 4: Including Lower of Cost or Market Inventory Adjustment in COM

The petitioners claim that the Department should include OBV's lower of cost or market (LCM) adjustment in the calculation of COP and CV. According to the petitioners, the SAA states that the Department normally will calculate costs on the basis of records kept by the producer of the merchandise, provided such records are kept in accordance with GAAP of the producing country and reasonably reflect the costs associated with production of the merchandise. See SAA at 834. According to the petitioners, OBV stated that its accounting practices are in full compliance with GAAP in the Netherlands. The petitioners, therefore, contend that the Department should revise OBV's COP and CV data to include the lower of cost or market adjustment reflected in OBV's accounting records and in OBV's financial statements.

OBV counters that the Department should not revise the reported costs to include the company's LCM adjustment reflected in the financial statements. According to OBV, this adjustment has no impact on the actual cost of materials used in production because it makes a monthly adjustment to the balance sheet reserve accounts. OBV further argues that inclusion of the adjustment is not necessary because it did not rely on inventory movement values to calculate its reported metal costs. Instead of

inventory movement values, OBV states that it used actual metal acquisition costs paid during the review period to compute metal costs. If the Department includes the entire LCM adjustment, OBV claims that metal costs will be distorted.

DOC Position: We agree with the petitioners in part because our general practice is to include the LCM adjustments associated with raw materials and work-in-process (WIP) in the respondent's COP and CV. We do not include the loss realized on holding finished goods (see, e.g., *Notice of Final Determination of Sales at Less Than Fair Value: Dynamic Random Access Memory Semiconductors of One Megabit and Above (DRAMs) From Taiwan*, 64 FR 56308, 56326 (October 19, 1999)); see also *Notice of Final Determination of Sales Less Than Fair Value: Stainless Steel Wire Rod from Italy*, 63 FR 40422, 40430 (July 29, 1998)).

As for OBV's concern that including the LCM adjustment distorts COP and CV, we disagree. In OBV's normal course of business, the company values its copper and zinc inventory at the lower of cost or market. Since the market price of inventoried copper and zinc (i.e., metals) fell below the acquisition costs, OBV had to recognize a loss on metals held in inventory in accordance with home market GAAP. Company officials noted that they did not include this loss in the calculation of the reported costs and identified the loss as a reconciling item. However, as noted above, we normally include this type of cost in the calculation of COP and CV. Consistent with section 773(f)(1)(A) of the Act, it is the Department's practice to rely upon a company's normal books and records where they are prepared in accordance with the home country's GAAP and reasonably reflect the cost of producing and selling the subject merchandise. In this case, we found, consistent with the Netherlands' GAAP, that OBV includes, in its normal books and records, the write-downs of its raw material inventories as an element of its current costs per its financial statements. See Cost Verification Exhibit 17, which contains worksheets that reconcile reported direct material costs to the corresponding amount reported on the audited income statement. In addition, we disagree with OBV's position that this cost should be excluded because it used acquisition cost to compute metal cost. We note that the LCM adjustment is a separate and unique expense associated with maintaining an adequate base stock of goods to service daily operating needs. For the final

results, we have included a portion of OBV's LCM adjustment relating to raw material and WIP in the calculation of COP and CV.

Comment 5: Commercial Quantities

The petitioners contend that OBV's request for revocation should be denied because OBV did not sell in commercial quantities during each of the three administrative reviews that formed the basis of OBV's revocation request. According to the petitioners, the Department is justified, under § 351.222 of the Department's regulations, in requiring OBV to have sold subject merchandise in the United States in commercial quantities during the three review periods that form the basis of OBV's revocation request. However, contrary to the Department's methodology in the preliminary results, which focused on OBV's shipments to the United States during the period covering the last three administrative reviews, the petitioners assert that commercial quantities should be evaluated in light of the entire history of the proceeding, not just a few segments. A historical overview of OBV's shipments to the United States, the petitioners continue, demonstrates that OBV has not been making sales to the United States in commercial quantities at prices above NV in the three review periods in question.

The petitioners argue that subsequent to the antidumping duty order and prior to the acquisition of Outokumpu American Brass (American Brass) in 1990 by OBV's parent company, Outokumpu Oyj (Outokumpu), OBV continued to export substantial quantities of subject merchandise to the United States at prices below NV, as evidenced by the margins calculated in each of the administrative reviews covering that period. Rather than eliminating the dumping, the petitioners contend, the Outokumpu Group shifted production from OBV to American Brass, thereby allowing the Outokumpu Group to maintain its U.S. customer base while avoiding the imposition of antidumping duties. The petitioners contend that OBV has been able to avoid a finding of dumping in the last three review periods by shipping a minimal amount of "niche" or "specialty" product to the United States at prices intended to result in a de minimis dumping margin.

Moreover, the petitioners allege that: (1) OBV's current shipments to the United States of the subject brass products are minuscule compared to shipment levels both prior and immediately subsequent to the imposition of the antidumping duty

order; (2) OBV's current shipments do not correspond to the current size of the U.S. market for radiator strip; (3) OBV's current shipments of subject merchandise to the United States are significantly lower than its level of exports of non-subject brass products that have minimal physical differences from subject merchandise; (4) OBV's current shipments of subject merchandise to the United States are significantly lower than its current home market shipments and its shipments of total shipments (i.e., both subject and non-subject merchandise) to other industrial countries; and (5) OBV's current shipments are not reflective of its projected shipment levels to the United States, which OBV has acknowledged will be at a level similar to the pre-order level and shipments during the first three annual reviews, where the company was found to be dumping. Based on the foregoing, the petitioners conclude that the Department should find that OBV has not made sales to the United States in commercial quantities and, accordingly, should deny OBV's request for revocation.

OBV counters that its sales to the United States during the three consecutive review periods that form the basis of its revocation request have been in commercial quantities and at prices above NV. According to OBV, the Department properly selected 1990, rather than the pre-order period, as the benchmark for the commercial quantities test because the commercial quantities test must be applied in light of Outokumpu's acquisition of American Brass. OBV disputes the contention that the company discontinued shipments to the United States because it was unable to sell in the United States at prices above NV; instead, OBV attributes its cessation of U.S. shipments in 1990 exclusively to the purchase of American Brass, which OBV characterizes as a "significant" and "unusual intervening event." Furthermore, OBV states that its parent company forbids OBV from shipping subject merchandise to the United States in order to prevent its products from competing with those of American Brass. OBV resumed shipments in order to service a niche market for certain U.S. customers of subject brass products that could not be produced efficiently by American Brass or where the customers specifically requested that the brass be produced by OBV.

OBV further contends that the petitioners' proposed assortment of alternative benchmarks are of no probative value in determining commercial quantities, arguing that: (1)

In light of American Brass' role in the U.S. market, a pre-order or post-order comparison is not a reliable indicator of OBV's ability to sell in the United States without dumping; (2) OBV did not need to continue exporting subject merchandise in substantial volumes to preserve its position in the U.S. market due to the fact that American Brass produced the same merchandise for sale in the United States; (3) shipment levels of non-subject merchandise do not provide a demonstrable basis for determining what constitutes commercial quantities of subject merchandise; (4) a comparison of OBV's U.S. shipments to its shipments to other industrial countries' markets is not of probative value because OBV's ability to sell in the U.S. market, unlike its ability to sell in other industrial countries' markets, is limited due to the presence of an affiliated company, American Brass; and (5) the notion of comparing current shipment levels to future shipment levels is flawed because the Department would be required to defer revocation in order to conduct subsequent reviews. Finally, OBV argues that a comparison of OBV's U.S. sales to third country sales demonstrates that OBV's U.S. sales are not aberrational, but instead reflect OBV's normal commercial activity. See, e.g., *Pure Magnesium from Canada*, 64 FR 12977, 12979 (March 16, 1999) (recognizing that comparisons of a respondent's U.S. sales to sales made in other markets by that respondent is a reliable indicator of whether the U.S. sales are in commercial quantities).

DOC Position: We agree with the petitioners that OBV's U.S. sales during the three administrative reviews under consideration for revocation purposes have not been made in commercial quantities. As we explained in the *Preliminary Results*, "the Department must be able to determine that past margins are reflective of a company's normal commercial activity." 64 FR 48760. Although OBV has demonstrated three consecutive years of sales at not less than NV, we find that the limited volume of exports to the United States of brass sheet and strip from the Netherlands do not reflect OBV's normal commercial behavior. Based on the facts on the record of this case, therefore, we find that OBV's sales to the United States have not been made in commercial quantities during any of the relevant administrative reviews considered for revocation in this proceeding.

We have developed a procedure for revocation that is described in 19 CFR 351.222. This regulation requires that a company requesting revocation must

submit a certification that the company sold the subject merchandise in commercial quantities in each of the three years forming the basis of the request. Therefore, we must determine, as a threshold matter, in accordance with our regulations, whether the company requesting revocation sold the subject merchandise in commercial quantities in each of the three years forming the basis of the request. In examining commercial quantities for purposes of revocation, the Department must be able to determine that past margins are reflective of the company's normal commercial activity. See *Certain Corrosion-Resistant Carbon Steel Flat Products from Canada*, 64 FR 2175. Sales during a POR which, in the aggregate, are of an abnormally small quantity, either in absolute terms or in comparison to an appropriate benchmark period, do not generally provide a reasonable basis for determining that the discipline of the order is no longer necessary to offset dumping. *Id.*; see also *Pure Magnesium From Canada*, 64 FR 12977 (March 16, 1999). However, the determination as to whether or not sales volumes are made in commercial quantities is made on a case-by-case basis, based on the unique facts of each proceeding. Neither the statute nor the Department's regulations prescribe a specific standard for determining whether sales have been made in commercial quantities. See section 751(d) of the Act; 19 CFR 351.222.

When determining whether a company's sales have been made in commercial quantities we must look at each case on an individual basis. In many instances, we will use the original period of investigation (*i.e.*, pre-order shipment levels) as a benchmark for a company's normal commercial behavior. The period of investigation generally provides a valid benchmark for assessing whether sales have been made in commercial quantities. As we stated in the *Preliminary Results*, however, where a company has experienced a substantial and unusual change in business practice since the imposition of the order that may explain a substantial sales drop-off in U.S. sales, a more recent POR that is reflective of the company's normal commercial experience may provide a more appropriate benchmark. See *Pure Magnesium from Canada*, 64 FR at 50489; *Professional Electric Cutting Tools from Japan: Preliminary Results of Antidumping Administrative Review and Intent to Revoke in Part*, 64 FR 43346, 43351 (August 10, 1999).

In this case, the quantity and number of OBV's U.S. sales of subject

merchandise have decreased since the imposition of the antidumping duty order, as evidenced by the volume of sales in the three reviews forming the basis of OBV's revocation request. In the *Preliminary Results*, however, we found that OBV's aggregate sales to the United States were made in commercial quantities during the relevant proceedings examined for purposes of the revocation determination. We based this finding on the fact that Outokumpu's acquisition of American Brass and the subsequent transfer of in-scope radiator strip production to the United States represented the type of "unusual occurrence" contemplated by the Department in promulgating its regulations as an acceptable explanation of why exports of subject merchandise have declined. See *Proposed Regulations*, 61 FR 7307, 7320 (Feb. 27, 1996). Specifically, we explained that:

Prior to this acquisition, in 1989 and 1990, OBV continued to ship in similar quantities to the pre-order period and the subsequent cessation of shipments until 1995 was an immediate result of the 1991 acquisition. Based upon these circumstances, it is reasonable to conclude that the company's commercial practices were permanently changed in 1991, and that 1991, rather than the pre-order period, should be the benchmark for measuring whether the company's sales during the three years without dumping were made in commercial quantities.

64 FR 48760. Thus, we preliminarily determined that the zero margins calculated for OBV in each of the last three administrative reviews were reflective of the company's normal commercial experience. Accordingly, we preliminarily determined that OBV met the requirements for revocation of the order on brass sheet and strip from the Netherlands with respect to three consecutive years of sales in commercial quantities at not less than NV.

Upon review of the comments of the parties, all of the evidence on the record, and the Department's past practice, we have determined that OBV's sales were not made in commercial quantities during the three years upon which OBV is relying to support its request for revocation. We agree that OBV's commercial practices changed subsequent to the 1990 purchase⁴ of American Brass by OBV's ultimate parent company, Outokumpu.

⁴ As discussed in a memorandum to the file dated December 20, 1999, we cited June 1991 in the *Preliminary Results* as the month and year of Outokumpu's acquisition of American Brass based on statements made on the record by OBV. However, after a thorough review of the responses and exhibits submitted by OBV, we confirmed with OBV that American Brass was acquired by Outokumpu in June 1990, rather than June 1991.

Contrary to our preliminary assessment of the effects of Outokumpu's purchase of American Brass on OBV, however, we now find that it is not reasonable to conclude that OBV's commercial practices were "permanently" changed or that OBV's current selling practice is reflective of the company's normal commercial experience.

First, following Outokumpu's 1990 purchase of American Brass, OBV did not maintain consistent export volumes of its "niche" products, but instead ceased selling to the United States altogether for over three years while American Brass provided subject merchandise entirely to Outokumpu's U.S. customer base. OBV reentered the U.S. market in 1995 when it began selling what it termed "niche products." Our preliminary finding regarding commercial quantities was based, in part, on the presumption that "OBV resumed shipments of in-scope radiator strip in 1995 to service a niche market for certain United States customers who prefer brass strip with more exacting tolerances, which for a variety of reasons cannot be produced efficiently by American Brass." See *Preliminary Results*, 64 FR at 48765. However, as stated by OBV at the public hearing, during the three year period in which OBV was shipping radiator strip to the United States, American Brass was also producing and selling the same products to the same customers. See Public Transcript of the Hearing on Brass Sheet and Strip from the Netherlands, dated November 2, 1999, at 183-85 (Hearing Transcript). Furthermore, in a prior submission OBV made the following statement with respect to the company's resumption of shipments to the United States:

In addition to the superior position of OBV, vis-a-vis American Brass, in terms of the production of quality radiator strip, OBV has resumed exporting subject radiator strip in order to accommodate the ability of American Brass to focus upon the production of brass strip for electrical connectors (i.e., "electrostrip" or "connector strip"). As explained by [American Brass' president] Mr. Bartel, the production of radiator strip is interfering with the ability of American Brass to focus on production "for the fastest growing segment of the brass strip market, i.e., brass strip used to manufacture electrical connectors."

See OBV's Memorandum in Support of Revocation, dated April 1, 1999, at 22-23. These statements further indicate that when OBV resumed shipping to the United States in 1995, its participation in the U.S. market was not limited to servicing unique customers with needs specially suited to OBV's abilities. Rather, for whatever considerations, it

was determined by Outokumpu that the U.S. customers who were purchasing certain subject brass products from American Brass would be supplied by OBV. Thus, we cannot reasonably conclude that OBV's participation in the U.S. market during the three year period under consideration has been meaningful.

Second, this case is distinguished from *Professional Electric Cutting Tools from Japan*, where respondent Makita made a substantial investment in a U.S. manufacturing facility, and subsequently shifted production of subject merchandise to that facility while maintaining consistent export volumes of its low-sales-volume "specialty" cutting tools. In that case, we found that the significant change in business practice provided a logical commercial explanation for Makita's relative drop in subject merchandise sales. Further, we noted that the U.S. production facility now manufactures comparable volumes of non-specialty merchandise that was previously being manufactured by Makita in Japan. Thus, regardless of any decrease in shipments during the course of that proceeding, we determined that Makita was selling in commercial quantities. Contrary to Makita, where less dependence was being placed on the home market manufacturing facilities, Outokumpu has recently made a substantial investment in OBV's manufacturing facility. It is Outokumpu's stated intention to shift production of brass radiator strip products from American Brass to OBV's manufacturing facilities in order to supply the U.S. market with subject merchandise from the Netherlands. See Hearing Transcript, at 167-70. As confirmed at the sales verification:

OBV officials stated that due to recent investment in both American Brass and OBV, OBV will begin to take over production of the approximate 7200 metric tons⁵ of subject radiator strip currently produced and sold in the U.S. by American Brass. Since OBV is currently producing to capacity, this additional demand would be met by adjusting their current product mix and cutting back on shipment to other export markets.

Sales Verification Report at 39.

In determining whether a company's exports to the United States constitutes "normal" commercial behavior for that company, where appropriate, we will weigh other factors. In this case, Outokumpu made a significant business decision to supply its U.S. customer base with subject merchandise

⁵ This is a range figure provided by the respondents.

produced at American Brass' U.S. facilities rather than from OBV's facilities in the Netherlands. However, the record indicates that the current Outokumpu business plan is not intended to be long-term or permanent in light of OBV's acknowledgment that its projected shipment levels to the United States, should the order be revoked, will be substantially greater than its current imports and at a level similar to when the order was imposed and the first three annual reviews were conducted. See Hearing Transcript, at 65-66. Given the temporary nature of American Brass' role in the Outokumpu business plan of servicing subject radiator strip customers in the U.S. market and the decision to transfer radiator strip production for purposes of servicing the U.S. market back to the Netherlands at pre-order levels, we find that OBV's pre-order import level is the appropriate benchmark.

Finally, based on the current record and similar to our findings in *Pure Magnesium from Canada*, we find that OBV's sales volume during the three consecutive review periods that form the basis of the revocation request are so small when compared to the pre-order benchmark that we are not able to conclude that the reviews are reflective of what the company's normal commercial experience would be without the discipline of an antidumping duty order. See *Pure Magnesium from Canada*, 64 FR 12977, 12982. As discussed in the business proprietary memorandum from Jarrod Goldfeder to John Brinkmann, "Shipments of Brass Sheet and Strip to the United States by Outokumpu Copper Strip B.V.," dated December 28, 1999 (*Commercial Quantities Memorandum*), OBV sold only a few tons of subject merchandise in the United States during the last three review periods, respectively, whereas during the period covered by the antidumping investigation, OBV made substantially greater sales. For example, in their brief the petitioners, citing U.S. Census Bureau data (which OBV did not contravene), state that OBV exported approximately 7000 tons of subject merchandise in 1987, the year in which the POI fell. See Petitioners' Case Brief, at Exhibit 8. In calendar years 1997 and 1998, during which the current POR falls, OBV exported to the United States approximately 110 tons of subject merchandise (23 tons and 86 tons in 1997 and 1998, respectively). See *Commercial Quantities Memorandum*, at Exhibit 1.

Thus, for the most recent review period under consideration for revocation, the total volume of

merchandise sold in calendar years 1997 and 1998 was approximately 1.6 percent of the volume of merchandise sold in 1987, *i.e.*, in the period preceding the imposition of the order. OBV's sales volume figures are so small, both in absolute terms and in comparison with the period of investigation, that we cannot reasonably conclude that the zero margins OBV received are reflective of the company's normal commercial experience. We further note that OBV's projected sales level to the United States of 7200 tons, which is similar to the amount sold prior to issuance of the order, is over 65 times greater than the amount sold during the period covered by the current administrative review. Consequently, this abnormally low level of sales activity during each of the three review periods forming the basis of the revocation request does not provide a reasonable basis for determining that the discipline of the antidumping duty order is no longer necessary to offset dumping. Based on the record evidence with respect to OBV's current sales practices, we find that the *de minimis* margins calculated for OBV were not based on sales volumes that are reflective of the company's normal commercial experience.

Moreover, even if we continued to rely upon the 1990 benchmark, rather than the pre-order period, for measuring whether the company's sales during the three years without dumping were made in commercial quantities, we would still conclude that OBV's total sales volume for each review is "abnormally small." In 1990, the last year in which OBV made sales to the United States prior to the transfer of production to American Brass, OBV sold approximately 4750 tons of subject merchandise in the United States. See Petitioners' Case Brief, at Exhibit 8. For each review period under consideration for revocation, the volume of merchandise sold was still only a little more than two percent of the volume of merchandise sold in 1990. Thus, by any measure, OBV's sales did not meet the minimal requirement of sales in commercial quantities that is necessary for the Department to rely on the three administrative reviews of *de minimis* margins as a reflective of normal business activity.

Finally, we disagree with OBV's argument that a comparison of OBV's U.S. sales to third country sales demonstrates that OBV's U.S. sales are not aberrational, but instead reflect OBV's normal commercial activity. In *Pure Magnesium from Canada*, the Department concluded that the respondent's number and volume sales

were not made in commercial quantities due, in part, upon an examination of the respondent's sales of pure magnesium to other markets for the three years in question, which showed that the respondent had maintained significant sales volumes of subject merchandise in other markets that were "markedly smaller and more distant than the U.S. market." 64 FR at 12980. However, the evidence placed on the record in this proceeding by OBV details the total volume of shipments to third countries, inclusive of both subject and non-subject brass merchandise. As such, we are unable to make an accurate comparison of OBV's shipments of subject brass products to the United States with its shipments of subject brass products to third country markets.

Comment 6: Likelihood of Future Dumping

In addition to their arguments regarding the commercial quantities threshold requirement, both OBV and the petitioners submitted comments on the likelihood of future dumping.

DOC Position: Because we have determined that OBV is not eligible for revocation, based on the fact that it did not make sales in commercial quantities during the three year period being analyzed, we do not reach the likelihood of future dumping issue.

Final Results of Review

As a result of our review, we determine that the following margins exist for the period August 1, 1997 through July 31, 1998:

Manufacturer/exporter	Margin (percent)
OBV	zero.

The Department shall determine, and the United States Customs Service shall assess, antidumping duties on all appropriate entries. In accordance with 19 CFR 351.212 (b)(1), we have calculated importer-specific assessment rates by dividing the dumping margin found on the subject merchandise examined by the entered value of such merchandise. We will direct the United States Customs Service to assess antidumping duties on appropriate entries by applying the assessment rate to the entered value of the merchandise entered during the POR, except where the assessment rate is zero or *de minimis* (see 19 CFR 351.106(c)(2)).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise from the Netherlands entered, or

withdrawn from warehouse, for consumption upon publication of these final results of administrative review, as provided by section 751(a)(2) (A) and (C) of the Act: (1) The cash deposit rate for OBV will be zero; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the original less-than-fair-value (LTFV) investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) if neither the exporter nor the manufacturer is a firm covered in this review or in any previous segment of this proceeding, the cash deposit rate will be 16.99 percent, the "all others" rate established in the LTFV investigation. See *Antidumping Duty Order of Sales at Less Than Fair Value; Brass Sheet and Strip From the Netherlands*, 53 FR 30455 (August 12, 1988).

These deposit requirements shall remain in effect until publication of the final results of the next administrative review.

This notice serves as final reminder to importers of their responsibility under 19 CFR 351.402 (f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred, and in the subsequent assessment of double antidumping duties.

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of return/ destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply is a violation of the APO.

This determination is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: December 28, 1999.

Holly A Kuga,

Acting Assistant Secretary for Import Administration.

[FR Doc. 00-286 Filed 1-5-00; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-351-602, A-570-814, A-588-602, A-583-605, A-549-807]

Continuation of Antidumping Duty Orders: Certain Carbon Steel Butt-Weld Pipe Fittings From Brazil, China, Japan, Taiwan, and Thailand

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of continuation of antidumping duty orders: Certain carbon steel butt-weld pipe fittings from Brazil, China, Japan, Taiwan, and Thailand.

SUMMARY: On December 3, 1999, the Department of Commerce ("the Department"), pursuant to sections 751(c) and 752 of the Tariff Act of 1930, as amended ("the Act"), determined that revocation of the antidumping duty orders on certain carbon steel butt-weld pipe fittings from Brazil, China, Japan, Taiwan, and Thailand are likely to lead to continuation or recurrence of dumping (64 FR 67847). On December 22, 1999, the International Trade Commission ("the Commission"), pursuant to section 751(c) of the Act, determined that revocation of the antidumping duty orders on certain carbon steel butt-weld pipe fittings from Brazil, China, Japan, Taiwan, and Thailand would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time (64 FR 71830). Therefore, pursuant to 19 CFR 351.218(e)(4), the Department is publishing notice of the continuation of the antidumping duty orders on certain carbon steel butt-weld pipe fittings from Brazil, China, Japan, Taiwan, and Thailand.

EFFECTIVE DATE: January 6, 2000.

FOR FURTHER INFORMATION CONTACT: Mark D. Young or Melissa G. Skinner, Office of Policy for Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Ave., NW, Washington, DC 20230; telephone: (202) 482-6397 or (202) 482-1560, respectively.

SUPPLEMENTARY INFORMATION:

Background

On May 3, 1999, the Department initiated, and the Commission instituted, sunset reviews (64 FR 23596 and 64 FR 23672, respectively) of the antidumping duty orders on certain carbon steel butt-weld pipe fittings from

Brazil, China, Japan, Taiwan, and Thailand pursuant to section 751(c) of the Act. As a result of its reviews, the Department found that revocation of the antidumping duty orders would likely lead to continuation or recurrence of dumping and notified the Commission of the magnitude of the margins likely to prevail were the orders to be revoked (see Final Results of Expedited Sunset Review: Certain Carbon Steel Butt-Weld Pipe Fittings From Brazil, China, Japan, Taiwan, and Thailand, 64 FR 67847 (December 3, 1999)).

On December 22, 1999, the Commission determined, pursuant to section 751(c) of the Act, that revocation of the antidumping duty orders on certain carbon steel butt-weld pipe fittings from Brazil, China, Japan, Taiwan, and Thailand would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time (see Certain Carbon Steel Butt-Weld Pipe Fittings From Brazil, China, Japan, Taiwan, and Thailand, 64 FR 71830 (December 22, 1999) and USITC Pub. 3263, Investigations Nos. 731-TA-308-310 and 520-521 (Review) (December 1999)).

Scope

The products covered by these reviews are pipe fittings from Brazil, China, Japan, Taiwan, and Thailand. Pipe fittings from Brazil, Taiwan, and Japan are defined as carbon steel butt-weld pipe fittings, other than couplings, under 14 inches in diameter, whether finished or unfinished form, that have been formed in the shape of elbows, tees, reducer, caps, etc., and, if forged, have been advanced after forging. These advancements may include any one or more of the following: coining, heat treatment, shot blasting, grinding, die stamping or painting. Such merchandise was classifiable under Tariff Schedules of the United States Annotated ("TSUSA") item number 610.8800. These imports are currently classifiable under the Harmonized Tariff Schedule of the United States ("HTSUS") item number 7307.93.30.

Pipe fittings from Thailand and China are defined as carbon steel butt-weld pipe fittings, having an inside diameter of less than 14 inches, imported in either finished or unfinished form. These formed or forged pipe fittings are used to join section in piping systems where conditions require permanent, welded connections, as distinguished from fittings based on other fastening methods (e.g., threaded grooved, or bolted fittings). These imports are currently classifiable under the HTSUS

item number 7307.93.30. The TSUSA and HTSUS subheadings are provided for convenience and United States Customs purposes. The written description remains dispositive as to the scope of the product coverage for each of the orders.

These reviews cover imports from all manufacturers and exporters of pipe fittings from Brazil, China, Japan, Taiwan, and Thailand.

Determination

As a result of the determinations by the Department and the Commission that revocation of these antidumping duty orders would be likely to lead to continuation or recurrence of dumping and material injury to an industry in the United States, pursuant to section 751(d)(2) of the Act, the Department hereby orders the continuation of the antidumping duty orders on certain carbon steel butt-weld pipe fittings from Brazil, China, Japan, Taiwan, and Thailand. The Department will instruct the U.S. Customs Service to continue to collect antidumping duty deposits at the rate in effect at the time of entry for all imports of subject merchandise. The effective date of continuation of these orders will be the date of publication in the *Federal Register* of this Notice of Continuation. Pursuant to sections 751(c)(2) and 751(c)(6) of the Act, the Department intends to initiate the next five-year review of these orders not later than December 2004.

Dated: December 29, 1999.

Holly Kuga,

Acting Assistant Secretary for Import Administration.

[FR Doc. 00-288 Filed 1-5-00; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-588-810]

Preliminary Results of Full Sunset Review: Mechanical Transfer Presses From Japan

AGENCY: Import Administration, International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of preliminary results of full sunset review: Mechanical transfer presses from Japan.

SUMMARY: On June 1, 1999, the Department of Commerce ("the Department") initiated a sunset review of the antidumping duty order on mechanical transfer presses ("MTPs") from Japan pursuant to section 751(c) of the Tariff Act of 1930, as amended ("the

Act"). On the basis of a notice of intent to participate and adequate substantive response filed on behalf of a domestic interested party, and inadequate response from respondent interested parties, the Department determined to conduct an expedited sunset review. However, upon reconsideration of our initial adequacy determination, the Department determines that it is appropriate in this case to conduct a full review. As a result of this review, the Department preliminarily finds that revocation of the antidumping duty order would be likely to lead to continuation or recurrence of dumping at the levels indicated in the Preliminary Results of Review section of this notice.

FOR FURTHER INFORMATION CONTACT:

Martha V. Douthit or Melissa G. Skinner, Office of Policy for Import Administration, International Trade Administration, U.S. Department of Commerce, 14th St. & Constitution Ave., NW, Washington, D.C. 20230; telephone (202) 482-5050 or (202) 482-1560, respectively.

EFFECTIVE DATE: January 6, 2000.

Statute and Regulations

This review is being conducted pursuant to sections 751(c) and 752 of the Act. The Department's procedures for the conduct of sunset reviews are set forth in *Procedures for Conducting Five-year ("Sunset") Reviews of Antidumping and Countervailing Duty Orders*, 63 FR 13516 (March 20, 1998) ("*Sunset Regulations*") and 19 CFR Part 351 (1999) in general. Guidance on methodological or analytical issues relevant to the Department's conduct of sunset reviews is set forth in the Department's Policy Bulletin 98:3—*Policies Regarding the Conduct of Five-year ("Sunset") Reviews of Antidumping and Countervailing Duty Orders; Policy Bulletin*, 63 FR 18871 (April 16, 1998) ("*Sunset Policy Bulletin*").

Scope

The merchandise covered by this order is MTPs from Japan. The term "mechanical transfer press" refers to automatic metal-forming machine tools with multiple die stations in which the workpiece is moved from station to station by a transfer mechanism designed as an integral part of the press and synchronized with the press action, whether imported as machines or parts suitable for use solely or principally with these machines. These presses may be assembled or unassembled. Spare and replacement parts are outside the scope of the order (see *Notice of Scope*

Rulings, 57 FR 19602 (May 7, 1992)). A destack sheet feeder designed to be used with a mechanical transfer press is an accessory and, therefore, is not within the scope of the order (see *Notice of Scope Rulings*, 57 FR 32973 (July 24, 1992)). The FMX cold forging press is within the scope of the order (see *Notice of Scope Rulings*, 59 FR 8910 (February 24, 1994)). Finally, certain mechanical transfer press parts exported from Japan are outside the scope of the order (see *Notice of Scope Rulings*, 62 FR 9176 (February 28, 1997)). This merchandise is currently classifiable under Harmonized Tariff Schedule ("HTS") item numbers 8462.99.0035 and 8466.94.5040. The HTS item numbers are provided for convenience and customs purposes. The written description remains dispositive.

History of the Order

On January 4, 1990, the Department issued a final determination of sales at less than fair value on imports of MTPs from Japan.¹ On February 16, 1990, the antidumping duty order on the subject merchandise was published in the *Federal Register*.²

In the antidumping duty order the Department established an estimated weighted-average dumping margin of 15.16 percent for Komatsu Ltd, 7.49 percent for Aida Engineering, Ltd. ("Aida"), and an "all others" rate of 14.51 percent. *Id.* There have been six administrative reviews of this order, and no investigations of duty absorption by the Department.

The order remains in effect for all producers and exporters of MTPs from Japan, except for Aida for which the Department revoked the antidumping duty order.³

Background

On June 1, 1999, the Department initiated a sunset review of the antidumping duty order on MTPs from Japan pursuant to section 751(c) of the Act. On June 16, 1999 we received a Notice of Intent to Participate on behalf of Verson Division of Allied Products Corporation ("Verson"), within the deadline specified in section 351.218(d)(1)(i) of the *Sunset Regulations*. We received a complete substantive response on July 1, 1999 from Verson, within the deadline

specified in section 351.218(d)(3)(i) of the *Sunset Regulations*. Verson claimed interested party status under section 771(9)(C) of the Act as a U.S. manufacturer of a domestic like product and stated it was the petitioner in the original investigation.

We received complete substantive responses from respondent interested parties, Komatsu, Ltd. ("Komatsu"), Hitachi Zosen Corporation ("HZ") and Fukui Machinery Co., ("Fukui") (collectively "the respondents"). Komatsu, HZ, and Fukui claimed interested party status as manufacturers and exporters of MTPs under section 771(9)(A) of the Act. Komatsu maintains that it was a respondent interested party in the original investigation and has participated in two of six subsequent administrative reviews conducted by the Department. Komatsu further notes that it is participating in the 1998–1999 administrative review that the Department is currently conducting. HZ and Fukui state that they did not participate in the original investigation; however, HZ states that it has participated in four of six subsequent administrative reviews and Fukui has participated in one administrative review.

On July 12, 1999, we received comments from Verson requesting that the Department determine that the individual respondent interested party responses to the notice of initiation are inadequate with regard to respondent interested parties as a whole. Verson argued, therefore, that an expedited review was appropriate. The regulations provide, at section 351.218(e)(1)(ii)(A), that the Secretary normally will conclude that respondent interested parties have provided adequate response to a notice of initiation where it receives complete substantive responses from respondent interested parties accounting on average for more than 50 percent, on a volume basis (or value basis, if appropriate) of the total exports of the subject merchandise to the United States over the five calendar years preceding the year of publication of the notice of initiation. In their substantive responses, the respondents provided the Department statistics on export volume and value of MTPs for the time period 1994 through 1998. After examining the statistical information, the Department concluded that it did not receive adequate response to the notice of initiation from respondent interested parties. As a result, pursuant to the regulations, on July 21, 1999, the Department determined to conduct an expedited sunset review of this order 19 CFR 351.218(e)(1)(ii)(C).

¹ See *MTPs From Japan; Final Determination of Sales at Less Than Fair Value*, 55 FR 335 (January 4, 1990).

² See *MTPs From Japan; Antidumping Duty Order*, 55 FR 5642 (February 16, 1990).

³ See *MTPs From Japan; Final Results of Antidumping Duty Administrative Review and Revocation of Antidumping Duty Administrative Order in Part*, 63 FR 37331 (July 10, 1998).

In accordance with section 751(c)(5)(C)(v) of the Act, the Department may treat a review as extraordinarily complicated if it is a review of a transition order (*i.e.*, an order in effect on January 1, 1995). Therefore, on October 12, 1999, the Department determined that the sunset review of the antidumping duty order on MTPs from Japan is extraordinarily complicated and extended the time limit for completion of the final results of this review until not later than December 28, 1999, in accordance with section 751(c)(5)(B) of the Act.⁴

Adequacy

As noted above, on July 21, 1999, the Department determined that, during the five-year period from 1994 to 1998, the average annual percentage of the respondents' exports of MTPs to the United States with respect to the total subject merchandise exports to the United States falls significantly below the 50 percent threshold that the Department normally will consider to be an adequate foreign response. In light of the fact that, on July 10, 1998, the order was revoked with respect to Aida, our reliance on total imports during that time resulted in an underestimation of the percent of exports accounted for by respondent interested parties. Although, absent Aida-specific export statistics, we are unable to determine the exact percentage of subject merchandise exports accounted for by respondent interested parties, given Aida's historic participation in administrative reviews, including our finding that Aida had exported in commercial quantities over a three consecutive year period, we determine that the respondent interested parties account for a significantly greater percent of exports of subject merchandise than we had originally estimated and, therefore, that respondent interested parties may account for more than the 50 percent threshold that the Department applies in its adequacy determinations. Additionally, interested parties have raised significant issues in their submissions with respect to the significant decline in import volumes and the unique nature of the market such that the Department believes it is appropriate to conduct a full review and allow submission of additional data.

Determination

In accordance with section 751(c)(1) of the Act, the Department is conducting this review to determine whether revocation of the antidumping order

would be likely to lead to continuation or recurrence of dumping. Section 752(c)(1) of the Act provides that, in making this determination, the Department shall consider the weighted-average dumping margins determined in the investigation and subsequent reviews and the volume of imports of the subject merchandise for the period before and the period after the issuance of the antidumping order. Pursuant to section 752(c)(3) of the Act, the Department shall provide to the International Trade Commission ("the Commission") the magnitude of the margin of dumping likely to prevail if the order is revoked.

The Department's preliminary determinations concerning continuation or recurrence of dumping and magnitude of the margin are discussed below. In addition, interested parties comments with respect to the continuation or recurrence of dumping and the magnitude of the margin are addressed within the respective sections below.

Continuation or Recurrence of Dumping

Drawing on the guidance provided in the legislative history accompanying the Uruguay Round Agreements Act ("URAA"), specifically the Statement of Administrative Action ("the SAA"), H.R. Doc. No. 103-316, vol. 1 (1994), the House Report, H.R. Rep. No. 103-826, pt. 1 (1994), and the Senate Report, S. Rep. No. 103-412 (1994), the Department issued its *Sunset Policy Bulletin* providing guidance on methodological and analytical issues, including the basis for likelihood determinations. The Department clarified that determinations of likelihood will be made on an order-wide basis (*see* section II.A.2 of the *Sunset Policy Bulletin*). Additionally, the Department normally will determine that revocation of an antidumping order is likely to lead to continuation or recurrence of dumping where: (a) Dumping continued at any level above *de minimis* after the issuance of the order, (b) imports of the subject merchandise ceased after the issuance of the order, or (c) dumping was eliminated after the issuance of the order and import volumes for the subject merchandise declined significantly (*see* section II.A.3 of the *Sunset Policy Bulletin*).

In its substantive response, Verson argues that revocation of the antidumping duty order would likely lead to continuation or recurrence of dumping by Japanese producers and exporters of MTPs. Verson maintains that the history of this order (*i.e.*, the

administrative review history) demonstrates that since the issuance of the order, respondents have not been able, on a continuous basis, to sell MTPs in the United States at fair value.

Verson argues that section 752(c)(1) of the Act instructs the Department to consider not only the weighted-average dumping margins determined in the original investigation and subsequent reviews but also the volume of imports for the period before and the period after the issuance of the order. Verson contends that since the issuance of the order, only one company (Aida) has made sales to the U.S. at not less than fair value over a consecutive three year period. Verson asserts that although since the issuance of the order, imports of MTPs from Japan have remained relatively stable, during many of the administrative reviews conducted by the Department, several Japanese producers have reported "no sales." In conclusion, Verson argues that a decline in import volume after the issuance of the order coupled with the continuation of dumping margins above *de minimis* is probative of the fact that producers and exporters of MTPs from Japan will continue to dump if the order is revoked. For these reasons, Verson maintains that the Department should determine that there is a likelihood of the continuation or recurrence of dumping of MTPs from Japan if the order is revoked.

In their substantive responses, the respondent interested parties argue that revocation of the order is not likely to lead to the continuation or recurrence of dumping. Komatsu argues that, with the exception of small dumping margins found in early reviews of Aida (a company for which the order has subsequently been revoked), in every single review the Department has found no dumping. Further, according to Komatsu, it is unlikely that this situation will change if the order is revoked. Komatsu argues that the original dumping finding was the result of a unique historical situation. Specifically, Komatsu argues that the mid-1980s saw unprecedented boom in demand for MTPs, with U.S. automakers retooling to compete with Japanese automakers and with Japanese automakers establishing transplant manufacturing operations in the United States. Komatsu asserts that once this process was completed in the late 1980s, there was a sharp drop in demand and since that time, the U.S. market for MTPs has been characterized by relatively few sales either for replacement of existing machines, or to supply the relatively few new automobile manufacturing plants that

⁴ See *Extension of Time Limit for Final Results of Five-Year Reviews*, 64 FR 5523 (October 12, 1999).

have been built. Further, Komatsu asserts that as the MTP market has matured to more of a replacement market, a new dynamic has been created in which the number of bidders considered for each purchase has been reduced. This fundamental change in the nature of competition, Komatsu argues, has reduced the degree of competition and led to findings by the Department in all of its administrative reviews that the Japanese manufacturers subject to the order have not engaged in dumping.

HZ and Fukui note that in making determinations of likelihood of continuation or recurrence of dumping, the statute requires the Department to consider the weighted-average dumping margins determined in the investigation and subsequent reviews and the volume of imports of the subject merchandise for the period before and the period after the issuance of the antidumping duty order. However, citing to the SAA, at 890, they assert that the Department recognizes that observed patterns regarding dumping margins and import volumes are not necessarily indicative of the likelihood of dumping. Further, HZ and Fukui assert that, in this case, good cause exists sufficient to warrant that the Department consider factors other than import volume in determining whether revocation of an antidumping duty order is likely to lead to a continuation or recurrence of sales at less than normal value. Citing to the Commission's final report in the original investigation, HZ and Fukui argue that MTPs are big-ticket, made-to-order products, with relatively low and irregular sales volumes, and with peak sales occurring as the presses reach the end of their useful life of nearly 20 years. Similar to the arguments of Komatsu, HZ and Fukui argue that the late 1980s witnessed an unexpected increase in U.S. demand for MTPs which resulted in an increase in the importation of foreign made presses, including presses from Italy, the United Kingdom, and Japan. Further, as demand slackened in the late 1980s and early 1990s, so too did imports, with imports from foreign countries generally, and Japan in particular, declining significantly. This trough in the business cycle has lasted throughout the 1990s and, HZ and Fukui assert that it is expected to continue for another five to eight years. HZ and Fukui argue that, accordingly, any comparison between shipments prior to the imposition of the order and following the imposition of the order would be meaningless because the import levels

from all producers declined, whether they were found to be dumping or not.

HZ and Fukui go on to assert that the extreme cyclical nature of the MTP market constitutes "good cause" for the Department to consider price, cost, market, and other economic factors in determining whether revocation of the order is likely to lead to continuation or recurrence of dumping. An examination of those factors, HZ and Fukui argue, will reveal that revocation of the order will not likely lead to continuation or recurrence of dumping.

We did not receive rebuttal from Verson or Komatsu. In their rebuttal comments, HZ and Fukui⁵ reiterate their arguments that there is no likelihood that revocation of the order will result in continuation or recurrence of dumping. Again, HZ and Fukui assert that comparison of the pre- and post-order export volumes does not provide a valid measure of likelihood of dumping. They argue that the presumption that a post-order decline in shipment volumes indicates the foreign producer's inability to move the pre-order volumes without dumping does not apply to big-ticket items such as MTPs given that MTPs are unique pieces of machinery always are manufactured to exacting customer specifications, with extremely long useful lives, and sporadic sales. Additionally, citing to the July 1, 1999, substantive response of Verson, at page 10, they assert that Verson acknowledges that the lack of sales following the imposition of the order is closely correlated to the nature of the marketplace which is characterized by a very limited number of high value transactions. HZ and Fukui further assert that, in the original investigation, Verson argued that it was the unique nature of the market, with sporadic sales, that caused injury to the domestic industry. Therefore, Verson cannot now assert that respondents' sporadic sales following the imposition of the order demonstrate an inability to sell in the United States at fair value.

HZ and Fukui also take issue with Verson's argument that only one Japanese respondent has made sales for three years in a row without dumping. HZ and Fukui assert that the entire sales process from initial bid to delivery can take in excess of two years and, as a result, sales are infrequent and rarely occur in two consecutive years, let alone three. Further, HZ and Fukui assert that because the MTPs manufactured by

⁵ In their rebuttal comments, HZ and Fukui announced a name change for Fukui, pursuant to a resolution of the shareholders. Fukui was formerly known as "Fukui Machinery Co., Ltd." The name change took effect on July 1, 1999.

Aida have more diverse applications and tend to be smaller than those manufactured by other Japanese respondents, these sales occur more frequently, thus enabling Aida to take advantage of the Department's policy allowing for revocation of the order for sales made three years in a row without dumping. In summary, HZ and Fukui argue that because of the unique nature of the market for MTPs, the Department's analysis of pre- and post-order import levels will not provide a reliable indicator of the likelihood of HZ and Fukui's resumption of dumping.

As noted above, in determining whether revocation of an order is likely to lead to continuation or recurrence of dumping, the Department considers the margins determined in the investigation and subsequent administrative reviews and the volume of imports for the period before and the period after the issuance of the order. In the original investigation, the Department estimated the margin of dumping for Komatsu at 15.16 percent, for Aida at 7.49 percent, and for "all others" at 14.51 percent. Although Aida was found to be dumping in the second and third administrative review, at rates of 0.87 percent and 3.51 percent, respectively, we subsequently revoked the order with respect to Aida (63 FR 37311 (July 11, 1998)) based on our determination that Aida subsequently made sales to the United States for three consecutive years without dumping.

Verson argues that margins above *de minimis* continue to exist. However, other than the post-investigation margins found for sales by Aida, for which the order has been revoked, the Department has found only zero margins for all of the Japanese respondents for which an administrative review has been conducted. With the exception of possible imports subject to the "all others" rate, dumping by the respondents Komatsu, HZ, and Fukui (as well as Ishikawajima-Harima Heavy Industry) has been eliminated since the issuance of the order. Our review of the public versions of Customs' annual reports to Congress on its administration of the antidumping and countervailing duty statutes indicates that no bonds have been posted on entries subject to this order since October 1, 1992. Therefore, the existence of an above *de minimis* all others rate is not controlling in this sunset review.

Verson also argues that none of the Japanese producers/exporters that remain subject to the order have made sales above fair value for a period of three consecutive years. However, three consecutive years of sales above fair value is the revocation standard in

administrative reviews conducted under section 351.222 of the regulations and is not controlling in this sunset review.

As noted in the *Sunset Policy Bulletin*, the Department normally will determine that revocation of an order is likely to lead to continuation or recurrence of dumping where dumping was eliminated after the issuance of the order and import volumes for the subject merchandise declined significantly. In their substantive and rebuttal comments, the respondents argue that, given the nature of the MTP market, the Department's reliance on the decrease between pre- and post-order export volumes as a basis for a determination that dumping would be likely to continue or recur would be inappropriate in this case. Although Verson did not provide any rebuttal to these arguments, respondents have not supported their assertions by placing facts or some sort of documentary evidence on the record. In essence, the respondents are claiming that the U.S. market for MTPs has shrunk without providing any support for this claim. While we agree with respondents that the Department has the discretion to deviate from its stated policies where the facts warrant such deviation, respondents have not provided any evidence to support their claims.

While the respondents provided argument that would suggest an explanation for the significant decrease in imports after the imposition of the order, given the absence of evidence with respect to pre- and post-order market share, we are not persuaded at this point that it is appropriate to deviate from our stated policy in this case. However, as indicated below, the Department is providing an opportunity for interested parties who have filed substantive responses in this review to provide additional factual evidence and arguments on this issue.

In sum, although we have determined that the level of respondents participation warrants a full review, we note the existence of additional producers/exporters that have waived their right to participate in this review, which under the statute constitutes grounds for finding likelihood (See section 751(c)(4)(B) of the Act). Therefore, we preliminarily determine that revocation of the order would likely result in continuation or recurrence of dumping.

Magnitude of the Margin

In the *Sunset Policy Bulletin*, the Department stated that, consistent with the SAA and House Report, the Department will provide to the Commission the company-specific

margins from the investigation because that is the only calculated rate that reflects the behavior of exporters without the discipline of an order. Further, for companies not specifically investigated, or for companies that did not begin shipping until after the order was issued, the Department normally will provide a margin based on the all others rate from the investigation. (See section II.B.1 of the *Sunset Policy Bulletin*.) Exceptions to this policy include the use of a more recently calculated margin, where appropriate, and consideration of duty absorption determinations. (See sections II.B.2 and 3 of the *Sunset Policy Bulletin*.)

As stated in the "History of the Order" section of this notice, the Department published a weighted-average dumping margin in the original investigation of 15.16 percent for Komatsu Ltd, 7.49 percent for Aida Engineering, Ltd., and of 14.51 percent for "all others."

In its substantive response, Verson cites to the *Sunset Policy Bulletin* and asserts that the Department makes clear that the magnitude of the margin of dumping in most cases is to be the company-specific rate from the original investigation, as that margin best reflects the behavior of the respondents free of the constraints of an antidumping duty order. Verson argues that, accordingly, the Department should report to the Commission the rates for Komatsu and "all others" from the original investigation as the magnitude of the margin likely to prevail if the antidumping duty order is revoked.

In their substantive responses, the respondents argue that a zero rate will likely prevail if the order on MTPs is revoked. Komatsu argues that, throughout the history of this order, the Department has consistently found no dumping by Komatsu and the other Japanese exporters. Therefore, the dumping margin for Komatsu and others will be zero should the order be revoked.

HZ and Fukui assert that the Department may, and in this case should, provide the Commission with a margin other than from the original investigation. In support of their argument that the Department select a margin other than the "all others" rate from the original investigation as representative of the magnitude of the margin likely to prevail with respect to their exports, HZ and Fukui argue that the "all others" rate from the investigation represents the weighted-average of the two companies subject to the original investigation and does not include HZ and Fukui sales.

Furthermore, HZ and Fukui contend that they have received a zero margin in all their administrative reviews conducted by the Department. In conclusion, they argue that the "all others" rate of 14.51 percent is not representative of the rate likely to prevail if the order is revoked.

We agree with HZ and Fukui that the Department has the discretion to report a company-specific margin for a company that did not participate in the original investigation where, as in the *Final Results of Expedited Sunset Review: Steel Wire Rope From the Republic of Korea*, 64 FR 42166 (August 9, 1999), where we deviated from our policy with respect to the use of the "all others" rate for Kumho, a company not subject to the original investigation. However, in that review, a case that did not involve declining import volumes, we noted that although Kumho did not participate in the Department's original investigation, Kumho had participated in each of the administrative reviews and maintained a zero or *de minimis* margin over the life of the order. While we do not believe that participation in each review is necessary, as noted below, we preliminarily determine that use of a more recently calculated rate is not appropriate in this review.

In the *Sunset Policy Bulletin*, the Department noted that it may, in response to an argument from an interested party, provide the Commission a more recently calculated rate for a particular company where, for that particular company, dumping margins declined or dumping was eliminated after the issuance of the order and import volumes remained steady or increased. Further, in analyzing import volumes, the Department normally will consider the company's relative market share, with such information to be provided by the parties. In this review, the respondents have made arguments that post-order export volumes, although significantly decreased from pre-order import volumes, nonetheless provide sufficient support for a determination that more recently calculated margins are probative of their behavior without the discipline of the order. For the reasons stated above, we preliminarily determine that the respondent interested parties' assertions have not been supported by any evidence. Specifically, in this review, the Department believes it more appropriate to base a determination with respect to the use of a more recently calculated margin on evidence regarding market share; such evidence currently is not on the record. Therefore, absent evidence that the respondents have maintained or

increased market share while eliminating dumping, we preliminarily determine that the margins from the original investigation are probative of the behavior of exporter without the discipline of the order.

Based on the above analysis, we preliminarily intend to report to the Commission the margins contained in the Preliminary Results of Review of this notice.

Preliminary Results of Review

As a result of this review, the Department preliminarily finds that revocation of the antidumping duty order would be likely to lead to continuation or recurrence of dumping at the levels indicated below.

Manufacturer/Exporter	Margin (percent)
Komatsu, Ltd. (Komatsu)	15.16
Aida Engineering, Ltd	(¹)
All Others	14.51

¹Revoked.

Any interested party may request a hearing within 30 days of publication of this notice in accordance with 19 CFR 351.310(c). Any hearing, if requested will be held on February 16, 2000, in accordance with 19 CFR 351.310(d). Interested parties may submit case briefs no later than February 7, 2000, in accordance with 19 CFR 351.309(c)(1)(i). We invite interested parties to submit arguments and, as an exception to our normal practice, factual evidence related to the issues identified in these preliminary results. Rebuttal briefs, which must be limited to issues raised in the case briefs, may be filed not later than February 14, 2000. Rebuttal briefs also may contain factual evidence to rebut, clarify, or correct factual evidence submitted in other parties' case briefs. The Department will issue a notice of final results of this sunset review no later than April 26, 2000.

This five-year ("sunset") review and notice are in accordance with sections 751(c), 752, and 777(i)(1) of the Act.

Dated: December 28, 1999.

Holly Kuga,

Acting Assistant Secretary for Import Administration.

[FR Doc. 00-284 Filed 1-5-00; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-357-804]

Silicon Metal From Argentina; Antidumping Duty Administrative Review: Rescission of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of Rescission of Antidumping Duty Administrative Review.

SUMMARY: On November 4, 1999, the Department of Commerce ("the Department") published in the *Federal Register* (64 FR 60161) a notice announcing the initiation of an administrative review of the antidumping duty order on silicon metal from Argentina. This administrative review covered one Argentine manufacturer and exporter of silicon metal, Electrometalurgica Andina S.A.I.C. ("Andina"), for the period of September 1, 1998 through August 31, 1999. The Department has now rescinded this review as a result of the absence of Andina's shipments and entries into the United States of subject merchandise during the period of review.

EFFECTIVE DATE: January 6, 2000.

FOR FURTHER INFORMATION CONTACT: Helen Kramer or Linda Ludwig, Office of AD/CVD Enforcement, Group III, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone (202) 482-0405 or 482-3833, respectively.

SUPPLEMENTARY INFORMATION:

Applicable Statute and Regulations

Unless otherwise indicated, all citations to the Tariff Act of 1930, as amended, are to the provisions effective January 1, 1995, the effective date of the amendments made to the Tariff Act by the Uruguay Round Agreements Act (URAA). In addition, unless otherwise indicated, all citations to the Department's regulations are to the regulations codified at 19 CFR part 351 (1999).

Scope of Review

The product covered by this review is silicon metal. During the less-than-fair-value (LTFV) investigation, silicon metal was described as containing at least 96.00 percent, but less than 99.99 percent, silicon by weight. In response

to a request by the petitioners for clarification of the scope of the antidumping duty order on silicon metal from the People's Republic of China, the Department determined that material with a higher aluminum content containing between 89 and 96 percent silicon by weight is the same class or kind of merchandise as silicon metal described in the LTFV investigation. See Final Scope Rulings—Antidumping Duty Orders on Silicon Metal From the People's Republic of China, Brazil and Argentina (February 3, 1993). Therefore, such material is within the scope of the orders on silicon metal from the PRC, Brazil and Argentina. Silicon metal is currently provided for under subheadings 2804.69.10 and 2804.69.50 of the Harmonized Tariff Schedule (HTS) and is commonly referred to as a metal. Semiconductor-grade silicon (silicon metal containing by weight not less than 99.99 percent of silicon and provided for in subheading 2804.61.00 of the HTS) is not subject to this review. These HTS subheadings are provided for convenience and U.S. Customs purposes. Our written description of the scope of the proceeding is dispositive.

Background

On September 9, 1999, the Department published a notice of opportunity to request an administrative review of the antidumping duty order on silicon metal from Argentina (64 FR 48890). On September 30, 1999, petitioners in this proceeding, requested a review of sales made by Andina during the period September 1, 1998 through August 31, 1999. On November 4, 1999, the Department initiated an administrative review (64 FR 60161).

On November 23, 1999, Andina submitted a certification to the Department that it did not, directly or indirectly, enter for consumption, or sell, export, or ship for entry for consumption in the United States subject merchandise during the period of review. The Department performed a customs query for entries from Argentina classified under HTS numbers 2804.69.10 and 2804.69.50 during the period of review and found no entries during that time period. In response to a telephone inquiry, counsel for petitioners stated they had no information to the contrary. See Memorandum to the File from Helen M. Kramer dated November 30, 1999. Therefore, we have determined that Andina made no entries of the subject merchandise into the customs territory of the United States during the period of review.

Pursuant to 19 CFR 351.213(d)(3), the Department may rescind an administrative review, in whole or only with respect to a particular exporter or producer, if the Secretary concludes that, during the period covered by the review, there were no entries, exports, or sales of the subject merchandise. In light of the fact that we determined that Andina did not export the subject merchandise into the territory of the United States during the POR in question, and there were no entries made by any other exporter or producer in Argentina, we are rescinding this review. This notice is published in accordance with 19 CFR 351.213(d)(4).

Dated: December 29, 1999.

Richard O. Weible,

*Acting Deputy Assistant Secretary,
Enforcement Group III.*

[FR Doc. 00-296 Filed 1-5-00; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

Annual Listing of Foreign Government Subsidies on Articles of Cheese Subject to an In-Quota Rate of Duty

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Publication of Annual Listing of Foreign Government Subsidies on

Articles of Cheese Subject to an In-Quota Rate of Duty.

SUMMARY: The Department of Commerce, in consultation with the Secretary of Agriculture, has prepared its annual list of foreign government subsidies on articles of cheese subject to an in-quota rate of duty during the period October 1, 1998 through September 30, 1999. We are publishing the current listing of those subsidies that we have determined exist.

EFFECTIVE DATE: January 1, 2000.

FOR FURTHER INFORMATION CONTACT: Tipten Troidl, Office of AD/CVD Enforcement VI, Group II, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Ave., NW, Washington, DC 20230, telephone: (202) 482-2786.

SUPPLEMENTAL INFORMATION: Section 702(a) of the Trade Agreements Act of 1979 (as amended) ("the Act") requires the Department of Commerce ("the Department") to determine, in consultation with the Secretary of Agriculture, whether any foreign government is providing a subsidy with respect to any article of cheese subject to an in-quota rate of duty, as defined in section 702(g)(b)(4) of the Act, and to publish an annual list and quarterly updates of the type and amount of those subsidies. We hereby provide the Department's annual list of subsidies on

articles of cheese that were imported during the period October 1, 1998 through September 30, 1999.

The Department has developed, in consultation with the Secretary of Agriculture, information on subsidies (as defined in section 702(g)(b)(2) of the Act) being provided either directly or indirectly by foreign governments on articles of cheese subject to an in-quota rate of duty. The appendix to this notice lists the country, the subsidy program or programs, and the gross and net amounts of each subsidy for which information is currently available.

The Department will incorporate additional programs which are found to constitute subsidies, and additional information on the subsidy programs listed, as the information is developed.

The Department encourages any person having information on foreign government subsidy programs which benefit articles of cheese subject to an in-quota rate of duty to submit such information in writing to the Assistant Secretary for Import Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230.

This determination and notice are in accordance with section 702(a) of the Act.

Dated: December 29, 1999.

Holly A. Kuga,

Acting Assistant Secretary for Import Administration.

APPENDIX—SUBSIDY PROGRAMS ON CHEESE SUBJECT TO AN IN-QUOTA RATE OF DUTY

Country	Program(s)	Gross ¹ subsidy (\$/lb)	Net ² subsidy (\$/lb)
Austria	European Union Restitution Payments	0.19	0.19
Belgium	EU Restitution Payments	0.07	0.07
Canada	Export Assistance on Certain Types of Cheese	0.23	0.23
Denmark	EU Restitution Payments	0.17	0.17
Finland	EU Restitution Payments	0.26	0.26
France	EU Restitution Payments	0.15	0.15
Germany	EU Restitution Payments	0.19	0.19
Greece	EU Restitution Payments	0.00	0.00
Ireland	EU Restitution Payments	0.10	0.10
Italy	EU Restitution Payments	0.13	0.13
Luxembourg	EU Restitution Payments	0.07	0.07
Netherlands	EU Restitution Payments	0.10	0.10
Norway	Indirect (Milk) Subsidy	0.34	0.34
	Consumer Subsidy	0.14	0.14
Total		0.48	0.48
Portugal	EU Restitution Payments	0.10	0.10
Spain	EU Restitution Payments	0.11	0.11
Switzerland	Deficiency Payments	0.25	0.25
U.K.	EU Restitution Payments	0.13	0.13

¹ Defined in 19 U.S.C. 1677(5).

² Defined in 19 U.S.C. 1677(6).

[FR Doc. 00-294 Filed 1-5-00; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

Export Trade Certificate of Review

ACTION: Notice of issuance of an Export Trade Certificate of Review, Application No. 99-00005.

SUMMARY: The Department of Commerce has issued an Export Trade Certificate of Review to California Almond Export Association, LLC ("CAEA"). This notice summarizes the conduct for which certification has been granted.

FOR FURTHER INFORMATION CONTACT: Morton Schnabel, Director, Office of Export Trading Company Affairs, International Trade Administration, 202-482-5131. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. Sections 4001-21) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. The regulations implementing Title III are found at 15 CFR part 325 (1999).

The Office of Export Trading Company Affairs ("OETCA") is issuing this notice pursuant to 15 CFR 325.6(b), which requires the Department of Commerce to publish a summary of a Certificate in the *Federal Register*. Under Section 305(a) of the Act and 15 CFR 325.11(a), any person aggrieved by the Secretary's determination may, within 30 days of the date of this notice, bring an action in any appropriate district court of the United States to set aside the determination on the ground that the determination is erroneous.

Description of Certified Conduct

Export Trade

1. Products

California almonds in processed and unprocessed form.

2. Export Trade Facilitation Services (as They Relate to the Export of Products)

All export trade-related facilitation services, including but not limited to: development of trade strategy; sales, marketing, and distribution; foreign market development; promotion; and all aspects of foreign sales transactions, including export brokerage, freight forwarding, transportation, insurance, billing, collection, trade documentation, and foreign exchange; customs, duties, and taxes; and inspection and quality control.

Export Markets

The Export Markets include all parts of the world except the United States (the fifty states of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, and the Trust Territories of the Pacific Islands).

Export Trade Activities and Methods of Operation

1. CAEA, on its own behalf or on behalf of all or less than all of its Members, through CAEA or through Export Intermediaries (to the extent provided in section 1.g) may:

a. *Sales Prices.* Establish sale prices, minimum sale prices, target sale prices and/or minimum target sale prices, and other terms of sale;

b. *Marketing and Distribution.* Conduct marketing and distribution of Products;

c. *Promotion.* Conduct promotion of Products;

d. *Quantities.* Agree on quantities of Products to be sold, provided each Member shall be required to dedicate only such quantity or quantities as each such Member shall independently determine. CAEA shall not require any Member to export a minimum quantity;

e. *Market and Customer Allocation.* Allocate geographic areas or countries in the Export Markets and/or customers in the Export Markets among Members;

f. *Refusals to Deal.* Refuse to quote prices for Products, or to market or sell Products, to or for any customers in the Export Markets, or any countries or geographical areas in the Export Markets;

g. *Exclusive and Nonexclusive Export Intermediaries.* Enter into exclusive and nonexclusive agreements appointing one or more Export Intermediaries (as defined under "Definitions" paragraph 1) for the sale of Products with price, quantity, territorial and/or customer restrictions as provided in sections 1.a through 1.f, inclusive, above; and

h. *Non-Member Activities.* Purchase Products from non-Members to fulfill specific sales obligations, provided that CAEA and/or its Members shall make such purchases only on a transaction-by-transaction basis and when the Members are unable to supply, in a timely manner, the requisite Products at a price competitive under the circumstances. In no event shall a non-Member be included in any deliberations concerning any Export Trade Activities.

2. CAEA and its Members may exchange and discuss the following information:

a. Information about sale and marketing efforts for the Export Markets, activities and opportunities for sales of Products in the Export Markets, selling strategies for the Export Markets, sales for the Export Markets, contract and spot pricing in the Export Markets, projected demands in the Export Markets for Products, customary terms of sale in the Export Markets, prices and availability of Products from competitors for sale in the Export Markets, and specifications for Products by customers in the Export Markets;

b. Information about the price, quality, quantity, source, and delivery dates of Products available from the Members to export;

c. Information about terms and conditions of contracts for sale in the Export Markets to be considered and/or bid on by CAEA and its Members;

d. Information about joint bidding or selling arrangements for the Export Markets and allocations of sales resulting from such arrangements among the Members;

e. Information about expenses specific to exporting to and within the Export Markets, including without limitation, transportation, trans- or intermodal shipments, insurance, inland freights to port, port storage, commissions, export sales, documentation, financing, customs, duties, and taxes;

f. Information about U.S. and foreign legislation and regulations, including federal marketing order programs, affecting sales for the Export Markets;

g. Information about CAEA's or its Members' export operations, including without limitation, sales and distribution networks established by CAEA or its Members in the Export Markets, and prior export sales by Members (including export price information); and

h. Information about export customer credit terms and credit history.

3. CAEA and its Members may prescribe the following conditions for admission of Members to CAEA and termination of membership in CAEA:

a. Membership shall be limited to Handlers as defined under "Definitions" paragraph 2.

b. Membership shall terminate on the occurrence of one or more of the following events:

i. withdrawal or resignation of a Member;

ii. Expulsion approved by a majority of all Members for a material violation of CAEA's Operating Agreement, after prior written notice to the Member proposed to be expelled and an opportunity of such Member to appear and be heard before a meeting of the Members;

iii. Death or permanent disability of a Member who is an individual or the dissolution of a Member other than an individual; and

iv. The bankruptcy of a Member as provided in CAEA's Operating Agreement.

4. CAEA and its Members may meet to engage in the activities described in paragraphs 1 through 3 above.

Definitions

1. "Export Intermediary" means a person (including a Member) who acts as a distributor, sales representative, sales or marketing agent, or broker, or who performs similar functions, including providing, or arranging for the provision of, Export Trade Facilitation Services.

2. "Handler" means a person who handles almonds grown in California as defined in 7 CFR Section 981.13, under the Order Regulating Handling of Almonds Grown in California.

3. "Member," within the meaning of section 325.2(1) of the Regulations, means the members of CAEA as set out in Attachment A and incorporated by reference.

Terms and Conditions of Certificate

1. Except as provided in paragraph 2(b) and (e) of the Export Trade Activities and Methods of Operation above, CAEA and its Members shall not intentionally disclose, directly or indirectly, to any Handler (including Members) any information about its or any other Handler's costs, production, capacity, inventories, domestic prices, domestic sales, domestic orders, terms of domestic marketing or sale, or U.S. business plans, strategies or methods, unless: (1) Such information is already generally available to the trade or public; (2) such disclosure is a necessary term or condition of an actual or potential bona fide sale or purchase of Products and the disclosure is limited to that prospective purchaser or seller; or (3) such disclosure is made in connection with the administration of the United States Department of Agriculture marketing order for almonds grown in California.

2. Each Member shall determine independently of other Members the quantity of Products the Member will make available for export or sell through CAEA. CAEA may not solicit from any Member specific quantities for export or require any Member to export any minimum quantity of Products.

3. Meetings at which CAEA allocates export sales among Members and establishes export prices shall not be open to the public.

4. Participation by a Member in any Export Trade Activity or Method of Operation under this Certificate shall be entirely voluntary as to that Member, subject to the honoring of contractual commitments for sales of Products in specific export transactions. A Member may withdraw from coverage under this Certificate at any time by giving a written notice to CAEA, a copy of which CAEA shall promptly transmit to the Secretary of Commerce and the Attorney General.

5. Any agreements, discussions, or exchanges of information under this Certificate relating to quantities of Products available for Export Markets, Product specifications or standards, export prices, Product quality or other terms and conditions of export sales (other than export financing) shall be in connection only with actual or potential bona fide export transactions or opportunities and shall include only those Members participating or having a genuine interest in participating in such transactions or opportunities, provided that CAEA and/or the Members may discuss standardization of Products for purposes of making bona fide recommendations to foreign governmental or private standard-setting organizations.

6. CAEA and its Members will comply with requests made by the Secretary of Commerce, on behalf of the Secretary or the Attorney General, for information or documents relevant to conduct under the Certificate. The Secretary of Commerce will request such information or documents when either the Attorney General or the Secretary believes that the information or documents are required to determine that the Export Trade, Export Trade Activities and Methods of Operation of a person protected by this Certificate of Review continue to comply with the standards of section 303(a) of the Act.

Protection Provided by Certificate

The Certificate protects CAEA, its Members, and their directors, officers, and employees acting on their behalf, from private treble damage actions and government criminal and civil suits under U.S. federal and state antitrust laws for the export conduct specified in this Certificate and carried out during its effective period in compliance with its terms and conditions.

A copy of this Certificate will be kept in the International Trade Administration's Freedom of Information Records Inspection Facility Room 4102, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230.

Dated: December 27, 1999.

Morton Schnabel,
Director, Office of Export Trading, Company Affairs.

Attachment A

Members (Within the meaning of Section 325.2(1) of the Regulations)

A & P Growers Cooperative, Inc., Tulare, CA
Almonds California Pride, Inc., Caruthers, CA
Baldwin-Minkler Farms, Orland, CA
Blue Diamond Growers, Sacramento, CA
Calcot, Ltd., Bakersfield, CA
California Independent Almond Growers, Ballico, CA
Campos Brothers, Caruthers, CA
Chico Nut Company, Chico, CA
Del Rio Nut Company, Livingston, CA
Dole Nut Company, Bakersfield, CA
Fair Trade Corner, Inc., Chico, CA
Gold Hills Nut Co., Inc., Ballico, CA
Golden West Nuts, Inc., Ripon, CA
Harris Woolf California Almonds, Huron, CA
Hilltop Ranch, Ballico, CA
Hughson Nut Company, Hughson, CA
Kindle Nut Company, Denair, CA
Paramount Farms, Inc., Los Angeles, CA
P-R Farms, Inc., Clovis, CA
Santa Fe Nut Company, Ballico, CA
South Valley Farms, Wasco, CA
Western Nut Company, Chico, CA

[FR Doc. 00-262 Filed 1-5-00; 8:45 am]

BILLING CODE 3510-DR-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[I.D. 101599J]

Reopening of Public Comment Period for Draft Environmental Impact Statement and Application for an Incidental Take Permit for the Simpson Timber Company, Northwest Operations, Habitat Conservation Plan, Thurston, Mason, and Grays Harbor Counties, Washington

AGENCIES: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration, Commerce; Fish and Wildlife Service (FWS), Interior.

ACTION: Notice of reopened public comment period.

SUMMARY: NMFS and FWS (the Services) are reopening the public comment period for the Draft Environmental Impact Statement (DEIS) and application for an Incidental Take Permit (Permit) for the Simpson Timber Company, Northwest Operations, Habitat Conservation Plan, Thurston, Mason, and Grays Harbor Counties,

Washington (Simpson). The Permit application includes: (1) the proposed Habitat Conservation Plan; and (2) the proposed Implementing Agreement. Direct mailings have been sent to affected State and local agencies, Federal agencies, Tribes, Federal and State legislators, public interest groups, and other interest parties, informing them of the reopening.

DATES: Written comments on the permit application, DEIS, Plan, and Implementing Agreement must be received from interested parties no later than January 14, 2000.

ADDRESSES: Requests for documents on CD ROM should be made by calling the U.S. Fish and Wildlife Service at (360)534-9330. Hardbound copies are also available for viewing, or partial or complete duplication, at the following libraries:

Olympia Timberland Library, Reference Desk, 313 8th Avenue SE, Olympia, WA, (360)352-0595;

William G. Reed Library, Reference Desk, 710 West Alder Street, Shelton, WA, (360)426-1362;

Hoodsport Timberland Library, 40 North Schoolhouse Hill Road, Hoodsport, WA, (360)877-9339;

Elma Timberland Library, Information Desk, 118 North 1st Street, Elma, WA, (360)482-3737;

W.H. Abel Public Library, Information Desk, 125 Main Street South, Montesano, WA, (360)249-4211; and, Aberdeen Timberland Library, Reference Desk, 121 East Market Street, Aberdeen, WA, (360)533-2360.

The documents are also available electronically on the World Wide Web at <http://www.r1.fws.gov/>.

Comments and requests for information should be directed to Linda Saunders, Project Biologist, Fish and Wildlife Service, 510 Desmond Drive, SE., Suite 102, Lacey, Washington, 98503-1273, (telephone: 360/753-5826; facsimile: 360/534-9331), and Mike Parton, Project Biologist, National Marine Fisheries Service, 510 Desmond Drive, SE., Suite 103, Lacey, Washington, 98503-1273 (telephone: 360/753-4650; facsimile: 360/753-9517). Comments and materials received will also be available for public inspection, by appointment, during normal business hours by calling (360) 534-9330.

SUPPLEMENTARY INFORMATION: On October 29, 1999 (64 FR 57630), the Services published a document in the **Federal Register** announcing the receipt of an application from Simpson for a Permit, and opening a comment period for the project. That document stated that comments would be accepted

through December 27, 1999. The Services are reopening the comment period in order to provide additional review and comment time, recognizing that the traditional holiday season during the latter part of December may have affected interested parties' ability to perform a thorough and comprehensive review of the documents.

Dated: December 28, 1999.

Thomas J. Dwyer,
Acting Regional Director, Fish and Wildlife Service, Region 1, Portland, Oregon.

Dated: December 30, 1999.

Craig Johnson,
Acting Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 00-263 Filed 1-5-00; 8:45 am]

BILLING CODE 3510-22-F, 4310-55-F

DEPARTMENT OF ENERGY

Notice Inviting Financial Assistance Applications

AGENCY: U.S. Department of Energy (DOE), National Energy Technology Lab (NETL).

ACTION: Notice Inviting Financial Assistance Applications.

SUMMARY: The Department of Energy announces that it intends to conduct a competitive Program Solicitation and award financial assistance (cooperative agreements) for the program entitled "Development and Demonstration of Black Liquor/Biomass Gasification in the Forest Products Industry." Through this solicitation, NETL seeks to support applications to improve the processing of Black Liquor and Biomass from the forest industry using Gasification Systems. Applications will be subjected to a review by a DOE technical panel, and awards will be made to a limited number of applicants based on a scientific and engineering evaluation of the responses received to determine the relative merit of the approach taken in response to this offering by the DOE, and funding availability.

FOR FURTHER SOLICITATION INFORMATION CONTACT: William Mundorf, U.S. Department of Energy, National Energy Technology Laboratory, Acquisition and Assistance Division, PO Box 10940, MS 921-143, Pittsburgh PA 15236-0940, Telephone: (412) 386-4483, FAX: (412) 386-6137, E-mail: mundorf@NETL.doe.gov. The solicitation (available in both WordPerfect 6.1 and Portable Document Format (PDF)) will be released on DOE's NETL World Wide Web Server Internet

System (<http://www.NETL.doe.gov/business/solicit>) on or about January 3, 2000.

SUPPLEMENTARY INFORMATION:

Title of Solicitation: "Development and Demonstration of Black Liquor/Biomass Gasification in the Forest Products Industry."

Objectives: Through Program Solicitation No. DE-PS26-00FT40772, the U.S. Department of Energy (DOE) seeks applications for cost-shared demonstration of technologies which will enhance economic competitiveness, improve energy efficiency, and reduce environmental impacts while providing quality products within the forest products industry. The focus of the research will address research priorities identified by the forest products industry in the Agenda 2020 The Path Forward: An Implementation Plan. Approximately \$14,000,000 fiscal year 2000 (FY 2000) federal funds are expected to be available to support the first year of a multi-year effort. DOE is looking for a path forward to demonstrate cost-effective, energy efficient, gasification technologies for integrated gasification combined cycle or gasification/cogeneration applications. Competitive development of combined cycle, gasification technologies (for both black liquor and biomass feedstocks) are well underway. However, large-scale pilot plant or demonstrations are needed to promote widespread adoption of advanced gasification technologies in the Forest Products industry. DOE anticipates awarding multiple cooperative agreements. Projects will be limited to eight years or less, but it is expected that successful demonstrations will be achieved in as early as three years. Proposals for projects which will both develop and demonstrate existing technologies will require a minimum 50% cost share of the total estimated project cost.

Eligibility: Eligibility for participation in this Program Solicitation is considered to be full and open. All interested parties may apply. The solicitation will contain a complete description of the technical evaluation factors and relative importance of each factor.

Program Technology Definition: The Department is interested in obtaining applications to improve the processing of Black Liquor and Biomass from forest products using gasification systems:

(A) Black Liquor Gasification Systems: Kraft black liquor and semi-chem caustic-carbonate liquor are mixtures of dissolved organic components resulting from the

processing of wood, inorganic cooking chemicals, and water. Though concentrated by multiple effects evaporators, these liquor still contain a high percentage of water and have sufficient heating value to be considered low quality fuels. The technical topic is for safe, integrated gasification systems which can permit the separation and recovery of the inorganic cooking chemicals while concurrently producing a combustible product gas from the organics. This product gas after cleaning must be a viable low-to-medium calorific value fuel. Key technical gaps that require demonstration include: materials of construction with known life expectancy, gas clean-up and demonstration of integrating gasification, power cycle and pulp mill systems. For systems employing cold gas clean-up, the key gaps are physical scale-up of the gasification processes under development and commercial demonstration. For systems with hot gas clean up, the clean-up system itself must be added as a serious technology gap; and

(B) Forest Products Biomass Gasification Systems: Wood room waste or hog fuel is conventionally burned in specifically designed boilers so as to capture a portion of the valuable energy sources found in Forest Products mills. They suffer from low power-to-steam output ratio and high capital and maintenance costs. The technical topic is for gasification systems which can utilize these fuels being mostly half water by weight and to produce a higher quality fuel gas. Such systems are required to be able to be integrated with gas turbines and steam turbines for electric power generation. These biomass gasification combined cycle systems must be able to offer a positive contribution to the reduction of greenhouse gas emissions. For systems using low-temperature gasification, destruction/removal of tars and other condensable organic compound clean-up, physical scale-up, and commercial demonstration of the integrated gasification combined cycle systems is an issue and must be proven on a pilot scale.

Awards: DOE anticipates issuing financial assistance (cooperative agreements) for each project selected. DOE reserves the right to support or not support, with or without discussions, any or all applications received in whole or in part, and to determine how many awards may be made through the solicitation subject to funds available. Approximately \$100 million of DOE funding is planned for this solicitation through the course of the program. The estimated funding by the DOE is

planned to be shared between three to four project awards. A 50% cost share of the total estimated project costs by the applicant is required, and details of the cost sharing requirement are contained in the solicitation.

Solicitation Release Date: The Program Solicitation is expected to be ready for release on or about January 3, 2000. Applications must be prepared and submitted in accordance with the instructions and forms contained in the Program Solicitation. Two open periods will be used to receive qualifying proposals. Initial proposals will be evaluated and selections made within six months of submittal. The proposal due date for the first evaluation period is February 29, 2000 and June 1, 2000 for the second and final.

Raymond D. Johnson,
Contracting Officer, Acquisition and Assistance Division.

[FR Doc. 00-289 Filed 1-5-00; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Savannah River

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Savannah River. Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770) requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Monday, January 24, 2000: 3:30 p.m.—9:00 p.m.; Tuesday, January 25, 2000: 8:30 a.m.—4:00 p.m.

ADDRESSES: All meetings will be held at: Hilton Oceanfront Resort, 23 Ocean Lane, Hilton Head Island, SC 29928.

FOR FURTHER INFORMATION CONTACT: Gerri Flemming, Office of Environmental Quality, Department of Energy Savannah River Operations Office, PO Box A, Aiken, SC 29802 (803) 725-5374.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE and its regulators in the areas of environmental restoration, waste management and related activities.

Tentative Agenda

Monday, January 24, 2000

3:30 p.m.—Executive Committee
6:30 p.m.—Public Comment Session
7:00 p.m.—Subcommittee Meetings

9:00 p.m.—Adjourn

Tuesday, January 25, 2000

8:30 a.m.

Approval of Minutes, Agency Updates (approximately 15 minutes)

Public Comment Session (5-minute rule, approximately 10 minutes)

Facilitator Update (approximately 15 minutes)

Long Term Stewardship (approximately 30 minutes)

Nuclear Materials Management Subcommittee Report (approximately 45 minutes)

Environmental Restoration and Waste Management Subcommittee Report (approximately 1¼ hours)

Public Comment (approximately 10 minutes)

12:00 p.m.

Lunch Break

Environmental Restoration and Waste Management Subcommittee Report continued (approximately 1 hour)

Risk Management and Future Use Subcommittee Report (approximately 30 minutes)

Administrative Subcommittee Report (approximately 30 minutes)

Officer and Subcommittee Chair Elections

Presentation of the year 2000 membership candidates

Board member removal consideration

Outreach Subcommittee Report (approximately 10 minutes)

Public Comments (approximately 10 minutes)

4:00 p.m. Adjourn

If needed, time will be allotted after public comments for items added to the agenda, and administrative details. A final agenda will be available at the meeting.

Public Participation: The meeting is open to the public. Written statements may be filed with the Committee either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Gerri Flemming's office at the address or telephone number listed above. Requests must be received 5 days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Official is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Each individual wishing to make public comment will be provided a maximum of 5 minutes to present their comments.

Minutes: The minutes of this meeting will be available for public review and copying at the Freedom of Information Public Reading Room, 1E-190, Forrestal

Building, 1000 Independence Avenue, SW, Washington, DC 20585 between 9 a.m. and 4 p.m., Monday–Friday except Federal holidays. Minutes will also be available by writing to Gerri Flemming, Department of Energy Savannah River Operations Office, PO Box A, Aiken, S.C. 29802, or by calling (803)–725–5374.

Issued at Washington, DC on December 27, 1999.

Rachel Samuel,

Deputy Advisory Committee Management Officer.

[FR Doc. 00–290 Filed 1–5–00; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Hanford

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Hanford Site. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Thursday, February 3, 2000: 9:00 a.m.–5:00 p.m.; Friday, February 4, 2000: 8:30 a.m.–4:00 p.m.

ADDRESS: Cavanaugh's, 1101 North Columbia Center Boulevard, Kennewick, WA 99336, 509–783–0611.

FOR FURTHER INFORMATION CONTACT: Gail McClure, Public Involvement Program Manager, Department of Energy Richland Operations Office, PO Box 550 (A7–75), Richland, WA, 99352; Ph: (509) 373–5647; Fax: (509) 376–1563.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE and its regulators in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda

- Tank Waste Treatment Program History and status of current plans for the treatment of the Hanford tank waste: Importance of tank waste treatment capability; pending program decisions.
- Update on Alternatives: Technical, Financial, Contractual: Fall back strategy (i.e., Parallel Path); BNFL Inc. and Readiness to Proceed; What site will do if the money is not forthcoming.
- FY 2002 Budget Process Discussion of priorities guiding

- development of the FY 2002 draft budget
- Discussion of the involvement of the Hanford Advisory Board and the general public in the process
- Emerging Waste Management Issues Issues surrounding the Low Level Waste and Mixed Low Level Waste Pending Records of Decision Idaho National Environmental and Engineering Laboratory High Level Waste Draft Environmental Impact Statement
- Public Involvement Briefing on Hanford Openness Workshops Report

Participation: The meeting is open to the public. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Gail McClure's office at the address or telephone number listed above. Requests must be received 5 days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Each individual wishing to make public comment will be provided equal time to present their comments.

Minutes: The minutes of this meeting will be available for public review and copying at the Freedom of Information Public Reading Room, 1E–190, Forrestal Building, 1000 Independence Avenue, SW, Washington, DC 20585 between 9 a.m. and 4 p.m., Monday–Friday, except Federal holidays. Minutes will also be available by writing to Gail McClure, Department of Energy Richland Operations Office, P.O. Box 550, Richland, WA 99352, or by calling her at (509) 373–5647.

Issued at Washington, DC on December 27, 1999.

Rachel M. Samuel,

Deputy Advisory Committee Management Officer.

[FR Doc. 00–291 Filed 1–5–00; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Office of Science; Fusion Energy Sciences Advisory Committee

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Fusion Energy Sciences Advisory Committee. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public

notice of these meetings be announced in the **Federal Register**.

DATES: Wednesday, February 2, 2000, 9 a.m. to 6 p.m.; Thursday, February 3, 2000, 9 a.m. to 12 p.m.

ADDRESSES: Holiday Inn/Goshen Hall; 2 Montgomery Village Avenue; Gaithersburg, Maryland.

FOR FURTHER INFORMATION CONTACT:

Albert L. Opdenaker, Office of Fusion Energy Sciences; U.S. Department of Energy; 19901 Germantown Road; Germantown, MD 20874–1290; Telephone: 301–903–4927.

SUPPLEMENTARY INFORMATION:

Purpose of the Meeting: The purpose of the meeting is to hear reports on several activities important to the fusion energy sciences program and to begin organizing to address new changes to the Committee.

Tentative Agenda

Wednesday, February 2, 2000

Report on the work of the National Research Council's Fusion Assessment Committee

Report on the status of the Integrated Program Planning Activity

Discuss the FESAC review of the fusion theory and modeling program

Public Comment

Adjourn

Thursday, February 3, 2000

Continue Discussions

Adjourn

Public Participation: The meeting is open to the public. If you would like to file a written statement with the Committee, you may do so either before or after the meeting. If you would like to make oral statements regarding any of the items on the agenda, you should contact Albert L. Opdenaker at 301–903–8584 (fax) or albert.opdenaker@science.doe.gov (email). You must make your request for an oral statement at least 5 business days before the meeting. Reasonable provision will be made to include the scheduled oral statements on the agenda. The Chairperson of the Committee will conduct the meeting to facilitate the orderly conduct of business. Public comment will follow the 10-minute rule.

Minutes: The minutes of this meeting will be available for public review and copying within 30 days at the Freedom of Information Public Reading Room; IE–190; Forrestal Building; 1000 Independence Avenue, SW; Washington, DC, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

Issued at Washington, DC, on December 27, 1999.

Rachel M. Samuel,
Deputy Advisory Committee Management
Officer.

[FR Doc. 00-292 Filed 1-5-00; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

Secretary of Energy Advisory Board; Notice of Open Teleconference Meeting

AGENCY: Department of Energy.

SUMMARY: This notice announces an open teleconference meeting of the Secretary of Energy Advisory Board's National Ignition Facility Laser System Task Force. The Federal Advisory Committee Act (Public Law 92-463, 86 Stat. 770), requires that agencies publish these notices in the **Federal Register** to allow for public participation. The purpose of the teleconference is to discuss the interim findings and recommendations of the National Ignition Facility Laser System Task Force.

Note: Copies of the interim findings and recommendations of the National Ignition Facility Laser System Task Force may be obtained from the following Internet address <http://www.hr.doe.gov/seab/> or by contacting the Office of the Secretary of Energy Advisory Board at (202) 586-7092.

NAME: Secretary of Energy Advisory Board—National Ignition Facility Laser System Task Force.

DATES: Monday, January 10, 2000, 4 pm–5:30 pm, Eastern Standard Time.

ADDRESSES: Participants may call the Office of the Secretary of Energy Advisory Board at (202) 586-7092 to reserve a teleconference line and receive a call-in number. Public participation is welcomed. However, the number of teleconference lines is limited and are available on a first come basis.

FOR FURTHER INFORMATION CONTACT: Betsy Mullins, Executive Director, or Richard Burrow, Deputy Director, Secretary of Energy Advisory Board (AB-1), U.S. Department of Energy, 1000 Independence Avenue, SW, Washington, D.C. 20585. (202) 586-7092 or (202) 586-6279 (fax).

SUPPLEMENTARY INFORMATION: The purpose of the NIF Task Force is to provide independent external advice and recommendations to the Secretary of Energy Advisory Board on the options to complete the National Ignition Facility (NIF) Project; to recommend the best technical course of action; and to review and assess the risks of successfully completing the NIF

Project. The NIF Task Force will focus on the engineering and management aspects of the proposed method for accomplishing the assembly and installation of the NIF laser system. The Task Force's review will cover the full scope of assembly and installation and the ability, within the proposed approach, to achieve the cleanliness requirements established for the operation of the laser. The review will also address: (1) The engineering viability of the proposed assembly and activation method; (2) the assembly and installation cleanliness protocols; (3) the management structure; and (4) the adequacy of the cost estimating methodology.

Tentative Agenda

Monday, January 10, 2000

- 4:00 pm–4:10 pm Welcome & Opening Remarks—Dr. John McTague, NIF Task Force Chairman
- 4:10 pm–4:30 pm Overview of the National Ignition Facility Laser System Task Force's Interim Findings and Recommendations—Dr. John McTague, NIF Task Force Chairman
- 4:30 pm–5:00 pm Public Comment Period
- 5:00 pm–5:30 pm NIF Task Force Review & Comment and Action—Dr. John McTague, NIF Task Force Chairman
- 5:30 pm Adjourn

This tentative agenda is subject to change.

Public Participation: In keeping with procedures, members of the public are welcome to observe the business of the NIF Task Force and submit written comments or comment during the scheduled public comment period. The Chairman of the Task Force is empowered to conduct the meeting in a fashion that will, in the Chairman's judgment, facilitate the orderly conduct of business. During its open teleconference meeting, the Task Force welcomes public comment. Members of the public will be heard in the order in which they sign up at the beginning of the meeting. The Task Force will make every effort to hear the views of all interested parties. You may submit written comments to Betsy Mullins, Executive Director, Secretary of Energy Advisory Board, AB-1, US Department of Energy, 1000 Independence Avenue, SW, Washington, D.C. 20585. This notice is being published less than 15 days before the date of the meeting due to the late resolution of programmatic issues.

Minutes: A copy of the minutes and a transcript of the open teleconference

meeting will be made available for public review and copying approximately 30 days following the meeting at the Freedom of Information Public Reading Room, 1E-190 Forrestal Building, 1000 Independence Avenue, SW, Washington, D.C., between 9:00 A.M. and 4:00 P.M., Monday through Friday except Federal holidays. Further information on the Secretary of Energy Advisory Board and its subcommittees may be found at the Board's web site, located at <http://www.hr.doe.gov/seab>.

Issued at Washington, DC, on January 3, 2000.

James N. Solit,
Advisory Committee Management Officer.
[FR Doc. 00-264 Filed 1-5-00; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

Bonneville Power Administration

Implementation of Regional Fish and Wildlife Policy

AGENCY: Bonneville Power Administration (BPA), Department of Energy (DOE).

ACTION: Notice of scoping meeting.

SUMMARY: This notice announces BPA's scoping meeting for its Implementation of Regional Fish and Wildlife Policy Environmental Impact Statement (EIS) being prepared in accordance with the National Environmental Policy Act (NEPA). BPA has established a scoping period during which all interested and affected persons and agencies are invited to comment on the scope of the proposed EIS. Scoping will help BPA ensure that a full range of issues related to the development and implementation of a regional fish and wildlife policy is addressed in the EIS, and also will identify significant or potentially significant impacts that may result from the implementation of such a policy.

DATES: Please send written comments to the address below no later than Tuesday, February 29, 2000. Comments may also be made at an EIS scoping meeting to be held at the Governor Hotel, Grand Ballroom, 611 SW 10th, Portland, Oregon, on Thursday, February 3, 2000, from 10 a.m. to 4 p.m. At the informal meeting, a brief overview of the EIS and presentation of background information will be followed by an open house during which attendees may discuss the EIS with BPA's EIS team. Written information will also be available, and BPA staff will answer questions and accept oral and written comments. The scoping meeting will be held in

conjunction with several other meetings related to fish and wildlife recovery efforts in the Pacific Northwest.

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. Please be sure to note that your comments are on the Implementation of Regional Fish and Wildlife Policy EIS.

FOR FURTHER INFORMATION, CONTACT: Charles C. Alton—KEC-4, Bonneville Power Administration, PO Box 3621, Portland, Oregon, 97208-3621, phone number 503-230-5878, fax number 503-230-5699.

SUPPLEMENTARY INFORMATION: 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. Consequently, BPA has a responsibility to understand the impacts of those efforts and to ensure it can fund them efficiently. Therefore, BPA is preparing 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. A Notice of Intent to Prepare an EIS was previously published in the *Federal Register* on October 20, 1999 (64 FR 56488).

Issued in Portland, Oregon, on December 22, 1999.

J.A. Johansen,

Administrator and Chief Executive Officer.
[FR Doc. 00-293 Filed 1-5-00; 8:45 am]

BILLING CODE 6450-01-U

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EC00-1-000, et al.]

Energy East Corporation and CMP Group, Inc., et al.; Electric Rate and Corporate Regulation Filings

December 29, 1999.

Take notice that the following filings have been made with the Commission:

1. Energy East Corporation and CMP Group, Inc.

[Docket No. EC00-1-000]

Take notice that on December 10, 1999, Energy East Corporation (Energy East) and CMP Group, Inc. (CMP Group), tendered for filing a letter with the Commission to update the Commission on matters that had occurred since their joint application of authorization and approval of their proposed merger was filed on October 1, 1999.

Comment date: January 20, 2000, in accordance with Standard Paragraph E at the end of this notice.

2. Commonwealth Chesapeake Company, L.L.C.

[Docket Nos. EG99-15-001 and EG00-59-000]

Take notice that on December 21, 1999, Commonwealth Chesapeake Company, L.L.C. (Commonwealth Chesapeake), tendered for filing an application for determination of exempt wholesale generator status, pursuant to Section 32(a)(1) of the Public Utility Holding Company Act of 1935 as amended (PUHCA), 15 U.S.C. 79z-5a(a)(1) (1994) and Section 365.8 of the Commission's Regulations, 18 CFR 365.8.

Commonwealth Chesapeake is a Virginia limited liability company that is constructing and will own and operate a 312 megawatt, oil-fired electric generating peaking facility to be located in Accomack County, Virginia. Commonwealth Chesapeake states that it will be engaged directly, or indirectly through one or more affiliates, as defined in Section 2(a)(11)(B) of PUHCA, and exclusively in the business of owning and/or operating an eligible facility and selling electric energy at wholesale.

Comment date: January 12, 2000, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

3. Commonwealth Edison Company; Commonwealth Edison Company of Indiana

[Docket No. ER99-3886-001]

Take notice that on December 21, 1999, Commonwealth Edison Company and Commonwealth Edison Company of Indiana tendered for filing in compliance with the Commission's September 29, 1999 Order Accepting for Filing, as Modified, Revisions to Open Access Tariff, 88 FERC ¶ 61,296.

Comment date: January 10, 2000, in accordance with Standard Paragraph E at the end of this notice.

4. ISO New England Inc.

[Docket No. ER00-749-000]

Take notice that on December 22, 1999, ISO New England Inc. (the ISO), tendered for filing a correction to its filing of December 8, 1999 in the referenced docket.

Copies of said filing have been served upon all Participants in the New England Power Pool (NEPOOL) and all non-Participant entities that are customers under the NEPOOL Open Access Transmission Tariff, as well as, on the governors and utility regulatory agencies of the six New England States.

Comment date: January 11, 2000, in accordance with Standard Paragraph E at the end of this notice.

5. PJM Interconnection, L.L.C.

[Docket No. ER00-889-000]

Take notice that on December 23, 1999, PJM Interconnection, L.L.C. (PJM), tendered for filing a Network Integration Transmission Service Agreement with Old Dominion Electric Cooperative (ODEC) and a Notice of Cancellation of a predecessor Network Integration Transmission Service Agreement with ODEC.

PJM requests a waiver of the 60-day notice requirement and an effective date of December 1, 1999 for the new Network Integration Service Agreement and the cancellation of the prior agreement.

Copies of this filing were served upon ODEC and the state commissions within the PJM control area.

Comment date: January 12, 2000, in accordance with Standard Paragraph E at the end of this notice.

6. PJM Interconnection, L.L.C.

[Docket No. ER00-890-000]

Take notice that on December 23, 1999, PJM Interconnection, L.L.C. (PJM), tendered for filing 18 signature pages of parties to the Reliability Assurance Agreement among Load Serving Entities in the PJM Control Area (RAA), four of which are replacement pages for entities

which have changed their corporate name, and an amended Schedule 17 listing the parties to the RAA.

PJM states that it served a copy of its filing on all parties to the RAA, including each of the parties for which a signature page is being tendered with this filing, and each of the state electric regulatory commissions within the PJM Control Area.

Comment date: January 12, 2000, in accordance with Standard Paragraph E at the end of this notice.

7. Delano Energy Company, Inc.

[Docket No. ER00-891-000]

Take notice that on December 23, 1999, Delano Energy Company, Inc. (Delano), tendered for filing a petition for waiver and blanket approvals under various regulations of the Commission and for an order accepting its proposed tariff governing negotiated market-based capacity and energy sales, including sales of ancillary services. If accepted for filing, Delano will use the market rate tariff to sell power from its generation facility.

Delano has requested an effective date for the market rate tariff as of January 1, 2000.

A copy of this filing was served on the California Public Utilities Commission.

Comment date: January 12, 2000, in accordance with Standard Paragraph E at the end of this notice.

8. Delano Energy Company, Inc.

[Docket No. ER00-892-000]

Take notice that on December 23, 1999, Delano Energy Company, Inc. (Delano), tendered for filing a notice to cancel FERC Electric Rate Schedule No. 1.

Delano has requested an effective date for notice of cancellation as of January 1, 2000.

A copy of this filing was served on the California Public Utilities Commission and Southern California Edison Company.

Comment date: January 12, 2000, in accordance with Standard Paragraph E at the end of this notice.

9. PacifiCorp

[Docket No. ER00-893-000]

Take notice that on December 23, 1999, PacifiCorp, tendered for filing in accordance with 18 CFR 35 of the Commission's Rules and Regulations, a Mutual Netting/Closeout Agreement (Netting Agreement) between PacifiCorp and Basin Electric Power Cooperative (Basin), City of Riverside, California (Riverside), San Diego Gas & Electric Company (San Diego), and The Energy Authority, Inc. (TEA).

Copies of this filing were supplied to the Washington Utilities and Transportation Commission and the Public Utility Commission of Oregon.

Comment date: January 12, 2000, in accordance with Standard Paragraph E at the end of this notice.

10. Onondaga Cogeneration Limited Partnership

[Docket No. ER00-895-000]

Take notice that on December 23, 1999, Onondaga Cogeneration Limited Partnership (Onondaga), tendered for filing pursuant to Rule 204 and Rule 205 (18 CFR 385.204, and 18 CFR 385.205) an application for waivers and blanket approvals under certain Commission Regulations and for an order accepting its FERC Electric Rate Schedule No. 2 to be effective at the earliest possible time, but no later than 60 days from the date of its filing.

Onondaga intends to engage in marketing and sales of electric energy and capacity at market-based rates. As described in the application, Onondaga is an affiliate of GPU, Inc., a public utility holding company and the parent company of Jersey Central Power & Light Company, Metropolitan Edison Company and Pennsylvania Electric Company.

Comment date: January 12, 2000, in accordance with Standard Paragraph E at the end of this notice.

11. Pacific Gas and Electric Company

[Docket No. ER00-900-000]

Take notice that on December 27, 1999, Pacific Gas and Electric Company (PG&E), tendered for filing a request to change its California Independent System Operator (ISO) Grid Management Charge (GMC) Pass Through rate from \$.7831 per MWh to \$.8300 per MWh. This filing is part of the comprehensive restructuring proposal for the California electric power industry that is before the Federal Energy Regulatory Commission.

PG&E requests that its filing be made effective January 1, 2000.

Copies of this filing have been served upon the California Public Utilities Commission and all other parties on the Service List to this proceeding.

Comment date: January 16, 2000, in accordance with Standard Paragraph E at the end of this notice.

12. Public Service Company of New Mexico

[Docket No. ER00-896-000]

Take notice that on December 23, 1999, Public Service Company of New Mexico (PNM), tendered for filing a proposed unbundled generation sales

agreement (Generation Agreement) between PNM and the United States Department of Energy on behalf of the United States Government (the Government) for wholesale power sales under PNM's Electric Coordination Tariff No. 1, providing for wholesale electric generation sales to the Government for the Government's wholesale loads, if any, at the United States Department of Energy's Sandia National Laboratories and the United States Department of Defense's Kirtland Air Force Base, collectively.

PNM requests an effective date as may be determined by the Commission, but no earlier than December 14, 1999, for the Generation Agreement, and further requests waiver of the requirements of 18 CFR 35.3(a) to allow the Agreement to become effective less than 60 days or more than 120 days after filing.

Comment date: January 12, 2000, in accordance with Standard Paragraph E at the end of this notice.

13. Arizona Public Service Company

[Docket No. ER00-901-000]

Take notice that on December 27, 1999, Arizona Public Service Company (APS), tendered for filing a Service Agreement to provide Retail Network Integration Transmission Service under APS' Open Access Transmission Tariff to the Arizona Public Service Company Merchant Group (Merchant Group).

A copy of this filing has been served on Merchant Group and the Arizona Corporation Commission.

Comment date: January 14, 2000, in accordance with Standard Paragraph E at the end of this notice.

14. Pacific Gas and Electric Company

[Docket No. ER00-902-000]

Take notice that on December 27, 1999, Pacific Gas and Electric Company (PG&E), tendered for filing an agreement between PG&E and Dynegy Power Services, Inc. (DPS) (collectively, Parties), entitled Settlement Agreement between Dynegy Power Services, Inc., and Pacific Gas and Electric Company. The Settlement Agreement is intended to, among other things, settle issues and disputes under PG&E Rate Schedule FERC No. 185.

Copies of this filing have been served upon DPS, CAISO and the California Public Utilities Commission.

Comment date: January 14, 2000, in accordance with Standard Paragraph E at the end of this notice.

15. Duke Energy Corporation

[Docket No. ER00-903-000]

Take notice that on December 27, 1999, Duke Energy Corporation (Duke),

tendered for filing a Service Agreement with Conectiv Energy Supply, Inc., for Non-Firm Transmission Service under Duke's Open Access Transmission Tariff.

Duke requests that the proposed Service Agreement be permitted to become effective on November 2, 1999 or upon acceptance by the Commission.

Duke states that this filing is in accordance with Part 35 of the Commission's Regulations and a copy has been served on the North Carolina Utilities Commission.

Comment date: January 14, 2000, in accordance with Standard Paragraph E at the end of this notice.

16. Duke Energy Corporation

[Docket No. ER00-904-000]

Take notice that on December 27, 1999, Duke Energy Corporation (Duke), tendered for filing a Service Agreement with Tampa Electric Company for Non-Firm Transmission Service under Duke's Open Access Transmission Tariff.

Duke requests that the proposed Service Agreement be permitted to become effective on April 22, 1999 or upon acceptance by the Commission.

Duke states that this filing is in accordance with Part 35 of the Commission's Regulations and a copy has been served on the North Carolina Utilities Commission.

Comment date: January 14, 2000, in accordance with Standard Paragraph E at the end of this notice.

17. Allegheny Energy Service Corporation on behalf of Allegheny Energy Supply Company, LLC

[Docket No. ER00-905-000]

Take notice that on December 27, 1999, Allegheny Energy Service Corporation on behalf of Allegheny Energy Supply Company, LLC (Allegheny Energy Supply), tendered for filing Supplement No. 15 to add one (1) new Customer to the Market Rate Tariff under which Allegheny Energy Supply offers generation services.

Allegheny Energy Supply requests a waiver of notice requirements to make service available as of December 23, 1999 to Rainbow Energy Marketing Corporation.

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: January 14, 2000, in accordance with Standard Paragraph E at the end of this notice.

18. Allegheny Energy Service Corporation on behalf of Allegheny Energy Supply Company, LLC

[Docket No. ER00-906-000]

Take notice that on December 27, 1999, Allegheny Energy Service Corporation on behalf of Allegheny Energy Supply Company, LLC (Allegheny Energy Supply), tendered for filing Supplement No. 13 to add one (1) new Customer to the Market Rate Tariff under which Allegheny Energy Supply offers generation services.

Allegheny Energy Supply requests a waiver of notice requirements to make service available as of December 5, 1999 to Commonwealth Edison Company.

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: January 14, 2000, in accordance with Standard Paragraph E at the end of this notice.

19. PacifiCorp

[Docket No. ER00-908-000]

Take notice that on December 27, 1999, PacifiCorp, tendered for filing in accordance with 18 CFR 35 of the Commission's Rules and Regulations, the Power Sales Agreement with Hinson Power Company under PacifiCorp's FERC Electric Tariff, First Revised Volume No. 12.

Copies of this filing were supplied to the Washington Utilities and Transportation Commission and the Public Utility Commission of Oregon.

Comment date: January 14, 2000, in accordance with Standard Paragraph E at the end of this notice.

20. Allegheny Energy Service Corporation on behalf of Allegheny Energy Supply Company, LLC

[Docket No. ER00-909-000]

Take notice that on December 27, 1999, Allegheny Energy Service Corporation on behalf of Allegheny Energy Supply Company, LLC (Allegheny Energy Supply), tendered for filing Supplement No. 14 to add two (2) new Customers to the Market Rate Tariff under which Allegheny Energy Supply offers generation services.

Allegheny Energy Supply requests a waiver of notice requirements to make service available as of December 6, 1999

to Sempra Energy Trading Corp., and Wabash Valley Power Association, Inc.

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: January 14, 2000, in accordance with Standard Paragraph E at the end of this notice.

21. Wisconsin Public Service Corporation

[Docket No. ER00-910-000]

Take notice that on December 27, 1999, Wisconsin Public Service Corporation (WPSC), tendered for filing an executed Service Agreement with POWEREX providing for transmission service under FERC Electric Tariff, Volume No. 1.

Comment date: January 14, 2000, in accordance with Standard Paragraph E at the end of this notice.

22. Allegheny Energy Service Corporation on behalf of Allegheny Energy Supply Company, LLC

[Docket No. ER00-907-000]

Take notice that on December 27, 1999, Allegheny Energy Service Corporation on behalf of Allegheny Energy Supply Company, LLC ("Allegheny Energy Supply") filed Supplement No. 10 to add three (3) new Customers to the Market Rate Tariff under which Allegheny Energy Supply offers generation services.

Allegheny Energy Supply requests a waiver of notice requirements to make service available as of November 29, 1999 to DTE Energy Trading, Inc., Northern Indiana Public Service Company and PP&L, Inc.

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: January 14, 2000, in accordance with Standard Paragraph E at the end of this notice.

23. Wisconsin Public Service Corporation

[Docket No. ER00-911-000]

Take notice that on December 27, 1999, Wisconsin Public Service Corporation (WPSC), tendered for filing an executed Service Agreement with

POWEREX providing for transmission service under FERC Electric Tariff, Volume No. 1.

Comment date: January 14, 2000, in accordance with Standard Paragraph E at the end of this notice.

24. Allegheny Energy Service Corporation on behalf of Allegheny Energy Supply Company, LLC

[Docket No. ER00-912-000]

Take notice that on December 27, 1999, Allegheny Energy Service Corporation on behalf of Allegheny Energy Supply Company, LLC (Allegheny Energy Supply), tendered for filing Supplement No. 12 to add four (4) new Customers to the Market Rate Tariff under which Allegheny Energy Supply offers generation services.

Allegheny Energy Supply requests a waiver of notice requirements to make service available as of December 2, 1999 to Citizens Power Sales, Horizon Energy Company d/b/a Exelon Energy, Merchant Energy Group of the Americas and TXU Energy Trading Company.

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: January 14, 2000, in accordance with Standard Paragraph E at the end of this notice.

25. Allegheny Energy Service Corporation on behalf of Allegheny Energy Supply Company, LLC

[Docket No. ER00-913-000]

Take notice that on December 27, 1999, Allegheny Energy Service Corporation on behalf of Allegheny Energy Supply Company, LLC (Allegheny Energy Supply), tendered for filing Supplement No. 11 to add one (1) new Customer to the Market Rate Tariff under which Allegheny Energy Supply offers generation services.

Allegheny Energy Supply requests a waiver of notice requirements to make service available as of December 1, 1999 to PG&E Energy Trading-Power, L.P.

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: January 14, 2000, in accordance with Standard Paragraph E at the end of this notice.

26. PacifiCorp

[Docket No. ER00-914-000]

Take notice that PacifiCorp on December 27, 1999, tendered for filing in accordance with 18 CFR 35 of the Commission's Rules and Regulations, Short-term Firm and Non-firm Point-To-Point Transmission Service Agreements with Deseret Generation and Transmission Cooperative (Deseret), Morgan Stanley Capital Group Inc. (Morgan Stanley) and PP&L Montana under PacifiCorp's FERC Electric Tariff, First Revised Volume No. 11.

Copies of this filing were supplied to the Washington Utilities and Transportation Commission and the Public Utility Commission of Oregon.

Comment date: January 14, 2000, in accordance with Standard Paragraph E at the end of this notice.

27. Chugach Electric Association, Inc.

[Docket No. NJ00-1-000]

Take notice that on December 27, 1999, Chugach Electric Association, Inc. (Chugach), tendered for filing a petition for a declaratory order determining that its open access transmission tariff satisfies the Commission comparability standards and is an acceptable reciprocity tariff. Chugach also seeks a waiver of the requirements of Order No. 889, on the ground that it is a small electric utility, and waiver of the filing fee otherwise applicable to a petition for declaratory order.

Comment date: January 26, 2000, 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, N.E., Washington, D.C. 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. 00-229 Filed 1-5-00; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EG00-60-000, et al.]

Saguaro Power Company, et al.; Electric Rate and Corporate Regulation Filings

December 30, 1999.

Take notice that the following filings have been made with the Commission:

1. Saguaro Power Company, a Limited Partnership

[Docket No. EG00-60-000]

Take notice that on December 27, 1999, Saguaro Power Company, a Limited Partnership filed with the Federal Energy Regulatory Commission an application for determination of exempt wholesale generator status pursuant to Section 32(a)(1) of the Public Utility Holding Company Act of 1935 (PUHCA). The applicant is a limited partnership organized under the laws of the State of California that is engaged directly and exclusively in owning and operating a 105 MW gas-fueled cogeneration facility (Facility) and selling electric energy at wholesale. The Facility is located near Henderson, Nevada.

Comment date: January 14, 2000, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

2. Sithe Northeast Management Co.

[Docket No. ER00-638-000]

Take notice that on December 23, 1999, Sithe Northeast Management Co., tendered for filing with the Federal Energy Regulatory Commission an amendment to the Conemaugh Operating Agreement to modify the termination provisions.

Comment date: January 12, 2000, in accordance with Standard Paragraph E at the end of this notice.

3. Sithe Northeast Management Co.

[Docket No. ER00-639-000]

Take notice that on December 23, 1999, Sithe Northeast Management Co. tendered for filing an amendment to the Keystone Operating Agreement to

modify the termination provisions originally filed with the Commission on November 23, 1999.

Comment date: January 12, 2000, in accordance with Standard Paragraph E at the end of this notice.

4. Minnesota Power, Inc.

[Docket No. ER00-645-000]

Take notice that on December 23, 1999, Minnesota Power, Inc., tendered for filing a signed Service Agreement with First Energy Corporation, with Entergy Power Marketing Corporation, and with Wisconsin Electric Power Company, under its market-based Wholesale Coordination Sales Tariff (WCS-2) to satisfy its filing requirements under this tariff.

Comment date: January 12, 2000, in accordance with Standard Paragraph E at the end of this notice.

5. Central Illinois Light Company

[Docket No. ER00-727-000]

Take notice that on December 23, 1999, Central Illinois Light Company (CILCO), 300 Liberty Street, Peoria, Illinois 61202, tendered for an Addendum to Service Agreement under its Market Rate Power Sales Tariff with its affiliate, NewEnergy, Inc.

CILCO requested an effective date of December 6, 1999, and requested a waiver of the Commission's notice requirements.

Copies of the filing were served on the affected customer and the Illinois Commerce Commission.

Comment date: January 12, 2000, in accordance with Standard Paragraph E at the end of this notice.

6. PacifiCorp

[Docket No. ER00-916-000]

Take notice that on December 27, 1999, PacifiCorp, tendered for filing in accordance with 18 CFR 35 of the Commission's Rules and Regulations, a fully executed umbrella service agreement (Service Agreement) with City of Riverside, California (Riverside).

Copies of this filing were supplied to the Washington Utilities and Transportation Commission and the Public Utility Commission of Oregon.

Comment date: January 14, 2000, in accordance with Standard Paragraph E at the end of this notice.

7. Pacific Gas and Electric Company

[Docket No. ER00-917-000]

Take notice that on December 23, 1999, Pacific Gas and Electric Company (PG&E), tendered for filing notice of termination of the Special Facilities Agreement for the Operation, Maintenance and Replacement of

Protection Facilities that Are Required for the Connection of the Delta Wind Energy Project to DWR's South Bay Pumping Plant, Contract #B55518, PG&E Rate Schedule FERC No. 100.

Copies of this filing have been served upon California Department of Water Resources and the California Public Utilities Commission.

Comment date: January 12, 2000, in accordance with Standard Paragraph E at the end of this notice.

8. Wisconsin Electric Power Company

[Docket No. ER00-919-000]

Take notice that on December 23, 1999, Wisconsin Electric Power Company (Wisconsin Electric), tendered for filing an amendment to its Revised Power Sales Agreement (PSA) with Wisconsin Public Power Inc., (WPPI).

Wisconsin Electric respectfully requests an effective date of sixty days after filing.

Copies of the filing have been served on WPPI, the Michigan Public Service Commission, and the Public Service Commission of Wisconsin.

Comment date: January 12, 2000, in accordance with Standard Paragraph E at the end of this notice.

9. New York Independent System Operator, Inc.

[Docket No. ER00-918-000]

Take notice that on December 27, 1999, the New York Independent System Operator, Inc. (NYISO), tendered revised Attachment L to the NYISO's Open Access Transmission Tariff (OATT).

The NYISO requests an effective date of November 18, 1999 and waiver of the Commission's notice requirements.

Copies of this filing were served on the Commission's Service List in Docket Nos. ER97-1523-000 *et al.*, on the parties to the Service Agreements to the ISO OATT and on the respective electric utility regulatory agencies in New York, New Jersey and Pennsylvania.

Comment date: January 14, 2000, in accordance with Standard Paragraph E at the end of this notice.

10. Oklahoma Gas and Electric Company

[Docket No. ER00-920-000]

Take notice that on December 23, 1999, Oklahoma Gas and Electric Company (OG&E), tendered for filing notification to cancel its Electric Service Agreement with Mannford Public Works Authority, which has been designated OG&E Rate Schedule FERC No. 96, pursuant to Section 35.15 of the Federal Energy Regulatory Commission's Regulations.

OG&E requests acceptance of its notice and waiver of the 60-day notice requirement to permit the cancellation to become effective January 26, 2000, or such later date as authorized by the Commission.

This filing has been served upon the affected purchaser.

Comment date: January 12, 2000, in accordance with Standard Paragraph E at the end of this notice.

11. MDU Resources Group, Inc.

[Docket No. ES00-11-000]

Take notice that on December 22, 1999, MDU Resources Group, Inc. (MDU Resources), tendered for filing an application pursuant to Section 204 of the Federal Power Act seeking authority to issue in the aggregate up to 3,839,920 shares of common stock. The common stock is to be issued from time to time pursuant to the terms of various stock incentive plans.

MDU Resources also requests an exemption from the Commission's competitive bidding and negotiated placement requirements of 18 CFR 34.2.

Comment date: January 20, 2000, in accordance with Standard Paragraph E at the end of this notice.

12. Pittsfield Generating Company, L.P.

[Docket No. QF88-21-008]

Take notice that on December 22, 1999, Pittsfield Generating Company, L.P., tendered for filing a request for waiver of the efficiency standard.

A copy of the filing was served on all parties listed in this docket, the Massachusetts Department of Telecommunications and Energy, Commonwealth Electric Company, Cambridge Electric Light Company, and New England Power Company.

Comment date: January 21, 2000, 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, N.E., Washington, D.C. 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. 00-259 Filed 1-5-00; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98-1-000]

Regulations Governing Off-the-Record Communications; Public Notice

December 30, 1999.

This constitutes notice, in accordance with 18 CFR 385.2201(h), of the receipt of exempt and prohibited off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive an exempt or a prohibited off-the-record communication relevant to the merits of a contested on-the-record proceeding, to deliver a copy of the communication, if written, or a summary of the substance of any oral communication, to the Secretary.

Prohibited communications will be included in a public, non-decisional file associated with, but not part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication, and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such requests only when it determines that fairness so requires.

Exempt off-the-record communications will be included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of exempt and prohibited off-the-record communications received in the Office of the Secretary within the preceding 14 days. The documents may be viewed on the Internet at <http://www.ferc.fed.us/>

[online/rims.htm](http://www.ferc.fed.us/online/rims.htm) (call 202-208-2222 for assistance).

Exempt

1. CP99-624-000, 12/21/99, LeRoy W. Carlson.
2. CP00-6-000, 12/19/99, James Martin.

Prohibited

1. ER99-3144-000, *et al.*, 12/14/99, Dale Sorgett.

David P. Boergers,
Secretary.

[FR Doc. 00-230 Filed 1-5-00; 8:45 am]

BILLING CODE 6717-01-M

ENVIRONMENTAL PROTECTION AGENCY

OPP-30000/46C; FRL-6486-7

Cyanazine; Cancellation Order

AGENCY: Environmental Protection Agency (EPA).
ACTION: Cancellation order.

SUMMARY: This order announces the cancellation of all cyanazine registrations as requested by E.I. duPont de Nemours and Company ("DuPont"), and subsequently agreed to by Griffin Corporation ("Griffin") and accepted by EPA, pursuant to section 6(f) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This order follows up a July 25, 1996, notice of final determination to terminate the cyanazine Special Review and EPA's acceptance of requests to voluntarily cancel all cyanazine product registrations effective December 31, 1999 (61 FR 39023)(FRL-5385-7). In this notice, EPA indicated that it would issue an order confirming the voluntary cancellations. As of December 31, 1999, any distribution, sale, or use of canceled cyanazine products is only permitted in accordance with the terms of the existing stocks provisions of this cancellation order.

DATES: The cancellations are effective December 31, 1999.

FOR FURTHER INFORMATION CONTACT: Pam Noyes, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, U.S. Environmental Protection Agency, Ariel Rios Building, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Telephone number: 703-308-8179, e-mail address: noyes.pam@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

You may be potentially affected by this action if you manufacture, sell,

distribute, or use cyanazine products. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit I of this document. The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, does not apply because this action is not a rule, for purposes of 5 U.S.C. 804(3). If you have any questions regarding the applicability of this action to a particular entity, consult the technical 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 copies of this document and other available support documents from the EPA Internet Home Page at <http://www.epa.gov/>. To access information about the risk assessment for cyanazine refer to the Atrazine, Simazine, Cyanazine; Notice of Initiation of Special Review (59 FR 60412)(FRL-4919-5) dated November 23, 1994. You may access this document by selecting "Laws and Regulations" on EPA's Home Page and then looking 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-30000/46C. 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 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.

II. Background

On November 23, 1994, EPA initiated a Special Review of atrazine, simazine, and cyanazine (58 FR 60412)(FRL-4919-5). The Agency initiated the Special review for cyanazine based on concerns that cyanazine may pose a risk of inducing cancer in humans from dietary, occupational, and residential exposure.

On August 2, 1995, EPA accepted DuPont's proposal to amend the terms and conditions of the cyanazine registrations. DuPont voluntarily proposed to amend its cyanazine registrations to incrementally reduce cyanazine maximum application rates in 1997, 1998, and 1999, and to terminate the production of cyanazine for use in the United States by the end of 1999. DuPont proposed that after December 31, 1999, they would not release for shipment any formulated end use products containing cyanazine for use in the United States. EPA agreed to authorize distribution and sale through September 30, 2002, of any existing stocks of cyanazine formulated end use products that were released for shipment on or before December 31, 1999. EPA also agreed to authorize use of these products in accordance with the product labels through December 31, 2002. For cyanazine technical products, DuPont proposed that technical products released for shipment by DuPont after July 25, 1996, bear labels subjecting end use products made from these technical products to the amended terms and conditions of registration. Finally, DuPont requested that EPA accept the voluntary cancellation of all registered DuPont cyanazine technical and end use products effective on December 31, 1999. DuPont waived any right to challenge EPA's final action on the Special Review or the terms and conditions of registration upon EPA's final acceptance of the proposed amendments.

After EPA initiated the cyanazine Special Review, Griffin filed an application to register pesticide products containing cyanazine, and subsequently agreed to the same terms and conditions of registration that were proposed by DuPont. EPA granted Griffin's applications and issued conditional registrations subject to the same terms and conditions proposed by DuPont.

On March 1, 1996, EPA issued a Notice of Preliminary Determination to Terminate the Special Review and a Notice of Receipt of Requests for Voluntary Cancellation of cyanazine registrations (61 FR 8186)(FRL-5352-6). In this notice, EPA outlined that it was

proposing to terminate the Special Review of cyanazine, based on the modified terms and conditions of the cyanazine registrations. The complete terms and conditions to amend the cyanazine registrations agreed to by the registrants are discussed in this Notice.

In the same Notice, EPA announced the receipt of requests from DuPont and Griffin to voluntarily cancel their registrations pursuant to FIFRA section 6(f)(7 U.S.C. 136d(f)). The registrants requested that the voluntary cancellations take effect December 31, 1999, consistent with the terms and conditions of registration proposed by DuPont and later agreed to by Griffin and accepted by EPA.

On July 25, 1996, EPA issued a Notice of Final Determination to Terminate Special Review of Cyanazine and a Notice of Voluntary Cancellation and Cancellation Order of the Cyanazine Product Registrations (61 FR 39023)(FRL-5385-7). This notice announced the conclusion of the Cyanazine Special Review based on the August 2, 1995, DuPont agreement to voluntarily modify the terms and conditions of the cyanazine registrations, which was later agreed to by Griffin. The notice also accepted the voluntary cancellation of the technical and end use products containing cyanazine pursuant to the registrant agreement, and indicated that a cancellation order would be issued confirming the cancellations.

On October 21, 1998, EPA issued a notice announcing the receipt of a request from DuPont and Griffin to amend the terms and conditions of the cyanazine registrations to allow a maximum use rate of 3.0 lbs/acre in 1999 instead of 1.0 lb/acre, as previously agreed (63 FR 56178)(FRL-6040-2). On January 22, 1999, EPA issued a notice to amend the terms and conditions of the cyanazine registrations, which included the Agency's basis for accepting the registrants request and its response to comments received (64 FR 3511)(FRL-6058-1).

Cyanazine production has declined steadily since the August 1995 acceptance of the DuPont and Griffin amendments to the terms and conditions of registration. There was no production of cyanazine technical in 1998.

III. Existing Stocks Provision

EPA has determined that, for any cyanazine formulated end use products that are released for shipment by a registrant on or before December 31, 1999, sale or distribution of such products may continue in accordance

with their labels through September 30, 2002. EPA also authorizes the continued use of such existing stocks in accordance with their labels through December 31, 2002. EPA prohibits the use of cyanazine end use products after December 31, 2002. The sale or distribution of technical cyanazine products, and the use of such products to formulate end use products for subsequent sale or distribution is prohibited after December 31, 1999. Any technical or end use product containing cyanazine may be exported pursuant to FIFRA sections 3 and 17.

IV. Cancellation Order

Pursuant to section 6(f) of FIFRA, EPA hereby orders that the registrations of cyanazine pesticide products by DuPont and Griffin be canceled effective December 31, 1999. The cyanazine technical and end use product registrations subject to this cancellation order are listed as follows:

- DuPont Bladex® 4L Herbicide (Reg.No. 352-470)
- DuPont Cyanazine Technical (Reg.No. 352-475)
- DuPont Bladex® 90DF Herbicide (Reg.No. 352-495)
- DuPont Extrazine® II 4L Herbicide (Reg.No. 352-500)
- DuPont Extrazine® II DF Herbicide (Reg.No. 352-577)
- Griffin Cyanazine Technical (Reg.No. 1812-364)
- Cy-Pro 90DF Herbicide (Reg.No. 1812-365)
- Cy-Pro 4L (Reg.No.1812-366)
- Cy-Pro AT 4L Herbicide (Reg.No. 1812-367)
- Cy-Pro AT DF Herbicide (Reg.No. 1812-368)

Any distribution, sale, or use of existing stocks of these products in a manner inconsistent with the terms of this Order or the Existing Stock Provision in Unit III of this **Federal Register** Notice will be considered a violation of section 12(a)(2)(K) of FIFRA and/or section 12(a)(1)(A) of FIFRA. For purposes of this Order, the term "existing stocks" is defined, pursuant to EPA's existing stocks policy (56 FR 29362, June 26, 1991), as those stocks of a canceled pesticide product that were in the United States and that were packaged, labeled, and released for shipment prior to the effective date of the cancellation.

List of Subjects

Environmental protection.

Dated: December 29, 1999.

James Jones,

Director, Registration Division, Office of
Pesticide Programs.

[FR Doc. 00-274 Filed 1-3-00; 1:54 pm]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

[FRL-6519-1]

Proposed CERCLA Administrative Cost Recovery Settlement; the WICO Superfund Site, St. Thomas, U.S. Virgin Islands

AGENCY: Environmental Protection
Agency.

ACTION: Notice; request public comment.

SUMMARY: In accordance with section 122(i) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (CERCLA), 42 U.S.C. 9622(i), notice is hereby given of a proposed administrative settlement for recovery of past response costs concerning the WICO Superfund Site (Site) located in the Estate Liverpool section of St. Thomas, U.S. Virgin Islands with the following settling party: the West Indian Company Limited. The settlement requires the settling party to pay \$412,094.38 to the Hazardous Substance Superfund in reimbursement of past response costs incurred with respect to the Site. The settlement includes a covenant not to sue the settling party pursuant to section 107(a) of CERCLA, 42 U.S.C. 9607(a) for all costs incurred at the Site by the United States Environmental Protection Agency (EPA) through February 11, 1999.

For thirty (30) days following the date of publication of this document, the U.S. Environmental Protection Agency (EPA) the Agency will receive written comments relating to the settlement. The Agency will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations which indicate that the proposed settlement is inappropriate, improper, or inadequate. The Agency's response to any comments received will be available for public inspection at the EPA, 290 Broadway, New York, New York 10007-1866.

DATES: Comments must be submitted on or before February 7, 2000.

ADDRESSES: The proposed settlement is available for public inspection at EPA, 290 Broadway, New York, New York 10007-1866. A copy of the proposed

settlement may be obtained from Elizabeth Leilani Davis, Assistant Regional Counsel, Office of Regional Counsel, New York/Caribbean Superfund Branch, 17th Floor, 290 Broadway, New York, New York 10007-1866. Comments should reference the WICO Superfund Site located in St. Thomas, U.S. Virgin Islands, EPA Index No. CERCLA-02-99-2021, and should be addressed to Elizabeth Leilani Davis, Assistant Regional Counsel, USEPA, 290 Broadway, New York, New York 10007-1866.

FOR FURTHER INFORMATION CONTACT: Elizabeth Leilani Davis, Assistant Regional Counsel, New York/Caribbean Superfund Branch, Office of Regional Counsel, U.S. Environmental Protection Agency, 17th Floor, 290 Broadway, New York, New York 10007. Telephone: (212) 637-3249.

Dated: December 20, 1999.

William J. Muszynski,

Acting Regional Administrator, Region 2.

[FR Doc. 00-271 Filed 1-5-00; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting; Notice

AGENCY: Federal Election Commission.

DATE AND TIME: Tuesday, January 11, 2000 at 10:00 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: Wednesday, January 12, 2000 at 10:00 a.m.

PLACE: 999 E Street, NW, Washington, DC., (Ninth Floor).

STATUS: This hearing will be open to the public.

MATTER BEFORE THE COMMISSION: Oral Hearing-Buchanan for President Committee, Inc.

DATE AND TIME: Thursday, January 13, 2000 at 10:00 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 1999-36: Campaign Advantage by counsel, Joseph E. Sandler.

Final Audit Report on Dear for Congress, Inc.

Routine Administrative Matters.

PERSON TO CONTACT FOR INFORMATION:

Mr. Ron Harris, Press Officer,
Telephone: (202) 694-1220.

Mary W. Dove,

Acting Secretary of the Commission.

[FR Doc. 00-424 Filed 1-4-00; 3:43 pm]

BILLING CODE 6715-01-M

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than January 19, 2000.

A. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63102-2034

1. Bradley Place Heath, Palestine, Illinois; to acquire additional voting shares of First National Bancshares in Newton, Inc., Newton, Illinois, and thereby indirectly acquire additional voting shares of First National Bank in Newton, Newton, Illinois.

Board of Governors of the Federal Reserve System, December 30, 1999.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 00-225 Filed 1-5-00; 8:45 am]

BILLING CODE 6210-01-P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval,

pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than January 28, 2000.

A. Federal Reserve Bank of Dallas (W. Arthur Tribble, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. Texas Capital Bancshares, Inc. Dallas, Texas; to acquire 100 percent of the voting shares of BankDirect, SSB, Dallas, Texas, a de novo savings bank.

Board of Governors of the Federal Reserve System, December 30, 1999.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 00-227 Filed 1-5-00; 8:45 am]

BILLING CODE 6210-01-P

FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in Permissible Nonbanking Activities or To Acquire Companies that are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR Part 225) to engage de novo, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than January 19, 2000.

A. Federal Reserve Bank of Cleveland (Paul Kaboth, Banking Supervisor) 1455 East Sixth Street, Cleveland, Ohio 44101-2566):

1. Rurban Financial Corp., Defiance, Ohio; to acquire FiData Technology, Inc., Franklin, Tennessee, and Financial Data Technology Corporation, Defiance, Ohio, and thereby engage in conducting permissible data processing activities, pursuant to § 225.28(b)(14) of Regulation Y.

Board of Governors of the Federal Reserve System, December 30, 1999.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 00-226 Filed 1-5-00; 8:45 am]

BILLING CODE 6210-01-P

FEDERAL TRADE COMMISSION

Granting of Request for Early Termination of the Waiting Period Under the Premerger Notification Rules

Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by Title II of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, requires persons contemplating certain mergers or acquisitions to give the Federal Trade Commission and the Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b)(2) of the Act permits the agencies, in individual cases, to terminate this waiting period prior to its expiration and requires that notice of this action be published in the **Federal Register**.

The following transactions were granted early termination of the waiting period provided by law and the premerger notification rules. The grants were made by the Federal Trade Commission and the Assistant Attorney General for the Antitrust Division of the Department of Justice. Neither agency intends to take any action with respect to these proposed acquisitions during the applicable waiting period.

Trans #	Acquiring	Acquired	Entities
Transactions Granted Early Termination—12/06/1999			
20000483	AT&T Corp	E! Entertainment Television, Inc	E! Entertainment Television, Inc.
20000615	BCI Growth IV, L.P	JC Acquisition LLC	North American Communication Corporation.
20000627	Arthur Skidmore	John Anderson	Coolidge Glass Company, Inc.
20000628	Provant, Inc	Larry E. Senn and Bernadette Senn	Senn-Delaney Leadership Consulting Group, Inc.
20000635	John J. Rigas	American Cable TV Investors 5, Ltd.	American Cable TV Investors 5, Ltd.
20000670	Tribune Company	Philip Heit	Meeks Heit Publishing Company.
20000671	Tribune Company	Linda Meeks	Meeks Heit Publishing Company.
20000701	Amazon.com, Inc	Pets.com, Inc	Pets.com, Inc.
20000703	Richard Li	SoftNet Systems, Inc	SoftNet Systems, Inc.
20000708	Flowserve Corporation	Innovative Valve Technologies, Inc	Innovative Valve Technologies, Inc.
20000709	Charming Shoppes, Inc	Catherines Stores Corporation	Catherines Stores Corporation.
20000711	RailWorks Corporation	Betty A. and Glenn P. Twigg	Twigg Corporation.
20000713	Red Hat, Inc	Cygnus Solutions	Cygnus Solutions.

Trans #	Acquiring	Acquired	Entities
20000714	Minnesota Mining and Manufacturing Company ("3M").	Minnesota Mining and Manufacturing Company.	Dyneon LLC.
20000715	United Dominion Industries Limited	Lawrence E. Johnson	Kelley Company, Inc.
20000720	T. Morris Hackney	Harold Ridgeway	Shelby Steel—Pell City, Inc., Shelby Steel—Vincent, Inc., Shelby Steel Fabricators, Inc.
20000722	CGW Southeast Partners IV, L.P.	Per-Se Technologies, Inc.	Impact Innovations Government Group, Inc.
20000725	Long Point Capital Fund, L.P.	Eurodesign Cabinets, Inc.	Eurodesign Cabinets, Inc.
20000726	Long Point Capital Fund, L.P.	Eurodesign Holdings, Inc.	Eurodesign Holdings, Inc.
20000727	Thomson S.A.	NEWCO	NEWCO.
20000728	Alcatel	NEWCO	NEWCO.
Transactions Granted Early Termination—12/07/1999			
20000616	Ronald W. Burkle	Wherehouse Entertainment, Inc.	Wherehouse Entertainment, Inc.
20000846	Thayer Equity Investors IV, L.P.	Career Blazers, Inc.	Career Blazers Personnel Services, Inc., Career Blazers, Inc., CBI CHC No. 1, CBI CHC No. 2, CBI NY Training, Inc., CBI PHC, Inc., Personnel One, Inc., Professional Drivers, Inc.
Transactions Granted Early Termination—12/08/1999			
19994441	Cisco Systems, Inc.	International Business Machines Corporation.	International Business Machines Corporation.
20000421	British Telecommunications plc	Sprint Corporation	Sprint Publishing & Advertising, Inc.
20000497	Omnipoint Corporation	Victoria G. Kane	East/West Communications, Inc.
20000561	PacifiCare Health Systems, Inc.	Texas Health Resources	Harris Methodist Health Insurance Company, Inc., Harris Methodist Texas Health Plan, Inc.
20000580	International Paper Company	Ace Packaging Systems, Inc.	Ace Packaging Systems, Inc.
20000593	BP Amoco p.l.c.	ProGas Limited	ProGas Limited.
20000692	Komatsu Forklift Co., Ltd.	Partek Corporation	Kalmar AC, Inc.
20000693	CoStar Group, Inc.	COMPS.COM, Inc.	COMPS.COM, Inc.
20000696	H P Bulmer Holdings PLC	American Hard Cider Company, Inc.	American Hard Cider Company, Inc.
20000723	OCM Principal Opportunities Fund, L.P.	Forcenergy Inc., as Debtor-in-Possession.	Forcenergy Inc., as Debtor-in-Possession.
20000724	General Motors Corporation	General Magic, Inc.	General Magic, Inc.
20000729	Fox Paine Capital Fund, L.P.	Watkins-Johnson Company	Watkins-Johnson Company.
20000730	Ashtead Group PLC	I. Edward Alter	Bob's Barricades.
20000731	Ashtead Group PLC	Alan Chester	Bob's Barricades.
20000732	Enron Corporation	PG&E Corporation	Harrier Power Corporation.
20000735	Semele Group Inc.	Gary D. Engle	Equis II Corporation.
20000737	Parthenon Investors, L.P.	Raymond Karsan Holdings, Inc.	Raymond Karsan Holdings, Inc.
20000741	C.H. Robinson Worldwide, Inc.	Paul Loeb	American Backhaulers, Inc.
20000744	Paul Loeb	C.H. Robinson Worldwide, Inc.	C.H. Robinson Worldwide, Inc.
20000774	Trident II, L.P.	Loews Corporation	AMS Services, Inc.
20000793	Hampshire Equity Partners II, L.P.	Industrial Powder Coatings Acquisition, Corp.	Industrial Powder Coatings Acquisition, Corp.
20000805	Delphi Automotive Systems Corporation	TRW Inc.	Lucas Diesel do Brasil Ltda, Lucas Diesel S.A. de C.V., Lucas Limited, Kelsey-Hayes Company.
Transactions Granted Early Termination—12/09/1999			
20000540	Liz Claiborne, Inc.	Donna Karan International Inc.	Donna Karan Studio.
20000581	Orius Corporation	Willis Stein & Partner II, L.P.	LISN Holdings, Inc.
20000582	Willis Stein & Partners II, L.P.	Orius Corporation	LISN Holdings, Inc.
20000677	J.H. Whitney IV, L.P.	Knology, Inc.	Knology, Inc.
20000702	Willis Stein & Partner II, L.P.	Electronic Data Systems Corporation	Appex, Inc.
20000705	AXA Reinsurance Company	White Mountains Insurance Group, Inc.	USF Reinsurance Company.
20000738	Corning Incorporated	Oak Industries Inc.	Oak Industries Inc.
20000762	VerticalNet, Inc.	Henry J. Bertolon, Jr.	NECX Exchange Trust.
20000763	Seagate Technology, Inc.	XIOtech Corporation	XIOtech Corporation.
20000766	RadiSys Corporation	International Business Machines Corporation.	International Business Machines Corporation.
20000768	Borden Chemicals and Plastics Limited Partnership.	BASAF Aktiengesellschaft	BASF Corporation.
20000772	The Interpublic Group of Companies	William and Suzanne Gordon	Graphic Orb, Inc.
20000773	AutoNation, Inc.	Estate of James M. Kline	Kline Tysons Imports, Inc.

Trans #	Acquiring	Acquired	Entities
20000775	Saint Vincents Catholic Medical Centers of New York.	Catholic Medical Center of Brooklyn and Queens, Inc.	Catholic Medical Center of Brooklyn and Queens, Inc., CMC Professional Registry, Inc., Queensbrook Insurance Ltd.
20000776	St. Vincent's Hospital & Med. Center of New York.	Sisters of Charity Services Corporation	Sisters of Charity Services Corporation.
20000777	Saint Vincents Catholic Medical Centers of New York.	St. Vincent's Catholic Med. Centers of New York.	St. Vincent's Catholic Med. Centers of New York.

Transactions Granted Early Termination—12/10/1999

20000622	FS Equity Partners IV, L.P., a Delaware limited partnership.	Medical Arts Press, Inc.	Medical Arts Press, Inc.
20000694	Icicle Seafoods, Inc.	NV Investment Holdings I, Inc.	NV Investment Holdings I, Inc.
20000742	Ingersoll-Rand Company	Ingersoll-Rand Company	Ingersoll-Dresser Pump Company.
20000743	Ingersoll-Rand Company	Halliburton Company	Dresser-Rand Company.
20000751	Cabletron Systems, Inc.	Efficient Networks, Inc.	Efficient Networks, Inc.
20000752	Efficient Networks, Inc.	Cabletron Systems, Inc.	FlowPoint Corp.
20000779	Fleet Boston Corporation	Arvig Enterprises, Inc.	Info Tel Communications, Inc.
20000780	Fleet Boston Corporation	Gilroy G. Arvig	Info Tel Communications, Inc.
20000782	Suez Lyonnaise des Eaux	Monsanto Company	Kelco Company, Monterey Kelp Corporation.
20000784	Phillips Petroleum Company	Kinder Morgan, Inc.	MidCon Gas Products of New Mexico Corp.
20000790	Jay S. Walker	priceline.com Incorporated	priceline.com Incorporated.
20000799	KT Holding Company	Arbitrade Holdings, LLC	Arbitrade Holdings, LLC.
20000803	Hoechst Aktiengesellschaft	ARIAD Pharmaceuticals, Inc.	Hoechst-ARIAD Genomics Center, LLC.
20000807	StoneBridge Partners Equity Fund II, L.P.	James A. Johnston	Johnson & Johnston Associates, Inc.
20000811	C. Richard Reese	Pierce Leahy Corp.	Pierce Leahy Corp.
20000812	Vincent J. Ryan	Pierce Leahy Corp.	Pierce Leahy Corp.
20000813	B. Thomas Golisano	Pierce Leahy Corp.	Pierce Leahy Corp.
20000814	Kent P. Dauten	Pierce Leahy Corp.	Pierce Leahy Corp.
20000815	Efraim Gildor	KT Holding Company	KT Holding Company.
20000816	Irvin Kessler	KT Holding Company	KT Holding Company.
20000817	Peter Hajas	KT Holding Company	KT Holding Company.
20000819	Caledonia Investments Plc	Sterling Industries Plc	Sterling Industries Plc.
20000824	Linsalata Capital Partners Fund III, L.P.	Gerald A. Conway	Fasteners For Retail, Inc.
20000825	First Data Corporation	Wells Fargo & Company	Wells Fargo & Company.
20000827	U.S. Foodservice	David L. Reese	Parkway Provision Company ET AL.
20000829	General Electric Company	The Arthur Coren Declaration of Trust dated 12/2/87.	Zenith Controls, Inc.
20000836	Gerald W. Schwartz	Hadley Family Trust—1985	Hadley Auto Transport, HFS Investments, Inc., Hadley Computer Services, Inc.
20000838	Crown Castle International Corp.	Virginia PCS Alliances, LC	Virginia PCS Alliances, LC.
20000849	Siemens Aktiengesellschaft	Eaton Corporation	Vickers, Incorporated.
20000850	Anglo American plc	Tarmac Plc	Tarmac Plc.
20000853	General Motors Corporation	Jeffrey K. Wetzel	Rick Warner Saturn of Salt Lake, Inc.
20000854	Vulcan Materials Company	Garves W. Yates & Sons, Inc.	Garves W. Yates & Sons, Inc.
20000856	Conestoga Enterprises, Inc.	TeleBeam, Incorporated	TeleBeam, Incorporated.
20000861	Wells Fargo & Company	Paul B. Milhous	Carson Industries, Inc.
20000862	Wells Fargo & Company	Robert E. Milhous	Carson Industries, Inc.
20000863	Doctors Community Healthcare Corporation.	The Greater Southeast Community Hospital Foundation, Inc.	The Greater Southeast Community Hospital Foundation, Inc.
20000864	John L. Morris	Bass Pro, Inc.	Bass Pro, Inc.
20000865	Gaylord Entertainment Company	Bass Pro, Inc.	Bass Pro, Inc.
20000866	J.W. Childs Equity Partners II, L.P.	Bass Pro, Inc.	Bass Pro, Inc.
20000870	Bally Total Fitness Holdings Corporation	Jack E. & Deane T. Garrison	Nautilus Plus of Oregon, Inc.
20000876	Building One Services Corporation	David Stone and Jennifer Stone	Tri States Electric Acquisition Corp., Tri-States Acq. Corp.
20000879	George S. Hofmeister	TRW Inc.	Kelsey-Hayes Company, Kelsey-Hayes Canada Ltd.
20000880	The FINOVA Group Inc.	Fremont General Corporation	Fremont General Corporation.
20000885	Dag Landvik	Tempur World, Inc.	Tempur World, Inc.
20000888	Mr. Eric T. Jacobsen	Sybase, Inc.	Sybase, Inc.
20000889	Mr. Daniel M. Schley	Sybase, Inc.	Sybase, Inc.
20000892	Media/Communications Partners III Limited Partnership.	Teltrust, Inc.	Teltrust, Inc.
20000893	BP Amoco p.l.c.	Repsol, S.A.	Repsol, S.A.
20000894	Hong Leong Investment Holdings Pte Ltd.	Lo Yuk Sui	Gateway Holding Corp. I, Regal Grand Holding Corp. I, RHI Boston Holding Corp. I, RHM Holdings Corp. I, Richfield Holding Corp. I.

Trans #	Acquiring	Acquired	Entities
20000895	OCM Principal Opportunities Fund, L.P	TCW Special Credits Fund V—The Principal Fund.	New Bristol Farms, Inc.
20000899	HAL Trust	Cole National Corporation	Cole National Corporation.
20000906	Tyco International, Ltd	Eric R. Cosman	Radionics, Inc.
20000912	First Union Corporation	Hosokawa Micron Corporation	Hosokawa Micron Corporation.
20000922	Clear Channel Communications, Inc	Clear Channel Communications, Inc	CCC-Houston AM, Ltd.
20000926	Industrial Growth Partners, L.P	Louisiana-Pacific Corporation	Associated Chemists, Inc.
20000928	Royal KPN N.V	Euoweb International Corp	Euoweb International Corp.
20000930	Olympus Growth Fund III, L.P	Doane Pet Care Enterprises, Inc	Doane Pet Care Enterprises, Inc.

Transactions Granted Early Termination—12/13/1999

20000660	Johnson & Johnson	Cygnus, Inc	Cygnus, Inc.
20000689	The Coastal Corporation	TransCanada PipeLines Limited	TransCanada Energy Marketing Inc., TransCanada Gas Processing USA Inc.
20000904	Repsol, S.A	Repsol, S.A	Repsol, S.A.
20000917	Jack P. Cook, Jr	Louis D. Root	Root Corporation.

FOR FURTHER INFORMATION CONTACT:

Sandra M. Peay or Parcellena P. Fielding, Contact Representatives, Federal Trade Commission, Premerger Notification Office, Bureau of Competition, Room 303, Washington, DC 20580, (202) 326-3100.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 00-261 Filed 1-5-00; 8:45 am]

BILLING CODE 6750-01-M

FEDERAL TRADE COMMISSION

[File No. 991-0167]

MacDermid, Inc., et al.; Analysis to Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint that accompanies the consent agreement and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before January 21, 2000.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, Room 159, 600 Pennsylvania Ave., NW, Washington, D.C. 20580.

FOR FURTHER INFORMATION CONTACT: Morris Bloom, FTC/S-3418, 600 Pennsylvania Ave., NW, Washington, D.C. 20580. (202) 326-2707.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade

Commission Act, 38 Stat. 721, 15 U.S.C. 46 and Section 2.34 of the Commission's Rules of Practice (16 CFR 2.34), notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for December 22, 1999), on the World Wide Web, at "<http://www.ftc.gov/os/actions97.htm>." A paper copy can be obtained from the FTC Public Reference Room, Room H-130, 600 Pennsylvania Avenue, NW, Washington, D.C. 20580, either in person or by calling (202) 326-3627.

Public comment is invited. Comments should be directed to: FTC/Office of the Secretary, Room 159, 600 Pennsylvania Ave., NW, Washington, D.C. 20580. Two paper copies of each comment should be filed, and should be accompanied, if possible, by a 3½ inch diskette containing an electronic copy of the comment. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with Section 4.9(b)(6)(ii) of the Commission's Rules of Practice (16 CFR 4.9(b)(6)(ii)).

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Orders ("Agreement") from MacDermid, Inc. ("MacDermid") and Polyfibron

Technologies, Inc. ("Polyfibron") to resolve competitive concerns arising out of MacDermid's proposed acquisition of Polyfibron. The Agreement includes a proposed Decision and Order (the "proposed Order") which would require MacDermid and Polyfibron ("respondents") to divest the Polyfibron business of producing and selling liquid photopolymers; to terminate their respective agreements to distribute sheet photopolymers in North America (MacDermid's 1998 distribution agreement with Asahi Chemical Industry Co., Ltd. ("Asahi"), and Polyfibron's 1995 distribution agreement with BASF Lacke + Farben AG ("BASF")); and to cease and desist from inviting, entering into or participating in any agreements with other photopolymer manufacturers that have as their effect any allocation, division or illegal restriction of competition. The Agreement also includes an Order to Maintain Assets which requires respondents to preserve the Polyfibron business of producing and selling liquid photopolymers as a viable, competitive, and ongoing business until the divestiture is achieved.

The proposed Order has been placed on the public record for thirty (30) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will review the Agreement and comments received and decide whether to withdraw its acceptance of the Agreement or make final the Agreement's proposed Order.

The proposed complaint alleges that the acquisition, if consummated, would violate Section 7 of the Clayton Act, 15 U.S.C. 18, as amended, and Section 5 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. 45, as amended,

in the following markets: (1) The research, development, manufacture, and sale of liquid photopolymers for use in the manufacture of flexographic printing plates for printing on packaging materials, such as corrugated containers and multi-wall bags ("Liquid Photopolymers"); and (2) the research, development and sale of solid sheet photopolymers for use in the manufacture of flexographic printing plates for printing on packaging materials such as plastic bags and other flexible packaging, as well as corrugated containers and multi-wall bags ("Sheet Photopolymers").

The proposed complaint alleges that the Liquid Photopolymer market in North America is highly concentrated, and that the proposed acquisition of Polyfibrion by MacDermid represents a virtual merger to monopoly in that market.

The proposed complaint also alleges that the Sheet Photopolymer market in North America is highly concentrated, with the pre-merger market being dominated by two firms, E.I. du Pont de Nemours & Co., Inc. ("DuPont") and Polyfibrion (selling its own-manufactured Sheet Photopolymer products, and those of BASF under the 1995 distribution agreement). Other firms that participate in the North American Sheet Photopolymer market are niche players with minor market shares. While MacDermid does not produce Sheet Photopolymers, it entered into a distribution agreement with Asahi in 1998 that gives it the right—which it has not yet exercised—to distribute and sell Asahi's Sheet Photopolymer products in North America. The proposed complaint alleges that the existence of the respective distribution agreements means that the present duopoly in the sale of Sheet Photopolymers in North America would be further entrenched, because the only two likely entrants, BASF and Asahi, are bound by the distribution agreements to sell only through polyfibrion and MacDermid, respectively.

The proposed complaint further alleges that the effect of the acquisition may be to substantially lessen competition and to tend to create a monopoly by, among other things, eliminating direct competition between MacDermid and Polyfibrion in the manufacture, distribution and sale of Liquid Photopolymers, entrenching the existing duopoly in North America in the sale of Sheet Photopolymers, increasing the likelihood that purchasers of Liquid Photopolymers and Sheet Photopolymers will be forced to pay higher prices, increasing the

likelihood that technical and sales services provided to customers will be reduced, and increasing the likelihood that innovation will be reduced. Customers have complained that the effect of the transaction would be increased prices for Liquid Photopolymers and Sheet Photopolymers and reduced technical service, support, and innovation.

The proposed complaint further alleges that entry into the relevant markets would not be timely, likely, or sufficient to deter or offset the adverse effects of the acquisition on competition. Entry is difficult in this market because of the length of time it would take and the expense that would be incurred in building appropriate chemical production facilities; the difficulty of perfecting the underlying polymer chemistry without violating existing patents; the need to offer to customers plate-making equipment on a consignment or lease basis and the concurrent difficulty and cost of obtaining a source of supply for plate-making equipment; and the difficulty of gaining recognition in a marketplace in which customers are reluctant to change from proven suppliers. In addition, the proposed complaint alleges that most customers in the relevant market for Liquid Photopolymers are engaged in long-term equipment and material supply contracts with either MacDermid or Polyfibrion, further reducing the number of customers available to a new entrant at any given time.

Finally, the proposed complaint alleges that the respondents have allocated markets for the sale of photopolymers with competitors, or invited competitors to allocate markets for the sale of photopolymers. Specifically, the complaint alleges that beginning in 1995, when MacDermid first entered the market for the production and sale of Liquid Photopolymers (by virtue of its acquisition of Hercules, Inc.'s photopolymer business), MacDermid and Asahi agreed to allocate markets such that MacDermid would not compete in the sale of Liquid Photopolymers in Japan and in other areas of the world in which Asahi sold Liquid Photopolymers while Asahi would not compete in the sale of Liquid Photopolymers in North America. In the case of Polyfibrion, the proposed complaint alleges that during the same period of 1995 through 1998, Polyfibrion engaged in discussions with Asahi that had as their purpose the division of markets between the two companies. The proposed complaint alleges that on several occasions during this time period, Polyfibrion invited Asahi to

agree not to compete in the sale of Sheet Photopolymers and Liquid Photopolymers in North America in return for Polyfibrion's agreement not to compete in the sale of Sheet Photopolymers and Liquid Photopolymers in Japan.

The proposed Order is designed to remedy the anticompetitive effects of the acquisition in the North American markets for Liquid Photopolymers and Sheet Photopolymers, as alleged in the complaint, by requiring the divestiture of Polyfibrion's Liquid Photopolymer business, by requiring the respondents to terminate their respective distribution agreements with Asahi and BASF, and by requiring the respondents to cease and desist from entering into, inviting or participating in any agreements to allocate, divide or illegally restrict competition in the relevant markets.

Under the terms of the proposed Order, respondents are required to divest Polyfibrion's North American Liquid Photopolymer business to Chemence, Inc. ("Chemence"), no later than twenty (20) days after the date the Order becomes final. Chemence currently produces adhesives, sealants and photopolymers for making printing stamps, using technology similar to that involved in Liquid Photopolymers. Chemence also produces a small amount of Liquid Photopolymers in its facilities in Alpharetta, Georgia, as well as in the United Kingdom.

Divestiture of Polyfibrion's Liquid Photopolymer business to Chemence is designed to promote the viability and competitiveness of the divested business by placing the business in the hands of a company with extensive expertise in photopolymer technology, expertise in related chemistries, and economies of scale resulting from shared research and development, overhead and production. The divestiture package, in turn, will permit Chemence to penetrate the North American market. It provides Chemence with a photopolymer technology that is well-known, well-respected and proven in the marketplace, access to plate-making equipment that it may offer to its resin customers, a sales and technical support force that is well-known in the industry, customer lists, and long-term equipment/resin supply contracts with those customers.

The proposed Order requires that respondents divest all trade secrets, know-how, trade marks and trade names, intellectual property, intangible assets, tangible assets including equipment, and supply contracts and business information (including purchasing, sales, marketing, licensing, and similar information) relating to

Polyfibrin's Liquid Photopolymer business. The proposed Order also requires that respondents provide incentives to certain employees identified by the acquirer as important to the continued competitiveness and viability of the Liquid Photopolymers business, to facilitate their transfer and the transfer of know-how to the acquirer.

The proposed Order to Maintain Assets requires that respondents preserve the Polyfibrin Liquid Photopolymer business as a viable and competitive business until it is transferred to the Commission-approved acquirer. It includes an obligation on respondents to build and maintain a sufficient inventory of Liquid Photopolymers to ensure there is no shortage of supply during the period that the business is being transitioned to the Commission-approved acquirer, and obligations to maintain an adequate workforce.

Both the proposed Order and the Order to Maintain Assets include provisions designed to protect the Commission-approved acquirer during the transition period from the possibility that respondents might target customers on the customer lists being transferred to the Commission-approved acquirer. The provisions prohibit respondents from soliciting Liquid Photopolymer customers of Polyfibrin for the transition period, which in any event is not to exceed ninety (90) days from the date the assets to be divested are transferred to the Commission-approved acquirer.

If, following receipt and review of public comments regarding the proposed Order, the Commission determines to disapprove the divestiture to Chemence, respondents are required to rescind the transaction with Chemence and divest Polyfibrin's Liquid Photopolymers business, within three (3) months, to an acquirer that receives the prior approval of the Commission. The proposed Order also provides that if respondents fail to divest the Liquid Photopolymers business as required by the proposed Order, the Commission may appoint a Divestiture Trustee to divest the business along with any assets related to the business that are necessary to effect the purposes of the proposed Order.

Under the terms of the proposed Order, respondents are required to terminate their distribution agreements with BASF and Asahi. These provisions of the proposed Order are designed to remedy the foreseeable anticompetitive effects of maintaining the existing duopoly in the sale of Sheet Photopolymers in North America.

Presently, DuPont and Polyfibrin represent over ninety (90) percent of the sales of Sheet Photopolymers in North America. The investigation revealed that prices for Sheet Photopolymers in North America are considerably higher than prices for Sheet Photopolymers in other areas of the world where all of the major world players—DuPont, Polyfibrin, BASF and Asahi—compete for business. Furthermore, the investigation revealed evidence of coordinated price activity in the sale of Sheet Photopolymers in North America among the two major firms. By requiring the respondents to terminate the distribution agreements with BASF and Asahi, the order frees BASF and Asahi to enter the North American market independently, and thereby to act as a competitive counterweight to DuPont and respondents.

Finally, the proposed Order requires that respondents cease and desist from inviting, creating, maintaining, adhering to, participating in, or enforcing any agreement with any producer of photopolymer products to allocate, divide or illegally restrict competition in the relevant markets. This provision of the proposed Order is designed to further enhance competition in the North American markets for Liquid Photopolymers and Sheet Photopolymers by ensuring that no potential entrant into these markets refrains from entering because of any illegal invitations from or arrangements with the respondents.

The proposed Order requires respondents to provide the Commission, within thirty (30) days of the date the Agreement is signed, with an initial report setting forth in detail the manner in which respondents will comply with the provisions relating to the divestiture of assets. The proposed Order further requires respondents to provide the Commission with a report of compliance with the Order within thirty (30) days following the date the Order becomes final and every thirty (30) days thereafter until they have complied with the divestiture provisions of the Order. Furthermore, the Order requires respondents to report annually to the Commission, for ten (10) years, regarding their compliance with the provisions of the Order relating to the Sheet Photopolymer distribution agreements and market allocation agreements.

The purpose of this analysis is to facilitate public comment on the proposed Order. This analysis is not intended to constitute an official interpretation of the Agreement or the proposed Order or in any way to modify

the terms of the Agreement or the proposed Order.

By direction of the Commission.

Benjamin I. Berman,
Acting Secretary.

[FR Doc. 00-260 Filed 1-5-00; 8:45 am]

BILLING CODE 6750-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-0529]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information contained in a guidance for industry entitled "Changes to an Approved NDA or ANDA." The guidance is intended to assist applicants in determining how they should report changes to an approved new drug application (NDA) or abbreviated new drug application (ANDA) under section 116 of the Food and Drug Administration Modernization Act (the Modernization Act), which provides requirements for making and reporting manufacturing changes to an approved application and for distributing a drug product made with such changes.

DATES: Submit written comments on the collection of information by March 6, 2000.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600

Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry: Changes to an Approved NDA or ANDA

On November 21, 1997, the President signed into law the Modernization Act (Public Law 105-115). Section 116 of the Modernization Act amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 506A (21 U.S.C. 356a), which describes requirements and procedures for making and reporting manufacturing changes to approved new drug and ANDAs', to new and abbreviated animal drug applications, and to license applications for biological products.

The guidance provides recommendations to holders of approved new drug and ANDA's who intend to make postapproval changes in accordance with section 506A of the act. The guidance covers recommended reporting categories for postapproval changes for drugs, other than specified biotechnology and specified synthetic biological products. Recommendations

are provided for postapproval changes in: (1) Components and composition, (2) sites, (3) manufacturing process, (4) specification(s), (5) package, (6) labeling, and (7) miscellaneous changes.

Section 116 of the Modernization Act amended the act by adding section 506A, which includes the following provisions:

1. A drug made with a manufacturing change, whether a major manufacturing change or otherwise, may be distributed only after the applicant validates the effects of the change on the identity, strength, quality, purity, and potency of the drug as these factors may relate to the safety or effectiveness of the drug (section 506A(a)(1) and (b) of the act). This section recognizes that additional testing, beyond testing to ensure that an approved specification is met, is required to ensure unchanged identity, strength, quality, purity, or potency as these factors may relate to the safety or effectiveness of the drug.

2. A drug made with a major manufacturing change may be distributed only after the applicant submits a supplemental application to FDA and the supplemental application is approved by the agency. The application is required to contain information determined to be appropriate by FDA and include the information developed by the applicant when "validating the effects of the change" (section 506A(c)(1) of the act).

3. A major manufacturing change is a manufacturing change determined by FDA to have substantial potential to adversely affect the identity, strength, quality, purity, or potency of the drug as these factors may relate to the safety or effectiveness of the drug. Such changes include: (1) A change made in the qualitative or quantitative formulation of the drug involved or in the specifications in the approved application or license unless exempted by FDA by regulation or guidance; (2) a change determined by FDA by regulation or guidance to require completion of an appropriate clinical study demonstrating equivalence of the drug to the drug manufactured without the change; and (3) other changes determined by FDA by regulation or guidance to have a substantial potential to adversely affect the safety or effectiveness of the drug (section 506A(c)(2) of the act).

4. FDA may require submission of a supplemental application for drugs made with manufacturing changes that are not major (section 506A(d)(1)(B) of the act) and establish categories of manufacturing changes for which a supplemental application is required (section 506A(d)(1)(C) of the act). In

such a case the applicant may begin distribution of the drug 30 days after FDA receives a supplemental application unless the agency notifies the applicant within the 30-day period that prior approval of the application is required (section 506A(d)(3)(B)(i) of the act). FDA may also designate a category of manufacturing changes that permit the applicant to begin distributing a drug made with such changes upon receipt by the agency of a supplemental application for the change (section 506A(d)(3)(B)(ii) of the act). If FDA disapproves a supplemental application, the agency may order the manufacturer to cease the distribution of drugs that have been made with the disapproved change (section 506A(d)(3)(B)(iii) of the act).

5. FDA may authorize applicants to distribute drugs without submitting a supplemental application (section 506A(d)(1)(A) of the act) and may establish categories of manufacturing changes that may be made without submitting a supplemental application (section 506A(d)(1)(C) of the act). The applicant is required to submit a report to FDA on such a change and the report is required to contain information the agency deems to be appropriate and information developed by the applicant when validating the effects of the change. FDA may also specify the date on which the report is to be submitted (section 506A(d)(2)(A) of the act). If during a single year an applicant makes more than one manufacturing change subject to an annual reporting requirement, FDA may authorize the applicant to submit a single report containing the required information for all the changes made during the year (annual report) (section 506A(d)(2)(B) of the act).

Section 506A of the act provides FDA with considerable flexibility to determine the information and filing mechanism required for the agency to assess the effect of manufacturing changes in the safety and effectiveness of the product. There is a corresponding need to retain such flexibility in the guidance on section 506A of the act to ensure that the least burdensome means for reporting changes are available. FDA believes that such flexibility will allow it to be responsive to increasing knowledge of and experience with certain types of changes and help ensure the efficacy and safety of the products involved. For example, a change that may currently be considered to have a substantial potential to have an adverse effect on the safety or effectiveness of the product may, at a later date, based on new information or advances in technology, be determined to have a

lesser potential to have such an adverse effect. Conversely, a change originally considered to have a minimal or moderate potential to have an adverse effect on the safety or effectiveness of the product may later, as a result of new information, be found to have an increased, substantial potential to adversely affect the product. The guidance enables the agency to respond

more readily to knowledge gained from manufacturing experience, further research and data collection, and advances in technology. The guidance describes the agency's current interpretation of specific changes falling into the four filing categories. Section 506A of the act explicitly provides FDA the authority to use guidance documents to determine the type of

changes that do or do not have a substantial potential to adversely affect the safety or effectiveness of the drug product. The use of guidance documents allows FDA to more easily and quickly modify and update important information.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Federal Food, Drug, and Cosmetic Act Section	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
506A(c)(1) and (c)(2) Prior Approval Supp.	594	3	1,744	120	209,280
506A(d)(1)(B), (d)(1)(C), and (d)(3)(B)(i) CBE in 30-days Supp.	594	5	2,754	80	220,320
506A(d)(1)(B), (d)(1)(C), and (d)(3)(B)(ii) CBE Supp.	486	1	486	80	38,880
506A(d)(1)(A), (d)(1)(C), (d)(2)(A), and (d)(2)(B) Annual Report	704	10	6,929	25	173,225
Total					641,705

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Section 506A(a)(1) and (b) of the act requires the holder of an approved application to validate the effects of a manufacturing change on the identity, strength, quality, purity, or potency of the drug as these factors may relate to the safety or effectiveness of the drug before distributing a drug made with the change. Under section 506A(d)(3)(A) of the act, information developed by the applicant to validate the effects of the change regarding identity, strength, quality, purity, and potency is required to be submitted to FDA as part of the supplement or annual report. Thus, no separate estimates are provided for these sections in Table 1 of this document; estimates for validation requirements are included in the estimates for supplements and annual reports. The guidance does not provide recommendations on the specific information that should be developed by the applicant to validate the effect of the change on the identity, strength (e.g., assay, content uniformity), quality (e.g., physical, chemical, and biological properties), purity (e.g., impurities and degradation products), or potency (e.g., biological activity, bioavailability, bioequivalence) of a product as they may relate to the safety or effectiveness of the product.

Section 506A(c)(1) and (c)(2) of the act sets forth requirements for changes requiring supplement submission and approval prior to distribution of the

product made using the change (major changes). Under this section, a supplement must be submitted for any change in the product, production process, quality controls, equipment, or facilities that has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as these factors may relate to the safety or effectiveness of the product. The applicant must obtain approval of a supplement from FDA prior to distribution of a product made using the change.

Based on data concerning the number of supplements received by the agency, FDA estimates that approximately 1,744 supplements will be submitted annually under section 506A(c)(1) and (c)(2) of the act. FDA estimates that approximately 594 applicants will submit such supplements, and that it will take approximately 120 hours to prepare and submit to FDA each supplement.

Section 506A(d)(1)(B), (d)(1)(C), and (d)(3)(B)(i) of the act sets forth requirements for changes requiring supplement submission at least 30 days prior to distribution of the product made using the change (moderate changes). Under this section, a supplement must be submitted for any change in the product, production process, quality controls, equipment, or facilities that has a moderate potential to have an adverse effect on the identity,

strength, quality, purity, or potency of the product as these factors may relate to the safety or effectiveness of the product. Distribution of the product made using the change may begin not less than 30 days after receipt of the supplement by FDA.

Based on the data concerning the number of supplements received by the agency, FDA estimates that approximately 2,754 supplements will be submitted annually under section 506A(d)(1)(B), (d)(1)(C), and (d)(3)(B)(i) of the act. FDA estimates that approximately 594 applicants will submit such supplements, and that it will take approximately 80 hours to prepare and submit to FDA each supplement.

Under section 506A(d)(3)(B)(ii) of the act, FDA may designate a category of changes for the purpose of providing that, in the case of a change in such category, the holder of an approved application may commence distribution of the drug upon receipt by the agency of a supplement for the change. Based on the data concerning the number of supplements received by the agency, FDA estimates that approximately 486 supplements will be submitted annually under section 506A(d)(3)(B)(ii) of the act. FDA estimates that approximately 486 applicants will submit such supplements, and that it will take approximately 80 hours to prepare and submit to FDA each supplement.

Section 506A(d)(1)(A), (d)(1)(C), (d)(2)(A), and (d)(2)(B) of the act sets forth requirements for changes to be described in an annual report (minor changes). Under this section, changes in the product, production process, quality controls, equipment, or facilities that have a minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as these factors may relate to the safety or effectiveness of the product must be documented by the applicant in the next annual report.

Based on the data concerning the number of supplements and annual reports received by the agency, FDA estimates that approximately 6,929 annual reports will include documentation of certain manufacturing changes as required under section 506A(d)(1)(A), (d)(1)(C), (d)(2)(A), and (d)(2)(B) of the act. FDA estimates that approximately 704 applicants will submit such information, and that it will take approximately 25 hours to prepare and submit to FDA the information for each annual report.

In the *Federal Register* of June 28, 1999 (64 FR 34608), FDA published a proposed rule to implement section 116 of the Modernization Act by revising current regulations at § 314.70 (21 CFR 314.70) on supplements and other changes to an approved application. In that same issue of the *Federal Register* (64 FR 34660), FDA published a notice of availability of a draft guidance for industry entitled "Changes to an Approved NDA or ANDA." On August 19, 1999, FDA held a public meeting to discuss and receive comments on the proposed regulations and the draft guidance (64 FR 42625, August 5, 1999).

The period for public comment on the proposed regulations closed on September 13, 1999, and FDA is currently reviewing the comments and preparing a final rule. The comment period for the draft guidance closed on August 27, 1999, and FDA has considered these comments when preparing the guidance that is the subject of this request.

In the *Federal Register* of November 23, 1999 (64 FR 65176), FDA requested emergency processing of this proposed collection of information under section 3507(j) of the PRA and 5 CFR 1320.13. The information is needed immediately to implement section 506A of the act. The use of normal information clearance procedures would likely result in the prevention or disruption of this collection of information because section 506A of the act takes effect on November 21, 1999. After November 20, 1999, and until final regulations are

promulgated revising § 314.70, section 506A of the act will be the sole basis for FDA's regulation of postapproval manufacturing changes for products approved under NDA's or ANDA's. The guidance provides recommendations to holders of approved new drug and ANDA's who intend to make postapproval changes in accordance with section 506A of the act. Section 506A of the act explicitly provides FDA the authority to use guidance documents to determine the type of changes that do or do not have a substantial potential to adversely affect the safety or effectiveness of the drug product.

OMB has now approved the collection of information and has assigned OMB control number 0910-0431. This 6-month approval expires on May 31, 2000. By that date, FDA hopes to have completed the normal information clearance process initiated by this 60-day notice, and the agency hopes to obtain OMB approval for this collection of information for the usual 3-year period. 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.

Dated: December 29, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00-236 Filed 1-5-00; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food And Drug Administration

[Docket No. 99F-5523]

Alcide Corporation; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Alcide Corp., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of acidified sodium chlorite solutions as an antimicrobial agent on poultry carcass parts.

DATES: Written comments on the petitioner's environmental assessment by February 7, 2000.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug

Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204-0001, 202-418-3074.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug and Cosmetic Act (sec. 409(b)(5)(21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 0A4705) has been filed by Alcide Corporation, 8561 154th Ave., NE, Redmond, WA 98052. The petition proposes to amend the food additive regulations in § 173.325 *Acidified sodium chlorite Solutions* (21 CFR 173.325) to provide for the safe use of acidified sodium chlorite solutions as an antimicrobial agent on poultry carcass parts.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before February 7, 2000, submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m. Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the *Federal Register*. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the *Federal Register* in accordance with 21 CFR 25.40(c).

Dated: December 9, 1999.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 00-238 Filed 1-5-00; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

National Mammography Quality Assurance Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: National Mammography Quality Assurance Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on January 31, 2000, 9 a.m. to 6 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Charles A. Finder, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-3332, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12397. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will: (1) Discuss the establishment of a proposed demonstration project to assess the efficacy of less than annual inspections as described in the Mammography Quality Standards Reauthorization Act of 1998, and (2) continue the discussion of the Mammography Quality Standards Act (the MQSA) compliance guidance. The committee will also receive updates on the status of facility noncompliance under final regulation inspections, accreditation and certification of full field digital mammography, States as certification agencies under the MQSA, and Voluntary Stereotactic Accreditation Programs. The MQSA compliance guidance documents, which are in a question and answer format, are available to the public on the Internet at <http://www.fda.gov/cdrh/mammography>. The guidance is being updated continually in response to questions that FDA receives from the public. Additional information regarding guidance updates may be obtained by calling the Information Line.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by January 10, 2000. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10:30 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 10, 2000, 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: December 28, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00-239 Filed 1-5-00; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Vaccines and Related Biological Products 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: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on January 27, 2000, 8 a.m. to 6:30 p.m., and on January 28, 2000, 8 a.m. to 3 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Nancy T. Cherry or Denise H. Royster, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12391. Please call the Information Line

for up-to-date information on this meeting.

Agenda: On January 27, 2000, the committee will: (1) Review the current understanding of the immune correlates of protection against invasive Haemophilus influenzae type b disease, and (2) discuss the potential clinical significance of reduced antibody responses to PRP (polyribitol phosphate) polysaccharide following administration of combination vaccines containing Haemophilus influenzae type b conjugate vaccines. On January 28, 2000, the committee will: (1) Discuss the influenza virus vaccine formulation for the 2000 to 2001 season, and (2) be briefed on selected individual research programs in the Laboratory of Pediatric and Respiratory Viral Diseases.

Procedure: On January 27, 2000, from 9 a.m. to 6:30 p.m., and on January 28, 2000, from 8 a.m. to 2:25 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by January 19, 2000. Oral presentations from the public will be scheduled between approximately 9:10 a.m. and 9:25 a.m. and between approximately 4 p.m. and 4:15 p.m. on January 27, 2000. Oral presentations from the public will be heard on January 28, 2000, between approximately 8:20 a.m. and 8:30 a.m., between approximately 1:30 p.m. and 1:40 p.m., and between approximately 2:15 p.m. and 2:25 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 19, 2000, 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 January 27, 2000, from 8 a.m. to 9 a.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)). This portion of the meeting will be closed to permit discussion of pending investigational new drug applications or pending product licensing applications. On January 28, 2000, from 2:25 p.m. to 3 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The meeting will be closed to discuss personal information concerning individuals associated with the research programs.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 23, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00-237 Filed 1-5-00; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health service

National Institute of Environmental Health Sciences, NIH; National Toxicology Program; Solicitation of Comments on Proposed Peer Review of Low-Dose Issues for Endocrine Disruptors

SUMMARY: NTP is soliciting comments on the planned scope and process for a proposed peer review of studies bearing on the question of whether endocrine disruptors may cause effects at doses lower than are tested using standard toxicological testing procedures. Nominations for peer reviewers, as well as nominations for studies to be reviewed, are also being solicited. Results from the peer review will help the U.S. Environmental Protection Agency (a member agency of the NTP) and, in particular the EPA's Endocrine Disruptor Screening Program, determine how to address low-dose questions in endocrine disruptor screening, testing, and hazard assessment.

Background

The U.S. Environmental Protection Agency (EPA) is implementing an Endocrine Disruptor Screening Program as required by the Food Quality Protection Act of 1996 (See 63 FR 71542-71568, Dec. 28, 1998). The EPA is in the process of choosing appropriate assays to use in this screening program and is also developing standardized, validated protocols for these assays. A critical aspect of protocol development is dose-setting. In recent years, there have been suggestions that hormonally active agents may cause effects at doses lower than those normally selected for toxicological testing. A review of the issue can be found in the National Academy of Science's recently-released report *Hormonally Active Agents in the Environment* (NRC [National Research Council], 1999, Washington, DC: National Academy Press, pp. 103-111).

The EPA has asked the National Toxicology Program to establish an independent panel of scientists to review the evidence related to low-dose effects and consider their implications

for the development, validation, and interpretation of test protocols. If this Panel concludes that significant effects at low doses occur and that the standard dose-setting paradigm is inadequate to detect such effects, the EPA intends to pursue in a separate forum the question of how to test for such effects, including endpoints to be tested, dose-setting protocols and appropriate test methods. If the Panel believes the current data to be inconclusive, it will be asked to describe specific research that would resolve the ambiguities.

Proposed Scope and Process for the review

A. Scope of the Review

Analysis will focus on interpretation of the major data sets showing or refuting effects at low doses. "Low doses" are defined for the purposes of discussion as "doses below the currently accepted No Observed Adverse Effect Level for that substance". The intent is to evaluate the presence or absence of low-dose effects in specific studies, then evaluate the likelihood and significance of these and/or other potential low-dose effects to humans.

The main topic to be addressed is evidence for defining the shape of the dose/response curves for endocrine-active substances in the low-dose region.

The review is expected to examine all evidence, including such things as relevant pharmacokinetic and mechanistic information, which may have a bearing on the low-dose issue. In order to come to disclosure on the central issue of whether there are sufficient grounds to change the traditional dose-setting paradigm for endocrine-active substances, it will not be possible to go into the details of non-central issues. Issues which may enter the discussion but which are not the central focus and will not get exhaustive review include:

- existence of inverted U-shaped dose/response curves as a general phenomenon in toxicology;
- completeness of the list of endpoints examined in two-generation toxicity tests;
- definition of "adversity".

B. Selection of Studies for Review

Given the breadth of the scope, many studies are likely to be considered relevant to the discussion. NTP proposes to divide studies into two categories: those which provide background information and those which are critical to the resolution of the issue. Hard copies of both the background information and critical studies will be provided to the Panel in

advance of the Peer Review Meeting. For the critical studies, principal investigators will be invited for in-depth discussions with the Panel, and the data sets from these critical studies will be subjected to independent analyses by the panel. NTP anticipates that approximately 10 to 12 studies might be designated critical.

C. Criteria for Selection of Studies for Review

Studies which provide direct evidence for the presence of effects related to the endocrine system at doses below the No Observed Adverse Effect Level will generally be considered critical. Studies which provide direct evidence against such effects at similar doses for the same chemical will also generally be considered critical. Studies which provide direct evidence for endocrine-related effects for chemicals for which NOAELs have not been established will generally be considered critical if there is reason to believe that normal procedures for establishing a NOAEL would set NOAELs at a higher level than those indicated by the study in question, as long as the difference in putative NOAELs would be due to dose/response considerations rather than to definitions of adversity or selection of endpoints for observation. Studies which provide direct evidence against effects at similar doses from chemicals for which such claims have been made will also generally be considered critical.

Pharmacokinetic and mechanistic studies which provide insight into the plausibility or relevance of effects established in the direct studies may be either critical or background information depending on how closely they address low-dose issues.

Studies of other endocrine effects caused by a substance for which a low-dose endocrine effect is established will be considered background information unless mechanistic information establishes a relevant relationship to the low-dose effect.

In general, potency per se, is not a central issue. Studies which show effects at low doses but whose central issue in setting a NOAEL is either the definition of adversity or the completeness of the list of endpoints for which observations are made will not be considered relevant to the dose/response issues that this peer review will address.

For background information, well-written reviews will be preferred over individual studies. Only studies or reviews which have been published in standard, peer-reviewed scientific journals or books will be considered.

Critical studies must be accepted for publication in a standard, peer-reviewed scientific journal or book by April 1, 2000. Studies presented at scientific meetings but not formally accepted for publication in a peer-reviewed journal will not be accepted.

Raw data for critical studies must be available for the Panel to review and analyze. "Raw data" includes data on individual laboratory animals, prior to aggregation by statistical or other methods. Data reported under Good Laboratory Practices, for example, will generally be considered "raw data".

D. Selection Procedure

An NTP interagency workshop organizing committee will choose the studies to be considered by the Panel.

NTP recognizes that the date of acceptance for publication cannot be predicted with accuracy. Similarly, cooperation by principal investigators to include a study in this review cannot be guaranteed. For planning purposes, it may become necessary to designate certain studies as "likely to be critical" before April 1 and to treat them as if they will be examined at the Panel meeting. However, the criteria will be applied on April 1.

E. Preliminary List of Published Studies To Be Considered by the Low-Dose Peer Review Panel

The NTP has compiled the attached preliminary list of relevant studies and invites public comment on the list.

F. Peer Review Panel Members

A panel of 16 to 20 members is anticipated. NTP is soliciting nominations for the Panel from the public. (See Guidelines for Submission of Comments below). Kinds of expertise that are likely to be relevant include reproductive biology (male and female, whole animal and cellular), endocrinology, pharmacology, statistical data analysis, and dose/response modeling. Expertise need not be limited to these areas, nor will these areas necessarily all be included on the Panel. NTP will try to ensure an appropriate breadth of expertise across the Panel. If there are particular kinds of expertise that you feel the Panel should include, please provide a justification in your comments, especially if the expertise is not covered in the list above.

Nominations should be accompanied by complete contact information, including name, address, institutional affiliation, telephone number, and e-mail address. Where possible, a Web page address for research interests and/or curriculum vitae should be included. To avoid the potential for candidates

being contacted by a large number of nominators, candidates need not be contacted prior to nomination. NTP will solicit curricula vitae and interest in participation at an appropriate time.

G. Criteria for Selection of Panel Members

Expertise in a scientific field relevant to the low-dose issue is required.

Investigators associated with critical studies will not be considered for the Panel. Principal investigators (or their designated co-authors) for critical studies will be asked to present their data and be available for discussion at the Peer Review Panel meeting, but will not be asked to be part of the Panel itself.

H. Selection Procedure

Panelists will be chosen after critical studies have been selected. An NTP interagency organizing committee will select panel members considering all nominations received from the public as well as nominations developed internally. All nominees will be contacted for interest and availability, and curricula vitae will be solicited from the nominees. Selection will be based on the CVs and accompanying information such as statements of research interest. Official invitations to participate will be sent out in approximately April of 2000. The final list of Peer Review panel members will be available to the public through the Endocrine Disruptor Screening Program's Internet Web site (<http://www.epa.gov/scinpol/oscpendo/index.htm>). Panel members will be paid as consultants, and candidates will be required to disclose potential conflicts of interest.

I. Subcommittee Structure

NTP proposes to have Subcommittees of the Peer Review Panel examine specific aspects of the low-dose issue. Subcommittee topics will be determined after studies for review have been selected. Topics that may be appropriate for Subcommittees include:

- Data Analysis and Statistics
- Pharmacokinetics, Receptor Binding, and Modeling
- Effects on Males
- Effects on Females

Comments on the appropriateness of having Subcommittees, and of the specific topics suggested, are welcome.

Approximate Schedule for the Review

A meeting of the Peer Review Panel is tentatively planned for late July 2000 in the Research Triangle Park, NC area. The entire peer review panel meeting will be open to the public, limited only

by space available. Details of the meeting location, dates, and times will be announced at a later time.

In order to meet this deadline, designation of critical studies will take place in March, with Panel selection to begin in the March/April time frame.

Between May and late June, the data analysis subcommittee will be asked to review the data on critical studies. Investigators may be asked to run analyses of their own data according to the specifications of the Data Analysis Subcommittee. Approximately four weeks before the Peer Review, this Subcommittee will have the opportunity to meet with the investigators by conference call (or, if necessary, at a central location) to ask questions and obtain additional data that might be needed in preparation for the Panel meeting. The findings of the Data Analysis Subcommittee will be made available to the full Peer Review Panel for discussion at the meeting.

On the first day of the Peer Review Meeting, presentation from principal investigators for the critical studies will be heard by the entire Panel. Also, the Data Analysis and Statistics Subcommittee will present its analysis of the data to the remainder of the Low-Dose Panel. Principal investigators of the critical studies will be available for comment.

On the second day, the remaining Subcommittee will meet separately for discussion. Members of the Data Analysis and Statistics Subcommittee will be asked to split up between the remaining subcommittees.

On the third day, the entire Panel will reconvene as a group to discuss the deliberations of each of the Panels and to integrate the separate aspects into a report.

Each of the Subcommittees, as well as the full Panel, will produce a written Report following the meeting, documenting the discussions and explaining reasons for the scientific judgments made. These reports will be submitted for publication in an appropriate peer-reviewed scientific journal. Reports will also be made on the NTP and EPA (Endocrine Disruptor Screening Program) Web sites.

Public Input Solicited

As described above, the NTP solicits comments on the scope and process for the review; comments on the NTP preliminary list of studies for review; the nomination of studies to be considered for review; and the nomination of peer review panel members. Comments, identified by docket control number OPPTS-42208A,

must be received on or before February 22, 2000.

Guidelines for Submission of Public Comments

EPA will manage the record-keeping aspects of the Peer Review as part of the Endocrine Disruptor Screening Program.

You can 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/>.

For general information about the Endocrine Disruptor Screening Program go to <http://www.epa.gov/scipoly/oscpendo/index.htm>.

The EPA has established an official record for this action under docket control number OPPTS-42208A. 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. 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 TSCA Nonconfidential Information Center, North East Mall Rm. B-607, Waterside Mall, 401 M St., SW, Washington, DC. The Center is open from noon to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Center is (202) 260-7099.

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 OPPTS-42208A in the subject line on the first page of your response.

1. By mail. Submit your comments to: Document Control Office (7407), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 401 M St., SW, Washington, DC 20460.

2. In person or by courier. Deliver your comments to: OPPT Document Control Office (DCO) in East Tower Rm. G-099, Waterside Mall, 401 M St. SW, Washington, DC. The DCO is open from

8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 260-7093.

3. Electronically. You may submit your comments electronically by e-mail to: "oppt.ncic@epa.gov," or mail your computer disk to the address identified above. Do not submit any information that you consider to be CBI. Electronic comments may be submitted in WordPerfect 6.1/8.0 or as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on standard disks in WordPerfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number OPPTS-42208A. Electronic comments may also be filed online at many Federal Depository Libraries.

Do not submit any information that you consider to be Confidential Business Information. If you believe that relevant information will be overlooked because of this restriction, please consult the person identified under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT:

James P. Kariya, Office of Science Coordination and Policy (7203), Office of Prevention, Pesticides, and Toxic Substances, Environmental Protection Agency, 401 M St. SW, Washington, DC 20460; telephone number: (202) 260-2916; e-mail address: kariya.jim@epa.gov.

Dated: December 28, 1999.

Kenneth Olden, Director, National Toxicology Program, Department of Health and Human Services.

Attachment—Preliminary List of Published Studies to Be Considered by the Low-dose Peer Review Panel

The NTP has compiled a preliminary list of relevant studies. The public is invited to comment on this list; suggestions for additions, deletions, and substitutions may be submitted. (See Section of this FR announcement on Guidelines for Submission of Public comments.) Submission of a complete copy of the journal article in which the study and its results are described is preferred, but a complete reference (authors' names, name of journal, volume, issue, pages, title, date) will be sufficient if the complete article cannot be submitted. Include a brief narrative explaining the reason for each addition, deletion, or substitution. Raw data need not be submitted at this stage.

Studies which are as yet unpublished but which are expected to be accepted for publication before April 1, 2000 may be nominated. An abstract of the study describing highlights of the study (including species and strain, dosing regimen, duration of study, number of animals per dose, endpoints evaluated and, if available, results)

must be submitted in order for the Selection Committee to be able to evaluate the likelihood that the study will be a critical study. As with published studies, a brief narrative explaining the significance of as yet unpublished studies should be included.

Studies which are completed but not published are not included here. This list is being provided as an example of the kinds of studies that may be appropriate for the Panel to consider. Final selection of studies has not been made.

Ashby J, Elliott BM. 1997. Reproducibility of endocrine disruption data. *Reg Toxicol Pharmacol* 26:94-95.

Ashby J, Tinwell H, Lefevre PA *et al.* 1997. Normal sexual development of rats exposed to butyl benzyl phthalate from conception to weaning. *Reg Toxicol Pharmacol* 26:102-118.

Boettger-Tong H, Murthy L, Chiapetta C, *et al.* 1998. A case of a laboratory animal feed with high estrogenic activity and its impact on *in vivo* responses to exogenously administered estrogens. *Environ Health Perspect* 106(7):369-373.

Cagen SZ, Waechter JM Jr, Dimond SS, *et al.* 1999. Normal reproductive organ development in CF-1 mice following prenatal exposure to bisphenol A. *Toxicol Sci* 50:36-44.

Colerangle JB, Roy D. 1997. Profound effects of the weak environmental estrogen-like chemical bisphenol A on the growth of the mammary gland of Noble rats. *J Steroid Biochem Molec Biol* 60(1-2), 153-160.

Mäkelä SI, Pyllkänen LH, Santti RSS, Adlercreutz H. 1995. Dietary soybean may be antiestrogenic in male mice. *J Nutr* 125:437-445.

Nagel SC, vom Saal FS, Thayer KA, *et al.* 1997. Relative binding affinity-serum modified access (RBA-SMA) assay predicts the relative *in vivo* bioactivity of the xenoestrogens bisphenol A and octylphenol. *Environ Health Perspect* 105:70-76.

Odum J, Pyrah ITG, Foster JR, *et al.* 1999. Comparative activities of p-nonylphenol and diethylstilbestrol in Noble rat mammary gland and uterotrophic assays. *Reg Toxicol Pharmacol* 29:184-195.

Portier C, Tritscher A, Kohl M, *et al.* 1993. Ligand/receptor binding for 2,3,7,8-TCDD: implications for risk assessment. *Fundamental and Applied Toxicol* 20:48-56.

Sharpe RM, Fisher JS, Millar MM, *et al.* 1995. Gestational and lactational exposure of rats to xenoestrogens results in reduced testicular size and sperm production. *Environ Health Perspect* 103(12): 1136-1143.

Sharp R, Turner KJ, Sumpter JP. 1998. Endocrine disruptors and testis development [letter]. *Environ Health Perspect* 106(5): A220-A221.

Sheehan DM, Willingham E, Gaylor D, *et al.* 1999. No threshold dose for estradiol-induced sex reversal of turtle embryos: how little is too much? *Environ Health Perspect* 107:155-159.

Spearow J, Doemeny P, Sera R, *et al.* 1999. Genetic variation is susceptibility to endocrine disruption by estrogen in mice. *Science* 285:1259-1261.

vom Saal FS, Quadagno DM, Even MD, *et al.* 1990. Biology of Reproduction 43:751-761.

vom Saal FS, Timms BG, Montano MM, *et al.* 1997. Prostate enlargement in mice due to

fetal exposure to low doses of estradiol or diethylstilbestrol and opposite effects at high doses. *Proc Natl Acad Sci USA* 94:2056-2061.

vom Saal FS, Cooke PS, Buchanan DL, *et al.* 1998. A physiologically based approach to the study of bisphenol A and other estrogenic chemicals on the size of reproductive organs, daily sperm production, and behavior. *Toxicol Indust Hlth* 14():239-260.

Welshons WV, Nagel SC, Thayer KA, *et al.* 1999. Low-dose bioactivity of xenoestrogens in animals: fetal exposure to low doses of methoxychlor and other xenoestrogens increases adult prostate size in mice. *Toxicol Indust Health* 15:12-25.

[FR Doc. 00-228 Filed 1-5-00; 8:45 am]

BILLING CODE 4140-01-M

U.S. DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Receipt of Applications for Permit

The following applicants have applied for a permit to conduct certain activities with endangered species. This notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, *as amended* (16 U.S.C. 1531, *et seq.*):

PRT-020848

Applicant: Frank H. Cooley, Jasper, TX 75951.

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus dorcas*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

The public is invited to comment on the following application for a permit to conduct certain activities with marine mammals. The application was submitted to satisfy requirements of the Marine Mammal Protection Act of 1972, *as amended* (16 U.S.C. 1361 *et seq.*) and the regulations governing marine mammals (50 CFR 18).

PRT-021018

Applicant: Thomas J. Hammond, Bloomfield Hills, MI.

The applicant requests a permit to import a polar bear (*Ursus maritimus*) sport-hunted from the Western Hudson Bay polar bear population, Northwest Territories, Canada for personal use.

PRT-014704

Applicant: Toledo Zoological Gardens, Toledo, OH.

Permit Type: Import permit.

Name and Number of Animals: Polar bear (*Ursus maritimus*) 0.1.

Summary of Activity To Be Authorized: The applicant requests an amendment to their

permit number MA014704-0 issued 09/10/1999 for the import of a captive born female polar bear from Germany. The applicant wishes to substitute a female captive born polar bear from Monde Sauvage Safari Park, Aywaille, Belgium, for this permit.

Source of Marine Mammals: Born in captivity on 11/10/1998, Aywaille, Belgium.

Period of Activity: Up to 5 years, if issued.

Concurrent with the publication of this notice in the **Federal Register**, the Office of Management Authority is forwarding copies of this application to the Marine Mammal Commission and the Committee of Scientific Advisors for their review.

Written data or comments, requests for copies of the complete application, or requests for a public hearing on this application should be sent to the U.S. Fish and Wildlife Service, Office of Management Authority, 4401 N. Fairfax Drive, Room 700, Arlington, VA 22203, telephone 703/358-2104 or fax 703/358-2281 and must be received within 30 days of the date of publication of this notice. Anyone requesting a hearing should give specific reasons why a hearing would be appropriate. The holding of such a hearing is at the discretion of the Director.

Dated: December 27, 1999.

Kristen Nelson,

Chief, Branch of Permits, Office of Management Authority.

[FR Doc. 00-224 Filed 1-5-00; 8:45 am]

BILLING CODE 4310-55-U

DEPARTMENT OF THE INTERIOR

Geological Survey

Application Notice Describing the Areas of Interest and Establishing the Closing Date for Receipt of Applications Under the Biological Resource Division Brucellosis Program for Fiscal Year (FY) 2000

AGENCY: Department of the Interior, U.S. Geological Survey.

ACTION: Notice.

SUMMARY: Applications are invited for a research projected on the improvements in ballistic delivery systems for brucellosis vaccination of free-ranging elk and bison of the Greater Yellowstone Area.

The purpose of this project is to develop methods of ballistic delivery that improve the distance, reliability, ease, and/or rapidity of Brucella vaccine parenteral delivery. Such methods will need to take into account vaccine composition and the targeted age and sex of bison and/or elk.

Applications may be submitted by educational institutions, private firms, private foundations, individuals, and agencies of state and local governments.

ADDRESSES: The project announcement is expected to be available on or about January 11, 2000. You may obtain a copy of Announcement No. 00CRPA0001 from the USGS contracts and Grants Information Site at <http://www.usgs.gov/contracts/nehpr/> or by writing Grace Oakeley, U.S. Geological Survey, Branch of Acquisition and Federal Assistance, P.O. Box 25046, MS 204B, Denver, Colorado 80225, or by fax (303-236-1710).

DATES: The closing date for receipt of applications will be on or about February 12, 2000. The actual closing date will be specified in Announcement No. 00CRPA0001.

FOR FURTHER INFORMATION CONTACT: Thomas Roffe, Associate Regional Chief Biologist, U.S. Geological Survey, BRD, FWP Bldg., Montana State University, 1400 S. 19th St., Bozeman, Montana 59717.

SUPPLEMENTARY INFORMATION: Authority for this program is contained in the Fish and Wildlife Act of 1956 (16 U.S.C. 742(a)-742d, 742e-742j-2) and the Fish and Wildlife Improvement Act of 1978, Public Law 95-616 (16 U.S.C. 753a). The Office of Management and Budget Catalog of Federal Domestic Assistance number is 15.808.

Carol Aten,

Acting Chief Biologist.

[FR Doc 00-240 Filed 1-5-00; 8:45 am]

BILLING CODE 4310-31-M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Information Collection Submission to OMB for Reinstatement Under Paperwork Reduction Act

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1980, as amended (44 U.S.C. 3501 *et seq.*), this notice announces that an information collection request was submitted to the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs for review and extension under 5 CFR 1320.10. The first notice requesting comments about OMB Control Number 1076-0135, "Public Law 102-477 Reporting," was published in the **Federal Register** on October 1, 1999 (64 FR 53403-53404).

DATES: Written comments must be received by February 7, 2000.

ADDRESSES: Written comments should be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Department of the Interior, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503. A copy should be sent to Lynn Forcia, Office of Economic Development, Bureau of Indian Affairs, 1849 C Street, NW, Mail Stop 4640-MIB, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or additional copies of the information collection instructions and the October 1, 1999 *Federal Register* Notice (64 FR 53403-53404) should be directed to Lynn Forcia, Bureau of Indian Affairs, Department of the Interior, 1849 C Street, NW, MS 4640-MIB, Washington, DC 20240 and (202) 219-5270. (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: A Report System for the Public Law 102-477 Demonstration Project expires January 31, 2000. This is a request for an extension of a previously approved information collection request.

Abstract: The information collection is needed to document satisfactory compliance with statutory requirements of the various integrated programs. Public Law 102-477 authorizes tribal governments to integrate federally funded employment, training and related services programs into a single, coordinated, comprehensive service delivery plan. Funding agencies include the Department of the Interior, Department of Labor and the Department of Health and Human Services. The Bureau of Indian Affairs is statutorily required to serve as the lead agency. Section II of this Act requires that the Secretary of the Interior make available a single universal report format which shall be used by a tribal government to report on integrated activities and expenditures undertaken. The Bureau of Indian Affairs shares the information collected from these reports with the Department of Labor and Department of Health and Human Services.

Method of Collection: Tribal governments voluntarily participating in Public Law 102-477 are required to annually complete two single page, one-sided report forms and one narrative report, which includes four pages of instruction. They replace 166 pages of instructions and applications representing three different agencies and twelve different funded but related programs. We estimate a 95 percent

reduction in reporting, which is consistent with the Paperwork Reduction Act and goals of the National Performance Review. The statistical and narrative report will be used to demonstrate how well a plan was executed in comparison to proposed goals. The financial status report will be used to track cash flow, and will allow an analysis of activities versus expenditures and expenditures to approved budget. It is a slightly modified SF 269-A (short form). These report forms and narrative are limited but satisfy the Department of Health and Human Services, Department of Labor and the Department of the Interior. They reduce the burden on tribal governments by consolidating data collection for employment, training, education, child care and related service programs. The reports are due annually. These forms have been developed within a partnership between tribes and representatives of all three Federal agencies, to standardize terms and definitions, eliminate duplication and reduce frequency of collection.

Respondents: Tribes participating in Public Law 102-477 will report annually. We currently anticipate there will be 37 grantees participating in the program as of January 1, 2000.

Burden: We estimate that completion of the reporting requirements will require 10 hours per year to complete for each grantee, times 37 grants equals 370 burden hours.

Public Comments and Responses

All comments were considered in preparing BIA's response. The comments received relating to the information collection and OMB's responses are summarized below. The Office of Management and Budget verbally recommended that we add questions to the reporting forms in order to provide additional information for the Department of Labor's new Welfare to Work program.

The Public Law 102-477 Tribal Work Group formed a subcommittee to review all Public Law 102-477 report forms including the OMB requested additions. The subcommittee included representatives from the Central Council of Tlingit and Haida Indians, Kodiak Area Native Association, the Shoshone Bannock Tribes, the Cook Inlet Tribal Council, the Sisseton-Wahpeton Sioux Tribe and the Indian and Native American Employment and Training Coalition. The subcommittee responded to the three recommendations from the Office of Management and Budget as follows: two suggestions for the Program Statistical report form, and one sentence for the Narrative portion of the report:

1. "Welfare to Work recipients entered unsubsidized employment."

Tribal subcommittee response: In the program consolidation authorized under Public Law 102-477 grantees no longer identify participants in each activity separately because the funding sources are not identified for each participant. Therefore, the subcommittee recommended the following addition to the form, and we have added: "Long term TANF recipients entered unsubsidized employment."

2. "Placements with duration of 180 days or more."

Tribal subcommittee response: The subcommittee stated that tracking participants for 180 days is very costly in terms of additional time and expense that could otherwise be spent toward finding unsubsidized employment for individuals. Therefore, the subcommittee recommended that grantees track clients for 90 days instead of 180 days. Tracking participants for 90 days would also be consistent with existing Department of Labor, JTPA requirements and because the participants continue to remain eligible for services during those 90 days. Therefore, we have decided to add the following question to the form: "Placements with duration of 90 days or more."

3. "The narrative should show the extent of participants in any Welfare to Work activities; e.g., the number of participants and what activities were included."

Tribal subcommittee response: The subcommittee agreed with the Office of Management and Budget that it was appropriate to add one sentence to the narrative instruction as follows: "The narrative should show the extent of participants in any Welfare to Work activities; e.g., the number of participants and what activities were included."

The Bureau of Indian Affairs also received comments from five Public Law 102-477 grantees and one other interested party, stating that the existing format has allowed tribes to spend more providing services to clients and less time completing report forms. Grantees stated that initiation of a Public Law 102-477 program resulted in the integration of several programs and resulted in the elimination of distinction between related tribal employment and training participants based on the source of funds for the services. The grantees stated they wanted no additional information collection elements and requested a face-to-face meeting with OMB prior to making any changes to the existing forms. We did not receive any written

comments from any of the other participating Federal agencies. We have incorporated the additions recommended by the Public Law 102-477 subcommittee because we believe the additional information is necessary to provide the Department of Labor and the Office of Management and Budget with the information necessary to adequately manage and evaluate the Welfare to Work program. The collection of the additional information is the minimum amount of information needed to accomplish this goal and to limit information collection and reporting requirements for grantee tribes, many with limited resources.

OMB is required to make a decision concerning this information collection request between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment will receive the best consideration by OMB if it is submitted early during this comment period. Written comments and recommendations concerning this information collection should be sent directly to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for the Department of the Interior, Docket Library, Room 10102, 725 17th Street, NW, Washington, DC 20503.

Dated: December 22, 1999.

Kevin Gover,

Assistant Secretary—Indian Affairs.

[FR Doc. 00-282 Filed 1-5-00; 8:45 am]

BILLING CODE 4310-02-P

OVERSEAS PRIVATE INVESTMENT CORPORATION

Submission for OMB Review; Comment Request

AGENCY: Overseas Private Investment Corporation (OPIC).

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 has prepared an information collection request for OMB review and approval and has requested public review and comment on the submission. OPIC published its first **Federal Register** Notice on this information collection request on October 20, 1999, in 64 FR #202, p. 56514, at which time a 60-calendar day comment period was announced. This comment period ended December 20, 1999. No comments were received in response to this Notice.

This information collection submission has now been submitted to

OMB for review. Comments are again 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 within 30 calendar days of this Notice.

ADDRESSES: Copies of the subject form and the request for review submitted to OMB may be obtained from the Agency Submitting Officer. Comments on the form should be submitted to the OMB Reviewer.

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.

OMB Reviewer: David Rostker, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Docket Library, Room 10102, 725 17th Street, NW., Washington, DC 20503, 202/395-3897.

Summary of Form Under Review

Type of Request: Approval of a revised form combining two existing forms, one for U.S. and one for foreign sponsors: OPIC 129 (OMB 3420-0018), which expires 1/31/2000, and OPIC 130 (OMB 3420-0017) which expires 2/29/2000, respectively.

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.

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: January 3, 2000.

Ralph Kaiser,

Senior Counsel for Administration,
Department of Legal Affairs.

[FR Doc. 00-295 Filed 1-5-00; 8:45 am]

BILLING CODE 3210-01-M

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review; Comment Request

December 30, 1999.

The Department of Labor (DOL) has submitted the following public information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. Chapter 35). A copy of the 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 at Mills-Ira@dol.gov.

Comments should be sent to the Office of Information and Regulatory Affairs, Attn: Desk Officer for Pension and Welfare Benefits Administration, Office of Management and Budget, Room 10235, Washington, DC 20503 ((202) 395-7316), within 30 days of the date of this publication in the **Federal Register**.

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: Department of Labor, Pension and Welfare Benefits Administration.

Title: Summary Plan Description Requirements under ERISA.

OMB Numbers: 1210-0039.

Frequency: On occasion.

Affected Public: Individuals or households; business or other for-profit; not-for-profit institutions.

Total Respondents: 2,641,818.

Total Responses: 160,703,000.

Estimated Total Burden Hours: 576,467.¹

Total Annualized Capital/Start-up costs: \$0.

Total Annual Cost (Operating and Maintenance): \$96,859,000.²

Description: Section 104(b)(1) of the Employee Retirement Security Act of 1974 (ERISA) requires that the administrator of an employee benefit plan furnish plan participants and beneficiaries with Summary Plan Descriptions (SPDs) which describe, in language understandable to an average plan participant, the benefits, rights and obligations of the participants in the plan. Plan administrators are required to furnish SPDs to participants and beneficiaries within 90 days after the participant is covered by the plan. The information required to be contained in the SPD is set forth in section 102(b) of the statute. To the extent that there is a material modification in the terms of the plan or a change in the information required to be contained in the SPD, section 104(b)(1) requires that the administrator furnish participants and beneficiaries with a summary of such changes within 210 days following the end of the plan year in which the change was adopted. Regulations published at 29 CFR 2520.102-3 provide guidance on the required contents of the SPD.

Ira L. Mills,

Departmental Clearance Officer.

[FR Doc. 00-265 Filed 1-5-00; 8:45 am]

BILLING CODE 4510-29-M

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Submissions to OMB for Reinstatement of Currently Approved Information Collections; Comment Request

AGENCY: National Credit Union Administration (NCUA).

ACTION: Request for comment.

SUMMARY: The NCUA intends to submit the following information collections to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. Chapter 35). These information collections are published to obtain comments from the public.

DATES: Comments will be accepted until March 6, 2000.

ADDRESSES: Interested parties are invited to submit written comments to NCUA Clearance Officer or OMB Reviewer listed below:

Clearance Officer: Mr. James L. Baylen, (703) 518-6411, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314-3428, Fax No. 703-518-6433, E-mail: jbaylen@ncua.gov.

OMB Reviewer: Alexander T. Hunt, (202) 395-7860, Office of Management and Budget, Room 10226, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Copies of the information collection requests, with applicable supporting documentation, may be obtained by calling the NCUA Clearance Officer, James L. Baylen, (703) 518-6411.

SUPPLEMENTARY INFORMATION: Proposal for the following collections of information:

OMB Number: 3133-0059.

Form Number: NA.

Type of Review: Extension of Currently Approved Collection.

Title: Part 715, NCUA Rules and Regulations (Existing §§ 701.12 and 701.13).

Description: The rule specifies the minimum annual audit a credit union is required to obtain according to its charter type and asset size, the licensing authority required of persons performing certain audits, the auditing principles that apply to certain audits, and the accounting principles that must be followed in reports filed with the NCUA Board.

Respondents: Federal credit unions.

Estimated No. of Respondents/Recordkeepers: 12,000.

Estimated Burden Hours Per Response: 5.75 hours.

Frequency of Response: Reporting and annually.

Estimated Total Annual Burden Hours: 100,906.

Estimated Total Annual Cost: None.

OMB Number: 3133-0137.

Form Number: NA.

Type of Review: Extension of Currently Approved Collection.

Title: Community Development Revolving Loan Program for Credit Unions Application for Funds.

Description: NCUA requests this information from credit unions to assess financial ability to repay the loans and to ensure that the funds are used to benefit the institution and community it serves.

Respondents: Federal credit unions.

Estimated No. of Respondents/Recordkeepers: 25.

Estimated Burden Hours Per Response: 8 hours.

Frequency of Response: Reporting and on occasion.

Estimated Total Annual Burden Hours: 200.

Estimated Total Annual Cost:

\$3,126.00.

By the National Credit Union Administration Board on December 23, 1999.
Becky Baker,

Secretary of the Board.

[FR Doc. 00-281 Filed 1-5-00; 8:45 am]

BILLING CODE 7535-01-U

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Submission to OMB for Reinstatement of Currently Approved Information Collections; Comment Request

AGENCY: National Credit Union Administration (NCUA).

ACTION: Request for comment.

SUMMARY: The NCUA intends to submit the following information collections to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (Public Law 104-13, 44 U.S.C. Chapter 35). These information collections were originally published on October 28, 1999. No comments were received.

DATES: Comments will be accepted until February 7, 2000.

ADDRESSES: Interested parties are invited to submit written comments to NCUA Clearance Officer or OMB Reviewer listed below:

Clearance Officer: Mr. James L. Baylen (703) 518-6411, National Credit

¹ This figure does not include estimated burden hours associated with PWBA's Notice of Proposed Rulemaking (63 FR 4506, September 9, 1998) which, if finalized as proposed, would amend the required content of Summary Plan Descriptions under ERISA and result in estimated burden of 1,928,889 hours.

² This figure does not include estimated costs associated with PWBA's Notice of Proposed Rulemaking (63 FR 4506, September 9, 1998) which, if finalized as proposed, would amend the required content of Summary Plan Descriptions under ERISA and result in estimated cost burden of \$216,316,365.

Union Administration, 1775 Duke Street, Alexandria, VA 22314-3428; Fax: 703-518-6433, e-mail: jbaylen@ncua.gov.

OMB Reviewer: Alexander T. Hunt (202) 395-7860, Office of Management and Budget, Room 10226, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Copies of the information collection requests, with applicable supporting documentation, may be obtained by calling the NCUA Clearance Officer, James L. Baylen, (703) 518-6411.

SUPPLEMENTARY INFORMATION: Proposal for the following collections of information:

OMB Number: 3133-0155.

Form Number: CLF 8705.

Type of Review: Extension of a currently approved collection.

Title: Central Liquidity Facility Prepayment, Security and Credit Reporting Agreement (Agent Member).

Description: Form used in conjunction with agent member's request for facility advances.

Respondents: Credit unions.

Estimated No. of Respondents/Recordkeepers: 36.

Estimated Burden Hours per Response: 1 hour.

Frequency of Response: Reporting: once.

Estimated Total Annual Burden Hours: 36.

Estimated Total Annual Cost: None.

OMB Number: 3133-0156.

Form Number: NCUA-7005.

Type of Review: Extension of a currently approved collection.

Title: Central Liquidity Facility Agent Request for Funds.

Description: Form used by agent member requesting a facility advance.

Respondents: Credit unions.

Estimated No. of Respondents/Recordkeepers: 40.

Estimated Burden Hours per Response: .25 hours.

Frequency of Response: Reporting: estimated 3 times.

Estimated Total Annual Burden Hours: 30.

Estimated Total Annual Cost: None.

OMB Number: 3133-0157.

Form Number: CLF-8706.

Type of Review: Extension of a currently approved collection.

Title: Central Liquidity Facility Repayment, Security and Credit Reporting Agreement (Agent Group Representative).

Description: Form used in conjunction with agent member's request for facility advance.

Respondents: Credit unions.

Estimated No. of Respondents/Recordkeepers: 36.

Estimated Burden Hours per Response: 1 hour.

Frequency of Response: Reporting: once.

Estimated Total Annual Burden Hours: 36.

Estimated Total Annual Cost: None.

OMB Number: 3133-0158.

Form Number: CLF-8700.

Type of Review: Extension of a currently approved collection.

Title: Central Liquidity Facility Application and Agreement for Agent Membership.

Description: Used to request agent membership in central liquidity facility.

Respondents: Credit unions.

Estimated No. of Respondents/Recordkeepers: 36.

Estimated Burden Hours Per Response: 1 hour.

Frequency of Response: Reporting: once.

Estimated Total Annual Burden Hours: 36.

Estimated Total Annual Cost: None.

OMB Number: 3133-0159.

Form Number: CLF-10.

Type of Review: Extension of a currently approved collection.

Title: Central Liquidity Facility Needs Loan Application.

Description: Establishes terms of relationship between credit unions, agent members and agent group representatives.

Respondents: Credit unions.

Estimated No. of Respondents/Recordkeepers: 100.

Estimated Burden Hours Per Response: .25 hours.

Frequency of Response: Reporting.

Estimated Total Annual Burden Hours: 25 hours.

Estimated Total Annual Cost: None.

By the National Credit Union Administration Board on December 23, 1999.

Becky Baker,

Secretary of the Board.

[FR Doc. 00-280 Filed 1-5-00; 8:45 am]

BILLING CODE 7535-01-U

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meeting; Notice

AGENCY HOLDING MEETING: National Science Foundation, National Science Board.

DATE AND TIME: January 13, 2000: 4 p.m., Closed Session.

PLACE: The National Science Foundation, 4201 Wilson Boulevard, Room 1205, Arlington, VA 22230.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED:

Closed Session (4:00 p.m.-5:00 p.m.)

—Future Budgets

—Science & Engineering Indicators—2000

Marta Cehelsky,

Executive Officer.

[FR Doc. 00-425 Filed 1-4-00; 3:43 pm]

BILLING CODE 7555-01-M

NUCLEAR REGULATORY COMMISSION

[Docket No. 50-400]

Carolina Power & Light Company; (Shearon Harris Nuclear Power Plant, Unit No. 1); Order Approving Application Regarding Proposed Corporate Restructuring of Carolina Power & Light Company by Establishment of a Holding Company

I

CP&L and the North Carolina Eastern Municipal Power Agency are the holders of Facility Operating License No. NPF-63 for Shearon Harris Nuclear Power Plant, Unit No. 1 (Harris), issued January 12, 1987. CP&L owns an 83.83% interest in Harris.

II

Pursuant to Section 184 of the Atomic Energy Act of 1954, as amended, and 10 C.F.R. § 50.80, CP&L filed an application dated September 15, 1999, which was supplemented by letters dated October 8, and November 10, 1999, requesting approval of the indirect transfer of Facility Operating License No. NPF-63 for Harris that would result from a proposed corporate restructuring of CP&L. Under the proposed restructuring, a new holding company, CP&L Holdings, Inc. ("Holdings"), will be formed and will become the parent company of CP&L. Current holders of CP&L common stock will receive, on a one-for-one basis, shares of common stock of Holdings such that Holdings will then own the common stock of CP&L. CP&L's ownership interests in, and its operation of, its nuclear facilities will not change. No direct transfer of the license will occur, as CP&L will continue to hold the license. No physical changes to the facility, or operational changes are being proposed in the application. According to the application, as a result of the new corporate structure, Holdings will be able to respond more effectively to increased competition in the energy industry. Notice of the application and

an opportunity for a hearing was published in the **Federal Register** on November 2, 1999 (64 FR 59220). No hearing requests were filed.

Under 10 CFR 50.80, no license shall be transferred, directly or indirectly, through transfer of control of the license, unless the Commission gives its consent in writing. Upon review of the information submitted by CP&L in its application, as supplemented, and other information before the Commission, the NRC staff has determined that the proposed restructuring of CP&L will not affect the qualifications of CP&L as holder of the license referenced above, and that the indirect transfer of the license, to the extent effected by the restructuring, is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission subject to the conditions set forth herein. These findings are supported by a Safety Evaluation dated December 29, 1999.

III

Accordingly, pursuant to Sections 161b, 161i, 161o, and 184 of the Atomic Energy Act of 1954, as amended, 42 USC §§ 2201(b), 2201(i), 2201(o) and 2234; and 10 CFR 50.80, *IT IS Hereby Ordered* that the application regarding the subject indirect transfer is approved, subject to the following conditions:

(1) CP&L shall provide the Director of the Office of Nuclear Reactor Regulation a copy of any application, at the time it is filed, to transfer (excluding grants of security interests or liens) from CP&L to its proposed parent or to any other affiliated company, facilities for the production, transmission, or distribution of electric energy having a depreciated book value exceeding ten percent (10%) of CP&L's consolidated net utility plant, as recorded on CP&L books of account, and

(2) should the restructuring of CP&L not be completed by December 30, 2000, this Order shall become null and void, provided, however, on application and for good cause shown, such date may be extended.

This Order is effective upon issuance.

For further details with respect to this action, see the initial application dated September 15, 1999, and supplements dated October 8, and November 10, 1999, and the Safety Evaluation dated December 29, 1999, which are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and accessible electronically through the ADAMS Public Electronic Reading Room link at the NRC Website (<http://www.nrc.gov>).

Dated at Rockville, Maryland, this 29th day of December 1999.

For the Nuclear Regulatory Commission.

Samuel J. Collins,

Director, Office of Nuclear Reactor Regulation.

[FR Doc. 00-252 Filed 1-5-00; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50-261 and 72-3]

In the Matter of Carolina Power and Light Company; (H.B.* Robinson Steam Electric Plant, Unit No. 2, and Independent Spent Fuel Storage Installation); Order Approving Application Regarding Proposed Corporate Restructuring of Carolina Power & Light Company by Establishment of a Holding Company

I

Carolina Power and Light Company (CP&L) owns a 100% interest in H. B. Robinson Steam Electric Plant, Unit No. 2 (Robinson) and the Robinson Independent Spent Fuel Storage Installation (ISFSI), and is the licensed operator of the facilities pursuant to Facility Operating License No. DPR-23, and Materials License No. SNM-2502, which were issued July 31, 1970, and August 13, 1986, respectively. Robinson and the associated ISFSI are located in Darlington County, South Carolina.

II

Pursuant to Section 184 of the Atomic Energy Act of 1954, as amended, and 10 C.F.R. §§ 50.80 and 72.50, CP&L filed an application dated September 15, 1999, which was supplemented by letters dated October 8, and November 10, 1999, requesting approval of the indirect transfer of Facility Operating License No. DPR-23 and Materials License No. SNM-2502 that would result from a proposed corporate restructuring of CP&L. Under the proposed restructuring, a new holding company, CP&L Holdings, Inc. ("Holdings"), will be formed and will become the parent company of CP&L. Current holders of CP&L common stock will receive, on a one-for-one basis, shares of common stock of Holdings such that Holdings will then own the common stock of CP&L. CP&L's ownership interests in, and its operation of, its nuclear facilities will not change. No direct transfer of the licenses will occur, as CP&L will continue to hold the licenses. No physical changes to the facilities or the ISFSI, or operational changes are being proposed in the application. According

to the application, as a result of the new corporate structure, Holdings will be able to respond more effectively to increased competition in the energy industry. Notice of the application and an opportunity for a hearing was published in the **Federal Register** on November 2, 1999 (64 FR 59220). No hearing requests were filed.

Under 10 CFR 50.80 and 72.50, no license shall be transferred, directly or indirectly, through transfer of control of the license, unless the Commission gives its consent in writing. Upon review of the information submitted by CP&L in its application, as supplemented, and other information before the Commission, the NRC staff has determined that the proposed restructuring of CP&L will not affect the qualifications of CP&L as holder of the licenses referenced above, and that the indirect transfer of the licenses, to the extent effected by the restructuring, is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission subject to the conditions set forth herein. These findings are supported by a Safety Evaluation dated December 29, 1999.

III

Accordingly, pursuant to Sections 161b, 161i, 161o, and 184 of the Atomic Energy Act of 1954, as amended, 42 U.S.C. §§ 2201(b), 2201(i), 2201(o) and 2234; and 10 CFR §§ 50.80 and 72.50, *It is hereby ordered* that the application regarding the subject indirect transfers is approved, subject to the following conditions:

(1) CP&L shall provide the Director of the Office of Nuclear Reactor Regulation and the Director of the Office of Nuclear Material Safety and Safeguards a copy of any application, at the time it is filed, to transfer (excluding grants of security interests or liens) from CP&L to its proposed parent or to any other affiliated company, facilities for the production, transmission, or distribution of electric energy having a depreciated book value exceeding ten percent (10%) of CP&L's consolidated net utility plant, as recorded on CP&L books of account, and

(2) Should the restructuring of CP&L not be completed by December 30, 2000, this Order shall become null and void, provided, however, on application and for good cause shown, such date may be extended.

This Order is effective upon issuance.

For further details with respect to this action, see the initial application dated September 15, 1999, and supplements dated October 8, and November 10, 1999, and the Safety Evaluation dated

December 29, 1999, which are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and accessible electronically through the ADAMS Public Electronic Reading Room link at the NRC Website (<http://www.nrc.gov>).

Dated at Rockville, Maryland, this 29th day of December 1999.

For the Nuclear Regulatory Commission,
William F. Kane,
Director, Office of Nuclear Material Safety
and Safeguards.

Samuel J. Collins,
Director, Office of Nuclear Reactor
Regulation.

[FR Doc. 00-255 Filed 1-5-00; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50-237 and 50-249]

Commonwealth Edison Company (Dresden Nuclear Power Station, Units 2 and 3); Exemption

I

Commonwealth Edison Company (ComEd, the licensee) is the holder of Facility Operating Licenses Nos. DPR-19 and DPR-25 for the Dresden Nuclear Power Station, Units 2 and 3. The licenses provide, among other things, that the licensee is subject to all rules, regulations, and orders of the Commission now or hereafter in effect.

Dresden Nuclear Power Station consists of two boiling water reactors located in Grundy County, Illinois.

II

Title 10 of the *Code of Federal Regulations* (10 CFR), Section 50.48, "Fire protection," paragraph (b) states, in part, that "all nuclear power plants licensed to operate prior to January 1, 1979 shall satisfy the applicable requirements of appendix R to this part, including specifically the requirements of sections III.G, III.J, and III.O." Appendix R, Section III.J, "Emergency lighting," requires that "Emergency lighting units with at least an 8-hour battery power supply shall be provided in all areas needed for operation of safe shutdown equipment and in access and egress routes thereto." This requirement applies to Dresden Nuclear Power Station, Units 2 and 3, since they were licensed to operate prior to January 1, 1979.

III

Section 50.12(a) of 10 CFR, "Specific exemptions," states:

The Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of the regulations of this part, which are—

(1) Authorized by law, will not present an undue risk to the public health and safety, and are consistent with the common defense and security.

(2) The Commission will not consider granting an exemption unless special circumstances are present.

Section 50.12(a)(2) of 10 CFR states that special circumstances are present whenever "(i) Application of the regulation in the particular circumstances * * * is not necessary to achieve the underlying purpose of the rule * * *."

Equipment needed for safe shutdown at Dresden, Units 2 and 3, is maintained inside the main power block and several buildings onsite. Emergency lighting is provided inside these buildings for areas needed for operation of safe shutdown equipment and for access and egress routes in accordance with 10 CFR Part 50, Appendix R, Section III.J. However, no emergency lighting meeting Section III.J requirements has been installed for outdoor routes between the main power block, the isolation condenser pumphouse, the cribhouse, or at the clean demineralized water storage tank (CDST). Because of cost and maintenance considerations, and after determining that application of Section III.J was not necessary to achieve the underlying purpose of the rule, the licensee submitted an exemption request with respect to emergency lighting for these outdoor routes and for reading the CDST level instrument.

The requested exemption from the requirements of Appendix R, Section III.J, would allow the use of hand-held portable lights, in the event that sufficient daylight or security lighting is not available, when transiting access and egress routes between the main power block, the isolation condenser pumphouse, the cribhouse, and the CDST, including reading the CDST level instrument. These buildings contain equipment relied upon in the detailed fire plans to mitigate the consequences of a fire that could affect the capability to place the reactor in cold shutdown. As stated above, emergency lighting is maintained within these structures as required by Appendix R, Section III.J. However, access and egress between these buildings, the CDST, and the main power block requires walking outdoors. These areas are normally lit by outdoor lighting powered by offsite power or emergency power from the security diesel. However, the normally installed

outdoor and security lighting does not meet the Appendix R requirements for an 8-hour battery power supply.

Under the proposed exemption, in the worst-case scenarios that postulate a fire concurrent with a loss of offsite power, the hand-held, battery-powered, portable lighting units currently maintained on site near the main control room would be used by the operations staff to allow transit between buildings and reading the CDST level instrument as required by the fire plans and operations procedures. The transit routes through these areas are along normally traveled and paved plant roadways that are maintained clear of obstructions and are provided snow removal. The portable lighting units provide an adequate level of illumination for transit and reading the CDST level instrument.

The hand-held, battery-powered, portable lighting units are administratively controlled and dedicated for operator use to perform safe shutdown activities during and following plant fires. These portable lighting units are verified to be functional in quarterly surveillance.

The underlying purpose of 10 CFR Part 50, Appendix R, Section III.J, is to provide adequate illumination to assure the capability of performing all necessary safe shutdown functions, as well as to assure personnel movement to and from the equipment and components that must be manually operated by plant personnel to effect safe shutdown during emergencies. In addition, the illumination must have a capability to allow sufficient time for normal lighting to be restored.

The availability of hand-held, battery-powered portable lights would serve the underlying purpose of the rule with respect to transit between the main power block, the isolation condenser pumphouse, the cribhouse, and the CDST, in that the use of such hand-held lights would provide adequate illumination to permit access to and egress from buildings containing safe shutdown equipment and components and reading the CDST level instrument. In addition, such hand-held lights would be available for use during an 8-hour period as required by the regulation.

The implementation of outdoor battery powered lighting units would result in expenditure of engineering, construction, and plant resources for their installation, maintenance, and operation. The associated costs would include engineering and installation of additional lighting units and supporting structures and increase surveillance and

maintenance of the additional lighting units.

On the basis of its evaluation, the staff concludes that with the availability of hand-held battery-powered portable lights for use during transit between site structures described above and for reading the CDST level instrument, the installation of emergency lighting units with at least an 8-hour battery supply for these transit routes and the CDST level instrument is not necessary to achieve the underlying purpose of Section III.J of Appendix R to 10 CFR Part 50. Thus, special circumstances are present as defined in 10 CFR 50.12(a)(2)(ii). The staff has further determined that, pursuant to 10 CFR 50.12, the requested exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security. Accordingly, the licensee's request for an exemption from the requirements of Section III.J to 10 CFR Part 50 to allow the use of alternate means of lighting for access and egress routes between the main power block, the isolation condenser pumphouse, the cribhouse, the CDST, and for reading the CDST level instrument at Dresden, Units 2 and 3, is acceptable to the staff.

In consideration of the foregoing, the Commission hereby grants the licensee an exemption from the requirements of 10 CFR Part 50, Appendix R, Section III.J, to provide emergency lighting units with at least an 8-hour battery power supply in all areas needed for operation of safe shutdown equipment and in access and egress routes thereto, for access and egress routes between the main power block, the isolation condenser pumphouse, the cribhouse, the CDST, and for reading the CDST level instrument at Dresden, Units 2 and 3, to the extent alternative means of lighting as described herein are available.

Pursuant to 10 CFR 51.32, the Commission has determined that granting of this exemption will have no significant effect on the quality of the human environment (64 FR 72701).

This exemption is effective upon issuance.

Dated at Rockville, Maryland, this 30th day of December 1999.

For the Nuclear Regulatory Commission.

Suzanne C. Black,

Acting Director, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.

[FR Doc. 00-254 Filed 1-5-00; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50-346]

FirstEnergy Nuclear Operating Company, Davis-Besse Nuclear Power Station, Unit 1; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is considering the issuance of exemptions from the provisions of: (1) 10 CFR 50.44, "Standards for Combustible Gas Control System in Light-Water-Cooled Power Reactors," which states requirements to control the hydrogen generated by Zircaloy or ZIRLO fuel cladding after a postulated loss-of-coolant accident (LOCA); (2) 10 CFR 50.46, "Acceptance Criteria for Emergency Core Cooling Systems for Light-Water Nuclear Power Reactors," which requires the calculated emergency core cooling system (ECCS) performance for reactors with Zircaloy or ZIRLO fuel cladding to meet certain criteria; and (3) Appendix K to 10 CFR Part 50, "ECCS Evaluation Models," which presumes the use of Zircaloy or ZIRLO fuel cladding when doing calculations for energy release, cladding oxidation and hydrogen generation after a postulated LOCA, for Facility Operating License No. NPF-3, issued to the FirstEnergy Nuclear Operating Company (the licensee), for operation of the Davis-Besse Nuclear Power Station, Unit 1, located in Ottawa County, Ohio.

Environmental Assessment

Identification of the Proposed Action

The licensee has requested exemptions from 10 CFR 50.44, 10 CFR 50.46 and 10 CFR 50 Appendix K regarding the proposed use of M5 advanced alloy for fuel assemblies. The proposed action would allow the licensee to use fuel assemblies with fuel rod cladding that falls outside of the definition of Zircaloy and ZIRLO in the cited regulations. These assemblies would be loaded into the Davis-Besse reactor during the refueling outage in the spring of 2000. The proposed action is in accordance with the licensee's application for exemption dated September 15, 1998.

Need for the Proposed Action

10 CFR 50.46(a)(1)(i) and Appendix K to 10 CFR Part 50 require the demonstration of adequate ECCS performance for light-water reactors that contain fuel consisting of uranium oxide pellets enclosed in Zircaloy or ZIRLO tubes. In addition, 10 CFR 50.44(a) addresses requirements to control

hydrogen generated by Zircaloy or ZIRLO fuel after a postulated LOCA. Each of these three regulations, either implicitly or explicitly, assume that either Zircaloy or ZIRLO is used as the fuel rod cladding material. In order to accommodate the high fuel rod burnups that are required for modern fuel management and core designs, Framatome Technologies, Inc. developed the M5 advanced fuel rod cladding and fuel assembly structural material. M5 is an alloy comprised primarily of zirconium (~99 percent) and niobium (~1 percent) that has demonstrated superior corrosion resistance and reduced irradiation induced growth relative to both standard and low-tin Zircaloy. However, since the chemical composition of the M5 advanced alloy differs from the specifications of either Zircaloy or ZIRLO, use of the M5 advanced alloy falls outside of the strict interpretation of these regulations. Therefore, approval of these exemptions is needed to permit the use of the M5 advanced alloy as a fuel rod cladding material at the Davis-Besse Nuclear Power Station.

10 CFR 50.12 permits the Nuclear Regulatory Commission to grant exemptions which are authorized by law, will not present an undue risk to the health and safety of the public, and are consistent with the common defense and security, provided that special circumstances are present. Pursuant to 10 CFR 50.12(a)(2)(ii), the Commission believes that special circumstances exist since application of the rule in this case would not achieve the underlying purpose of the rule. The underlying purpose of 10 CFR 50.46 and Appendix K to 10 CFR Part 50 is to establish requirements for emergency core cooling systems. The underlying purpose of 10 CFR 50.44 is to control hydrogen generated by the metal/water reaction after a postulated LOCA, regardless of fuel cladding material. The licensee addressed the safety impact of using M5 fuel in its amendment application dated September 8, 1998.

The staff has evaluated this impact and has concluded that use of the M5 advanced alloy as a fuel rod cladding material remains bounded by the original design basis for the Davis-Besse facility. Therefore, since the underlying purposes of 10 CFR 50.44, 10 CFR 50.46, and 10 CFR 50 Appendix K are achieved through the use of the M5 advanced alloy as a fuel rod cladding material, the special circumstances required by 10 CFR 50.12(a)(2)(ii) for the granting of exemptions are met.

Environmental Impacts of the Proposed Action

With regard to potential radiological impacts to the general public, the exemptions under consideration involve features located entirely within the restricted area as defined in 10 CFR Part 20. The new fuel assemblies meet the same design bases as the fuel that is currently in the reactor. No safety limits have been changed or setpoints altered as a result of the use of these new assemblies. The FSAR analyses are bounding for the new assemblies as well as for the rest of the core. The advanced zirconium-based alloys Zircaloy and ZIRLO have been shown through testing to perform satisfactorily under conditions representative of a reactor environment and the material properties of M5 are very similar to these alloys.

With regard to the potential environmental impacts associated with the transportation of the M5 clad fuel assemblies, the advanced cladding has no impact on previous assessments determined in accordance with 10 CFR 51.52.

The proposed action will not significantly 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 nonradiological impacts, the proposed action does not involve any historic sites. It does not affect nonradiological plant effluents and has no other environmental impact. Therefore, there are no significant nonradiological environmental impacts associated with the proposed action.

Accordingly, the NRC 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 Related to the Operation of Davis-Besse Nuclear Power Station, Unit 1," dated October 1975.

Agencies and Persons Consulted

In accordance with its stated policy, on December 7, 1999, the staff consulted with the Ohio State official, Carol O'Claire, of the Ohio Emergency Management Agency, regarding the environmental impact of the proposed action. The State official had no comments.

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 September 15, 1998, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC. Publicly available records will be accessible electronically from the ADAMS Public Library component on the NRC Web site, <http://www.nrc.gov> (the Electronic Reading Room).

Dated at Rockville, Maryland, this 30th day of December 1999.

For the Nuclear Regulatory Commission.

Anthony J. Mendiola,
Chief, Section 2, Project Directorate III,
Division of Licensing Project Management,
Office of Nuclear Reactor Regulation.

[FR Doc. 00-251 Filed 1-5-00; 8:45 am]

BILLING CODE 7590-01-P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 24227; 812-11670]

New Covenant Funds and New Covenant Trust Company, N.A.; Notice of Application

December 29, 1999.

AGENCY: Securities and Exchange Commission ("Commission").

ACTION: Notice of an application for an order under section 6(c) of the Investment Company Act of 1940 (the "Act") for an exemption from section 15(a) of the Act and rule 18f-2 under the Act.

SUMMARY OF APPLICATION: The requested order would permit applicants, New Covenant Funds (the "Investment

Company") and New Covenant Trust Company, N.A. (the "Adviser"), to enter into and materially amend subadvisory agreements without obtaining shareholder approval.

FILING DATES: The application was filed by July 2, 1999, and amended on November 8, 1999. Applicants have agreed to file an amendment during the notice period, the substance of which is reflected in this notice.

HEARING OF NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on January 24, 2000, and should be accompanied by proof of service on applicants, in the form of an affidavit, or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, Commission, 450 Fifth Street, NW., Washington, DC 20549-0609; Applicants, 200 East 12th Street, Jeffersonville, Indiana 47130.

FOR FURTHER INFORMATION CONTACT: Deepak T. Pai, Senior Counsel, at (202) 942-0574 or George J. Zornada, Branch Chief, at (202) 942-0564, (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the Commission's Public Reference Branch, 450 Fifth Street, NW, Washington, DC 20549-0102 (202) 942-8090.

Applicants' Representations

1. The Investment Company, a Delaware business trust, is registered under the Act as an open-end management investment company. The Investment Company offers shares in four separate series: New Covenant Growth Fund, New Covenant Balanced Growth Fund, New Covenant Income Fund, and New Covenant Balanced Income Fund (the "Funds"), each with its own distinct investment objectives, policies, and restrictions.¹

¹ Applicants also request relief for (a) any series of the Investment Company organized in the future ("Future Series"), and (b) any registered open-end management investment companies or series of those companies advised in the future by the

2. The Adviser is not required to be registered as an investment adviser under the Investment Advisers Act of 1940 (the "Advisers Act"). The Advisers serves an investment adviser to each Fund pursuant to an investment management agreement between the Adviser and the Investment Company ("Investment Management Agreement"). The Investment Management Agreement has been approved by the initial shareholder of each Fund and by a majority of the Investment Company's board of trustees ("Board"), including a majority of the trustees who are not "interested persons" (as defined in section 2(a)(19) of the Act) (the "Independent Trustees").

3. Under the Investment Management Agreement, the Adviser, subject to Board oversight, provides general management of the Funds' operations. The Advisers seeks to enhance performance and reduce market risk by allocating management of the assets of certain of the Funds among multiple specialist subadvisers ("Subadvisers"). Under investment subadvisory agreements ("Investment Subadvisory Agreements"), the specific investment decisions for each Fund are made by one or more Subadvisers, each of whom has discretionary authority to invest all or a portion of the assets of a particular Fund, subject to general supervision by the Adviser and the Board. Currently, the Adviser employs eight Subadvisers, each of which is registered under the Advisers Act. Any future Subadviser will be registered under the Advisers Act or will be exempt from registration. The Adviser monitors the performance of each Fund and each Subadviser and will recommend that the Board employee or terminate particular Subadvisers to achieve the overall investment objectives of a particular Fund. The Adviser pays the Subadvisers' fees out of the fees the Adviser receives from the Funds. The Adviser selects Subadvisers for the Funds based on the continuing quantitative and qualitative evaluation of their skills and proven abilities in managing assets pursuant to a particular investment style.

4. Applicants request relief to permit the Adviser to enter into and materially amend Investment Subadvisory Agreements without obtaining

shareholder approval. The requested relief will not extend to a Subadviser that is an "affiliated person," as defined in section 2(a)(3) of the Act, of the Investment Company or the Adviser, other than by reason of serving as a Subadviser to one or more of the Funds (an "Affiliated Subadviser"). None of the current Subadvisers is an Affiliated Subadviser.

Applicants' Legal Analysis

1. Section 15(a) of the Act provides, in relevant part, that it is unlawful for any person to act as an investment adviser to a registered investment company except under a written contract approved by a majority of the investment company's outstanding voting shares. Rule 18f-2 under the Act provides that each series or class of stock in a series company affected by a matter must approve the matter if the Act requires shareholder approval.

2. Section 6(c) of the Act provides that the Commission may exempt persons or transactions from the provisions of the Act, or from any rule thereunder, to the extent that the exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policies and provisions of the Act. Applicants request an exemption under section 6(c) of the Act from section 15(a) of the Act and rule 18f-2 under the Act to permit them to enter into and materially amend Investment Subadvisory Agreements without shareholder approval.

3. Applicants assert that a Fund's investors rely on the Adviser for investment management services and submit that the role of the Subadvisers, from the perspective of the investor, is comparable to that of the individual portfolio advisers employed by other advisory firms. Applicants contend that requiring shareholder approval of the Investment Subadvisory Agreements would increase the Investment Company's expenses and delay the prompt implementation of actions considered advisable by the Board. Applicants note that the Investment Management Agreement will continue to be fully subject to section 15 of the Act and rule 18f-2 thereunder.

Applicants' Conditions

Applicants agree that any order granting the requested relief will be subject to the following conditions:

1. Before a Fund or a Future Fund may rely on the order requested in the application, the operation of the Fund or a Future Fund in the manner described in the application will be approved by a majority of the Fund's or

Future Fund's outstanding voting securities, as defined in the Act, or, in the case of a Fund or Future Fund whose public shareholders purchased shares on the basis of a prospectus containing the disclosure contemplated by condition 2 below, by the sole initial shareholder(s) before offering shares of such Fund or Future Fund to the public.

2. Any Fund or Future Fund relying on the requested relief will disclose in its prospectus the existence, substance, and effect of any order granted pursuant to the application. In addition, any such Fund will hold itself out to the public as employing the "Subadviser" structure described in the application. The prospectus with respect to the Funds and any Future Fund will prominently disclose that the Adviser has the ultimate responsibility (subject to oversight by the Board) to oversee the Subadvisers and recommend their hiring, termination and replacement.

3. The Adviser will provide general management services to the Investment Company and the Funds, including overall supervisory responsibility for the general management and investment of each Fund, and, subject to review and approval by the Board will (i) set each Fund's overall investment strategies; (ii) evaluate, select, and recommend Subadvisers to manage all or a part of Fund's assets; (iii) when appropriate, allocate and reallocate a Fund's assets among Subadvisers; (iv) monitor and evaluate the performance of Subadvisers; and (v) implement procedure reasonably designed to ensure that the Subadvisers comply with the relevant Fund's investment objective, policies, and restrictions.

4. At all times, a majority of the Board will be Independent Trustees, and the nomination of new or additional Independent Trustees will be placed within the discretion of the then existing Independent Trustees.

5. Neither the Investment Company nor the Adviser will enter into Investment Subadvisory Agreements on behalf of the Funds with any Affiliated Subadviser without such agreement, including the compensation to be paid thereunder, being approved by the shareholders of the applicable Fund.

6. When a change of Subadviser is proposed for a Fund with an Affiliated Subadviser, the Board, including a majority of the Independent Trustees, will make a separate finding, reflected in the minutes of meetings of the Board that any change of Subadviser is in the best interest of the Fund and its shareholders, and does not involve a conflict of interest from which the Adviser or Affiliated Subadviser derives an inappropriate advantage.

Adviser or a person controlling, controlled by, or under common control (within the meaning of section 2(a)(9) of the Act) with the Adviser that uses the adviser/subadviser structure described in the application and complies with the terms and conditions of the application (together with Future Series, "Future Funds"). Each existing registered open-end management investment company that currently intends to rely on the application is named as an applicant. (p. 5)

7. No trustee or officer of the Investment Company or director or officer of the Adviser will own directly or indirectly (other than through a pooled investment vehicle that is not controlled by any such person) any interest in a Subadviser except for ownership of interests in the Adviser or any entity that controls, is controlled by, or is under common control with the Adviser, or ownership of less than 1% of the outstanding securities of any class of equity or debt securities of any publicly traded company that is either a Subadviser of an entity that controls, is controlled by, or is under common control with a Subadviser.

8. Within 90 days of the hiring of any new Subadviser, shareholders will be furnished all information about the new Subadviser that would be contained in a proxy statement, including any change in such disclosure caused by the addition of the new Subadviser. Each Fund will meet this condition by providing shareholders with an information statement meeting the requirements of Regulation 14C, Schedule 14C, and Item 22 of Schedule 14A under the Securities Exchange Act of 1934 within 90 days of the hiring of a Subadviser.

For the Commission, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 00-231 Filed 1-5-00; 8:45 am]

BILLING CODE 8010-01-M

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 24226; 812-11668]

Manufacturers Investment Trust and Manufacturers Securities Services, LLC; Notice of Application

December 29, 1999.

AGENCY: Securities and Exchange Commission ("Commission").

ACTION: Notice of an application under section 6(c) of the Investment Company Act of 1940 ("Act") for an exemption from section 15(a) of the Act and rule 18f-2 under the Act.

Summary of Application: Applicants, Manufacturers Investment Trust (the "Trust") (formerly NASL Series Trust) and Manufacturers Securities Services, LLC (the "Adviser") (formerly NASL Financial Services, Inc.), request an order that would permit applicants to enter into and materially amend sub-advisory agreements without

shareholder approval. The order would supersede a prior order.

Filing Dates: The application was filed on June 22, 1999 and amended on October 8, 1999. Applicants have agreed to file an amendment during the notice period, the substance of which is reflected in this notice.

Hearing or Notification of Hearing: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicant with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 pm on January 24, 2000 and should be accompanied by proof of service on applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons may request notification of a hearing by writing to the Commission's Secretary.

ADDRESSES: Secretary, Securities and Exchange Commission, 450 5th Street NW, Washington, DC 20549-0609. Applicant, c/o John W. Blouch, Esq., Jones & Blouch L.L.P., 1025 Thomas Jefferson St., NW, Suite 405 West, Washington, DC 20007.

FOR FURTHER INFORMATION CONTACT: Lawrence W. Pisto, Senior Counsel, at (202) 942-0527, or George J. Zornada, Branch Chief at (202) 942-0564, Office of Investment Company Regulation, Division of Investment Management.

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the Commission's Public Reference Branch, 450 5th Street NW, Washington, DC 20549-0102 (tel. 202-942-8090).

Applicants' Representations

1. The Trust, a Massachusetts business trust, is registered under the Act as an open-end management investment company. The Trust is currently comprised of thirty-nine series ("Portfolios"), each of which has its own investment objectives, and policies.¹ The shares of the Portfolios serve as funding vehicles for variable

¹ Applicants also request relief with respect to future series of the Trust and all future registered open-end management investment companies that are: (a) Advised by the Adviser or any entity controlling, controlled by, or under common control within the Adviser, and (b) which operate in substantially the same manner as the Trust and comply with the terms and conditions contained in the application. The Trust is the only existing investment company that currently intends to rely on the order.

annuity contracts and life insurance contracts offered through separate accounts of subsidiaries of The Manufacturers Life Insurance Company, a Canadian life insurance company ("Manulife").

2. The Adviser, a Delaware limited liability company, serves as investment adviser to each of the Portfolios, and is registered as an investment adviser under the Investment Advisers Act of 1940 ("Advisers Act"). The Adviser is an indirectly-owned subsidiary of Manulife.

3. The Adviser serves as investment adviser to the Portfolios pursuant to an investment advisory agreement between the Adviser and the Trust that was approved by the board of trustees of the Trust (the "Board"), including a majority of the trustees ("Trustees") who are not "interested persons," as defined in section 2(a)(19) of the Act ("Independent Trustees"), and the shareholders of the Trust ("Investment Advisory Agreement"). Under the Investment Advisory Agreement, the Adviser has overall general supervisory responsibility for the investment program of the Portfolios and recommends to the Board the selection of one or more subadvisers (each a "Manager" and collectively, "Managers") to provide one or more Portfolios with day-to-day portfolio management services ("Manager of Managers Strategy"). Each Manager is an investment adviser registered or exempt from registration under the Advisers Act, and performs services pursuant to a written agreement with the Adviser (the "Portfolio Management Agreement"). Managers' fees are paid by the Adviser out of its fees from the Portfolios at rates negotiated with the Managers by the Adviser. The Portfolios currently have 16 Managers.

4. The Trust has operated under a prior order ("Original Order") granting relief for the Manager of Managers Strategy since December 31, 1996.² The Adviser makes qualitative evaluations of each Manager's skills and demonstrated performance in managing assets under particular investment styles. The Adviser recommends to the Board for selection those Managers that have consistently distinguished themselves

² Investment Company Act Release Nos. 22382 (Dec. 9, 1996) (notice) and 22429 (Dec. 31, 1996) (order). The Original Order was granted to NASL Financial Services, Inc., NASL Series Trust and North American Funds. NASL Financial Services, Inc. has been merged into another wholly-owned subsidiary of Manulife. NASL Series Trust's name has been changed to Manufacturers Investment Trust. The Adviser is no longer advising North American Funds; consequently it is not a party to this application. The Original Order also granted relief from certain disclosure requirements.

and demonstrated a high level of service and responsibility to investors. The Adviser reviews, monitors and reports to the Board regarding the performance and procedures of the Managers. The Adviser may recommend to the Board reallocation of assets of a Portfolio among Managers, if necessary, and the Adviser also may recommend hiring additional Managers or the termination of Managers in appropriate circumstances.

5. Applicants request relief to permit the Adviser to enter in and materially amend Portfolio Management Agreements without shareholder approval.³ The order would supersede the Original Order. The requested relief will not extend to a Manager that is an affiliated person, as defined in section 2(a)(3) of the Act, of the Trust or the Adviser, other than by reason of serving as a Subadviser to one or more of the Portfolios (an "Affiliated Manager"). Currently, one of the Managers is an Affiliated Manager.

Applicants' Legal Analysis

1. Section 15(a) of the Act provides, in relevant part, that it is unlawful for any person to act as an investment adviser to a registered investment company except pursuant to a written contract that has been approved by the vote of the company's outstanding voting securities. Rule 18f-2 under the Act provides that each series or class of stock in a series company affected by a matter must approve such matter if the Act requires shareholder approval.

2. Section 6(c) of the Act provides that the Commission may exempt any person, security, or transaction or any class or classes of persons, securities, or transactions from any provision of the Act, or from any rule thereunder, if such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants request an exemption under section 6(c) of the Act from section 15(a) of the Act and rule 18f-2 under the Act to permit them to enter into and materially amend Portfolio Management Agreements without shareholder approval.

3. Applicants assert that under the Manager of Managers Strategy, the Portfolios' shareholders rely on the Adviser to select and monitor one or more Managers best suited to achieve a Portfolios' investment objectives. Applicants contend that, from the

perspective of the investor, the role of the Managers is comparable to that of individual portfolio managers employed by other investment advisory firms. Applicants contend that requiring shareholder approval of Portfolio Management Agreements would impose expenses and unnecessary delays on the Portfolios, and may preclude the Adviser from promptly acting in a manner considered advisable by the Board. Applicants note that the Investment Advisory Agreement between the Trust and the Adviser will remain subject to section 15(a) of the Act and rule 18f-2 under the Act, including the requirements for shareholder approval.

Applicants' Conditions

Applicants agree that any order granting the requested relief will be subject to the following conditions:

1. No Portfolio will enter into a Portfolio Management Agreement with an Affiliated Manager without such agreement, including the compensation to be paid thereunder, being approved by the shareholders of the Portfolio (or, if the Portfolio serves as a funding medium for any sub-account of a registered separate account, pursuant to voting instructions by the unitholders of the sub-account).

2. At all times, a majority of the Trustees will be Independent Trustees, and the nomination of new or additional Independent Trustees will be at the discretion of the then-existing Independent Trustees.

3. When a Manager change is proposed for a Portfolio with an Affiliated Manager, the Trustees, including a majority of the Independent Trustees, will make a separate finding, reflected in the Trust's Board minutes, that the change is in the best interests of the Portfolio and its shareholders (or, if the Portfolio serves as a funding medium for any sub-account of a registered separate account, in the best interests of the Portfolio and the unitholders of any sub-account) and that the change does not involve a conflict of interest from which the Adviser or the Affiliated Manager derives an inappropriate advantage.

4. Before a Portfolio may rely on the order, the operation of the Portfolio in the manner described in the application will be approved by a majority of the Portfolio's outstanding voting securities (or, if the Portfolio serves as a funding medium for any sub-account of a registered separate account, pursuant to voting instructions provided by the unitholders of the sub-account), as defined in the Act, or in the case of a new Portfolio whose public

shareholders (or variable contract owners through a separate account) purchase shares on the basis of a prospectus(es) containing the disclosure contemplated by Condition 6 below, by the sole initial shareholder(s) before the shares of such Portfolio are offered to the public (or the variable contract owners through a separate account).

5. The Adviser will provide management services to the Trust and its Portfolios, including overall supervisory responsibility for the general management and investment of each Portfolio's securities portfolio, and, subject to review and approval by the Board will (a) set each Portfolio's overall investment strategies; (b) evaluate, select and recommend Managers to manage all or a part of a Portfolio's assets; (c) when appropriate, allocate and reallocate a Portfolio's assets among multiple Managers; (d) monitor and evaluate the investment performance of Managers; and (e) implement procedures reasonably designed to ensure that the Managers comply with the relevant Portfolio's investment objectives, policies, and restrictions.

6. Each Portfolio relying on the requested relief will disclose in its prospectus the existence, substance and effect of any order granted pursuant to this application. In addition, any such Portfolio will hold itself out as employing the Manager of Managers Strategy described in the application. The prospectus will prominently disclose that the Adviser has ultimate responsibility to oversee the Managers and recommend their hiring, termination, and replacement.

7. No Trustee or officer of the Trust or officer or director of the Adviser will own directly or indirectly (other than through a pooled investment vehicle that is not controlled by that trustee, officer or director) any interest in a Manager except for (i) ownership of interests in the Adviser or any entity that controls, is controlled by, or is under common control with the Adviser; or (ii) ownership of less than 1% of the outstanding securities of any class of equity or debt securities of a publicly-traded company that is either a Manager or an entity controls, is controlled by, or is under common control with a Manager.

8. Within 90 days of the hiring of any new Manager, the Adviser will furnish shareholders (or, if the Portfolio serves as a funding medium for any sub-account of a registered separate account, the Adviser will furnish the unit holders of the sub-account) with respect to the appropriate Portfolio all information about the new Manager that would be included in a proxy statement. Such

³ The term "shareholder" includes variable life insurance policy and variable annuity contract owners that are unitholders of any separate account for which the Portfolios serve as a funding medium.

information will include any changes caused by the addition of a new Manager. To meet this condition, the Adviser will provide shareholders (or, if the Portfolio serves as a funding medium for any sub-account of a registered separate account, then by providing unitholders of the sub-account) with an information statement meeting the requirements of Regulation 14C, Schedule 14C, and Item 22 of Schedule 14A under the Securities Exchange Act of 1934.

For the Commission, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 00-232 Filed 1-5-00; 8:45 am]

BILLING CODE 8010-01-M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-42269; File No. S7-24-89]

Joint Industry Plan; Solicitation of Comments and Order Approving Amendment No. 10 to Reporting Plan for Nasdaq/National Market Securities Traded on an Exchange on an Unlisted or Listed Basis, Submitted by the National Association of Securities Dealers, Inc., and the Boston, Chicago, Philadelphia and Cincinnati Stock Exchanges

December 23, 1999.

I. Introduction

On December 6, 1999, the National Association of Securities Dealers, Inc. ("NASD"), on behalf of itself and the Boston Stock Exchange, Inc. ("BSE"), the Chicago Stock Exchange, Inc. ("CHX"), the Philadelphia Stock Exchange, Inc. ("PHLX"), and the Cincinnati Stock Exchange ("Cincinnati") submitted to the Securities and Exchange Commission ("Commission" or "SEC") Amendment No. 10 to a joint transaction reporting plan ("Plan")¹ for Nasdaq/National

Market ("Nasdaq/NM") (previously referred to as Nasdaq/NMS) securities traded on an exchange on an unlisted or listed basis.² This notice and order approves the amendment, which would add Cincinnati as a Participant to the Plan and make technical changes to the Plan to reflect that the Midwest Stock Exchange now is called the Chicago Stock Exchange.

II. Background

The Commission originally approved the Plan on June 26, 1990.³ The Plan governs the collection, consolidation and dissemination of quotation and transaction information for Nasdaq/NM securities listed on an exchange or traded on an exchange pursuant to a grant of UTP.⁴ The Commission originally approved trading pursuant to the Plan on a one-year pilot basis, with the pilot period to commence when transaction reporting pursuant to the Plan commenced. Accordingly, the pilot period commenced on July 12, 1993.⁵ The Plan has since been in operation on an extended pilot basis.⁶

same standards that previously applied to Commission review of UTP applications. The present order fulfills these Section 12(f) requirements.

² The signatories to the Plan, *i.e.*, the NASD, the CHX (previously, the Midwest Stock Exchange, Inc.), the PHLX, and the BSE, are the "Participants." The BSE, however, joined the Plan as a "Limited Participant," and reports quotation information and transaction reports only in Nasdaq/NM securities listed on the BSE. Originally, the American Stock Exchange, Inc., was a Participant to the Plan, but did not trade securities pursuant to the Plan, and withdrew from participation in the Plan in August 1994.

³ See Securities Exchange Act Release No. 28146 (June 26, 1990), 55 FR 27917 (July 6, 1990) ("1990 Approval Order").

⁴ See Section 12(f)(2) of the Act. See also December 1998 Extension Order, *infra* note 6, for a more in depth description of the Plan.

⁵ See letter from David T. Rusoff, Foley & Lardner, to Betsy Prout, Division of Market Regulation, SEC, dated May 9, 1994.

⁶ See Securities Exchange Act Release No. 34371 (July 13, 1994), 59 FR 37103 (July 20, 1994); Securities Exchange Act Release No. 35221 (January 11, 1995), 60 FR 3886 (January 19, 1995); Securities Exchange Act Release No. 36102 (August 14, 1995), 60 FR 43626 (August 22, 1995); Securities Exchange Act Release No. 36226 (September 13, 1995), 60 FR 49029 (September 21, 1995); Securities Exchange Act Release No. 36368 (October 13, 1995), 60 FR 54091 (October 19, 1995); Securities Exchange Act Release No. 36481 (November 13, 1995), 60 FR 58119 (November 24, 1995); Securities Exchange Act Release No. 36589 (December 13, 1995), 60 FR 65696 (December 20, 1995); Securities Exchange Act Release No. 36650 (December 28, 1995), 61 FR 358 (January 4, 1996); Securities Exchange Act Release No. 36934 (March 6, 1996), 61 FR 10408 (March 13, 1996); Securities Exchange Act Release No. 36985 (March 18, 1996), 61 FR 12122 (March 25, 1996); Securities Exchange Act Release No. 37689 (September 16, 1996), 61 FR 50058 (September 24, 1996); Securities Exchange Act Release No. 37772 (October 1, 1996), 61 FR 52980 (October 9, 1996); Securities Exchange Act Release No. 38457 (March 31, 1997), 62 FR 16880 (April 8,

III. Description of the Plan

The Plan provides for the collection from Plan Participants and the consolidation and dissemination to vendors, subscribers and others of quotation and transaction information in "eligible securities."⁷ The Plan contains various provisions concerning its operation, including: Implementation of the Plan; Manner of Collecting, Processing, Sequencing, Making Available and Disseminating Last Sale Information; Reporting Requirements (including hours of operation); Standards and Methods of Ensuring Promptness, Accuracy and Completeness of Transaction Reports; Terms and Conditions of Access; Description of Operation of Facility Contemplated by the Plan; Method and Frequency of Processor Evaluation; Written Understandings of Agreements Relating to Interpretation of, or Participation in, the Plan; Calculation of the Best Bid and Offer; Dispute Resolution; and Method of Determination and Imposition, and Amount of Fees and Charges.⁸

IV. Discussion

The Commission finds that it is consistent with Section 11A⁹ of the Act to add Cincinnati as a Participant to the Plan and to make technical changes to the Plan to reflect that the Midwest Stock Exchange is now called the Chicago Stock Exchange. Section 11A directs the Commission to facilitate the development of a national market system for securities, "having due regard for the public interest, the protection of investors, and the

1997); Securities Exchange Act Release No. 38794 (June 30, 1997) 62 FR 36586 (July 8, 1997); Securities Exchange Act Release No. 39505 (December 31, 1997) 63 FR 1515 (January 9, 1998); Securities Exchange Act Release No. 40151 (July 1, 1998) 63 FR 36979 (July 8, 1998); Securities Exchange Act Release No. 40869 (December 31, 1998), 64 FR 1834 (January 12, 1999) ("December 1998 Extension Order"); and Securities Exchange Act Release No. 41392 (May 12, 1999), 64 FR 27839 (May 21, 1999) ("May 1999 Approval Order"); Securities Exchange Act Release No. 42268 (December 23, 1999).

⁷ The Plan defines "eligible security" as any Nasdaq/NM security as to which unlisted trading privileges have been granted to a national securities exchange pursuant to Section 12(f) of the Act or that is listed on a national securities exchange. On May 12, 1999, the Commission expanded the number of eligible Nasdaq/NM securities that may be traded by the CHX pursuant to the Plan from 500 to 1000. (See May 1999 Approval Order, *supra* note 6.

⁸ The full text of the Plan, as well as a "Concept Paper" describing the requirements of the Plan, are contained in the original filing which is available for inspection and copying in the Commission's public reference room.

⁹ 15 U.S.C. 78k-1. In approving this amendment, the Commission has considered the amendment's impact on efficiency, competition, and capital formations. 15 U.S.C. 78c(f).

¹ Section 12(f) of the Securities Exchange Act of 1934 ("Act") describes the circumstances under which an exchange may trade a security that is not listed on the exchange, *i.e.*, by extending unlisted trading privileges ("UTP") to the security. See 15 U.S.C. 781(f). Section 12(f) required exchanges to apply to the Commission before extending UTP to any security. In order to approve an exchange UTP application for a registered security not listed on any exchange ("OTC/UTP"), Section 12(f) required the Commission to determine that various criteria had been met concerning fair and orderly markets, the protection of investors, and certain national market initiatives. Section 12(f) was amended on October 22, 1994; the amendment removed the application requirement. OTC/UTP is now allowed only pursuant to a Commission order or rule, which is to be issued or promulgated under essentially the

maintenance of fair and orderly markets," and cites as an objective of that system the "fair competition * * * between exchange markets and markets other than exchange markets."¹⁰ When the Commission first approved the Plan on a pilot basis, it found that the Plan "should enhance market efficiency and fair competition, avoid investor confusion, and facilitate regulatory surveillance of concurrent exchange and OTC trading."¹¹ The Commission now finds that adding a Participant to the Plan furthers these same goals.

Section 1C of the Plan provides that a national securities exchange in whose market eligible securities become traded, may become a Participant, provided that the exchange executes a copy of the Plan and pays its share of development costs as specified in Section XIV of the Plan. Cincinnati has filed an executed copy of the Plan with the Commission, and the Participants have represented to the Commission that Cincinnati has paid its share of the development costs specified in Section XIV of the Plan. Accordingly, the Commission finds that Cincinnati has satisfied the requirements listed in the Plan to become a participant.

The Commission also finds that the technical amendments to the Plan are consistent with the Act. The Commission believes that the Plan should accurately reflect the Participants. Thus, it is appropriate that all references to the Midwest Stock Exchange are changed to the Chicago Stock Exchange, and that the Plan itself be modified to provide for a symbol for CHX.

V. Solicitation of Comment

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed 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 NW, Washington, DC 20549-0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed amendment that are filed with the Commission, and all written communications relating to the proposed amendment between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at

the Commission's Public Reference Room. All submissions should refer to File No. S7-24-89 and should be submitted by February 10, 2000.

VI. Conclusion

It is therefore ordered, pursuant to Sections 12(f) and 11A of the Act and paragraph (c)(2) of Rule 11Aa3-2 thereunder, that Amendment No. 10 to the Plan, is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.¹²

Margaret H. McFarland,
Deputy Secretary.

[FR Doc. 00-279 Filed 1-5-00; 8:45 am]

BILLING CODE 8010-01-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

[CGD17-99-013]

Application for Recertification of Prince William Sound Regional Citizens' Advisory Council

AGENCY: Coast Guard, DOT.

ACTION: Notice of availability; request for comments.

SUMMARY: The Coast Guard announces the availability of the application for recertification submitted by the Prince William Sound Regional Citizens' Advisory Council (PWSRCAC). A recertification would be valid for a year. Under the Oil Terminal and Oil Tanker Environmental Oversight and Monitoring Act of 1990, the Coast Guard also may certify, on an annual basis, an alternative voluntary advisory group instead of the Regional Citizens' Advisory Council for Prince William Sound.

DATES: Comments must reach the Seventeenth Coast Guard District on or before February 7, 2000.

ADDRESSES: You may mail your comments to the Seventeenth Coast Guard District (mor), P.O. Box 25517, Juneau, AK 99802. You may also deliver them to the Juneau Federal Building, room 753, 709 W 9th Juneau, AK between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

The Seventeenth Coast Guard District maintains the public docket for this recertification process. Comments regarding recertification will become part of this docket and will be available for inspection or copying at the Juneau Federal Building, room 753, 709 W 9th Juneau, AK, between 8 a.m. and 4 p.m.,

Monday through Friday, except Federal holidays. You may also access this docket via the ARRT web site: www.akrrt.org.

A copy of the application is also available for inspection at the Prince William Sound Regional Citizens' Advisory Council's Offices, at 3709 Spenard Rd., Anchorage, Alaska, 99503 or 154 Fairbanks Dr., P.O. Box 3089, Valdez, Alaska, 99686, between the hours of 8 a.m. and 5 p.m. Monday through Friday. The telephone number is (907) 277-7222 in Anchorage, Alaska and (907) 835-5957 in Valdez, Alaska.

FOR FURTHER INFORMATION CONTACT: For general information regarding the PWSRCAC, see their web site: www.pwsrcac.org. For questions on viewing, or submitting material to the docket contact LCDR Larry Musarra, Seventeenth Coast Guard District (mor), (907) 463-2211.

SUPPLEMENTARY INFORMATION:

Request for Comments

The Coast Guard encourages interested persons to submit written data, views, or arguments. It solicits comments from interested groups including oil terminal facility owners and operators, owners and operators of crude oil tankers calling at terminal facilities, and fishing, aquacultural, recreational and environmental citizens groups, concerning the recertification application of PWSRCAC. Persons submitting comments should include their names and addresses, identify this rulemaking (CGD17-99-013) and the specific section of this document to which each comment applies, and give the reason for each comment. Please submit two copies of all comments and attachments in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. Persons wanting acknowledgment of receipt of comments should enclose stamped, self-addressed postcards or envelopes.

The Coast Guard plans no public hearing. Persons may request a public hearing by writing to Commander (m), 17th Coast Guard District, P.O. Box 25517, Juneau, AK 99802. The request should include the reasons why a hearing would be beneficial. If there is sufficient evidence to determine that oral presentations will aid this recertification process, the Coast Guard will hold a public hearing at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

The Coast Guard published guidelines on December 31, 1992 (57 FR 626000), to assist groups seeking recertification

¹⁰ 15 U.S.C. 78k-1(a)(1)(C)(ii).

¹¹ See *supra* note 3.

¹² 17 CFR 200.30-3(a)(29).

under the Oil Terminal and Oil Tanker Environmental Oversight and Monitoring Act of 1990 (33 U.S.C. 2732) (the Act). The Coast Guard issued a policy statement on July 7, 1993 (58 FR 36505), to clarify the factors that the Coast Guard would be considering in making its determination as to whether advisory groups should be certified in accordance with the Act; and the procedures which the Coast Guard would follow in meeting its certification responsibilities under the Act.

The Coast Guard has received an application for recertification of PWSRCAC, the currently certified advisory group for the Prince William Sound region. In accordance with the review and certification process contained in the policy statement, the Coast Guard announces the availability of that application.

At the conclusion of the comment period, the Coast Guard will review all application materials and comments received and will take one of the following actions:

(a) Recertify the advisory group under 33 U.S.C. 2732(o).

(b) Issue a conditional recertification for a period of 90 days, with a statement of any discrepancies, which must be corrected to qualify for recertification for the remainder of the year.

(c) Deny recertification of the advisory group if the Coast Guard finds that the group is not broadly representative of the interests and communities in the area or is not adequately fostering the goals and purposes of 33 U.S.C. 2732.

The Coast Guard will notify PWSRCAC by letter of the action taken on its application. A notice will be published in the *Federal Register* to advise the public of the Coast Guard's determination.

Dated: December 28, 1999.

T.J. Barrett,

Rear Admiral, U.S. Coast Guard, Commander, Seventeenth Coast Guard District.

[FR Doc. 00-249 Filed 1-5-00; 8:45 am]

BILLING CODE 4910-15-M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Coast Guard

Woodrow Wilson Bridge; Potomac River, District of Columbia and Prince George's County, MD

AGENCY: Federal Highway Administration, Coast Guard, DOT.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Federal Highway Administration together with the Coast Guard, U.S. Army Corps of Engineers, District of Columbia Department of Health, Maryland State Highway Administration, Virginia Department of Transportation and Maryland Department of Environment will hold two public hearings to receive information concerning the environmental and navigational impacts of the replacement of the Woodrow Wilson Bridge. The bridge is located on Interstate 495/95 where it crosses the Potomac River, mile 103.80, at District of Columbia and Prince George's County, Maryland. The hearings will allow interested persons to present comments and information concerning the bridge alternative under consideration.

DATES: The hearing will start 7 p.m. on Tuesday, February 8, and Thursday, February 10, 2000 and display materials will be available beginning at 5:30 p.m. on these dates. Comments must be received by February 25, 2000. Requests to speak at either hearing and requests for services must be received by February 1, 2000.

ADDRESSES: The hearing on February 8 will be held at Best Western Potomac View, 6400 Oxon Hill Road, Oxon Hill, Maryland 20745. On February 10, the hearing will be at Radisson Hotel—Old Town Alexandria, 901 North Fairfax Street, Alexandria, Virginia 22314. Written comments may be submitted to, and will be available for examination between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal holidays, at the office of the Commander (Aowb), Fifth Coast Guard District, 431 Crawford Street, Portsmouth, Virginia 23703-5004. Please submit all comments in an unbound format, no larger than 8 by 11 inches, suitable for copying and electronic filing. Persons wanting acknowledgement of receipt of comments should enclose a stamped, self-addressed postcard or envelope.

Requests to speak at either hearing and requests to be placed on the project mailing lists may be submitted to Ms. Norine Walker, P.E., at the Woodrow Wilson Bridge Center, 1800 Duke Street, Suite 200, Alexandria, Virginia 22314 or 6009 Oxon Hill Road, Suite 410, Oxon Hill, Maryland 20745.

FOR FURTHER INFORMATION CONTACT: Mr. John Gerner, Project Manager (FHWA), Woodrow Wilson Bridge Center, 1800 Duke Street, Suite 200, Alexandria, Virginia 22314 (703 519-9800); Mr. N.E. Mpras, Chief, Office of Bridge Administration, Commandant (G-OPT), U.S. Coast Guard, 2100 Second Street, SW, Washington, DC 20593 (202 267-

0368); or Ms. Ann Deaton, Chief, Bridge Administration Branch, Fifth Coast Guard District, Federal Building, 431 Crawford Street, Portsmouth, Virginia 23704-5004 (757 398-6222).

SUPPLEMENTARY INFORMATION:

Background

The Federal Highway Administration (FHWA) proposes to replace the Woodrow Wilson Bridge over the Potomac River and to modify the associated roadway and interchanges in a 7.5 mile section of I-95/I-495 (Capital Beltway) from west of Telegraph Road (VA 241) in Virginia to east of Indian Head Highway (MD 210) in Maryland. The western portion of the project corridor is located in Fairfax County and the City of Alexandria in Virginia. The drawspans on the Woodrow Wilson Bridge are located in the southern tip of the District of Columbia. The eastern portion of the corridor is located in Prince George's County, Maryland. The purpose of the proposed action is to address existing capacity constraints, safety, and structural deficiencies associated with the Woodrow Wilson Bridge, and to enhance vehicular mobility in the corridor while addressing environmental and community concerns.

The new Woodrow Wilson Bridge will replace the existing bridge with two new, parallel, double leaf, bascule drawbridges, each with a 366-foot span and a clearance of 70 feet over the navigation channel. One span will carry eastbound traffic and the other westbound traffic, and the structure will be constructed approximately 30 feet south of the existing bridge. The westbound span, carrying the inner loop of the Capital Beltway, would be 124 feet wide, including a 12-foot wide pedestrian/bicycle facility with a 2-foot wide barrier. The eastbound span, carrying the outer loop of the Capital Beltway, would be 110 feet wide. Eleven "V"-shaped, concrete piers will support the bridges. The bridges will be protected at the navigational channel by twelve, 45-foot diameter, sheet pile dolphins with a pipe pile supported, concrete guideway with fendering north and south of the bridge piers. The bridges would include a total of 12 lanes (six lanes in each direction). Each bridge is 4,100 feet long, over Maryland water, with a total length of 6,075 feet.

The FHWA is the lead Federal agency for the environmental documentation for this project. The Coast Guard has been involved as a cooperating agency during the preparation of the Draft Supplemental Environmental Impact Statement (DSEIS). The U.S. Coast Guard is the Federal agency responsible

for protecting the freedom of navigation with due consideration being given to the quality of the human environment and by taking a balanced approach to total transportation systems, both land and water modes. The Coast Guard must ensure that proposed bridge projects provide for the reasonable needs of present and prospective marine transportation. Interested and affected parties are requested to express their views, in writing, on the impacts of the construction of the proposed bridges on navigation and the quality of the human environment, including impacts on historic, recreational, endangered species, and wetlands, giving sufficient detail to establish a clear understanding of their reasons for support of or opposition to the proposed work.

Procedural

Individuals and representatives of organizations that wish to present testimony at either Hearing or who want to be placed on the project mailing list, may submit a request to Ms. Norine Walker, P.E., at the Woodrow Wilson Bridge Center, 1800 Duke Street, Suite 200, Alexandria, Virginia 22314 or 6009 Oxon Hill Road, Suite 410, Oxon Hill, Maryland 20745. Requests to speak should be received no later than February 1, 2000 in order to ensure proper schedule of the hearing. Attendees at the hearing who wish to present testimony and have not previously made a request to do so, will follow those on the previously established list. Brochures and forms for written comments will be sent to those on the mailing list. Written statements and other exhibits in lieu of or in addition to oral presentation at the Hearing may be submitted to Ms. Walker at the address under **ADDRESSES** until February 25, 2000, in order to be included in the Public Hearing Transcript.

Information on Services for Individuals With Disabilities

Appropriate auxiliary aids and services for qualified individuals with disabilities or non-English speaking persons will be provided upon request. Please submit requests for these services to Ms. Norine Walker, at the address under **ADDRESSES** in writing or by calling either of the Woodrow Wilson Bridge Centers at 703-519-9800 or 301-686-0000 or fax request to 703-548-4593 or 301-868-0001 or teletype to 1-800-735-2258 (MD Statewide toll free). Any requests for an oral or sign language interpreter must be received by February 1, 2000.

Dated: December 30, 1999.

George K. Frick, Jr.,

Acting Division Administrator, Federal Highway Administration.

Terry M. Cross,

Rear Admiral, U.S. Coast Guard, Director of Operations Policy.

[FR Doc. 00-258 Filed 1-5-00; 8:45 am]

BILLING CODE 4910-22-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

[USCG 1999-6722]

Merchant Marine Personnel Advisory Committee

AGENCY: Coast Guard, DOT.

ACTION: Notice of meetings.

SUMMARY: The Merchant Marine Personnel Advisory Committee (MERPAC) and its working groups will meet to discuss various issues relating to the training and fitness of merchant marine personnel. MERPAC advises the Secretary of Transportation on matters relating to the training, qualifications, licensing, certification and fitness of seamen serving in the U.S. merchant marine. All meetings will be open to the public.

DATES: MERPAC will meet on Tuesday, January 25, 2000, from 8 a.m. to 4 p.m. and on Wednesday, January 26, 2000, from 8 a.m. to 4 p.m. These meetings may adjourn early if all business is finished. Written material and requests to make oral presentations should reach the Coast Guard on or before January 11, 2000. Requests to have a copy of your material distributed to each member of the committee or subcommittee should reach the Coast Guard on or before January 4, 2000.

ADDRESSES: MERPAC will meet on both days in Room A-300 of the Maritime Institute of Technology and Graduate Studies (MITAGS), 5700 Hammonds Ferry Road, Linthicum Heights, MD 21090. Further directions regarding the location of MITAGS may be obtained by contacting Ms. Kate Gossard of MITAGS at (410) 859-5700. Send written material and requests to make oral presentations to Commander Steven J. Boyle, Commandant (G-MSO-1), U.S. Coast Guard Headquarters, 2100 Second Street SW, Washington, DC 20593-0001. This notice is available on the Internet at <http://dms.dot.gov>.

FOR FURTHER INFORMATION CONTACT: Commander Steven J. Boyle, Executive Director of MERPAC, or Mr. Mark C. Gould, Assistant to the Executive Director, telephone 202-267-0229, fax

202-267-4570, or e-mail mgould@comdt.uscg.mil.

SUPPLEMENTARY INFORMATION: Notice of these meetings is given under the Federal Advisory Committee Act, 5 U.S.C. App. 2.

Agenda of January 25, 2000, Meeting

The full committee will meet to discuss the objectives for the meeting. The committee will then break up into the following working groups: the working group on the International Convention on the Standards of Training, Certification and Watchkeeping (STCW), specifically addressing the Assessment of Proficiencies as Mandated by the Amended 1995 STCW Convention; the working group on the Methods of Demonstrating Competence in Crisis Management and Human Behavior, and; the working group on Simulator Standards for Demonstrating Competence in Ratings Forming Part of a Navigational Watch. New working groups may be formed to address any new issues or tasks. At the end of the day, the working groups will make a report to the full committee on what has been accomplished in their meetings. No action will be taken on these reports on this date.

Agenda of January 26, 2000, Meeting

The agenda includes the following:

- (1) Introduction.
- (2) Working Group Reports.
 - (a) Assessment of Proficiencies as Mandated by the Amended 1995 STCW Convention
 - (b) Methods of Demonstrating Competence in Crisis Management and Human Behavior
 - (c) Simulator Standards for Demonstrating Competence in Ratings Forming Part of a Navigational Watch
- (3) Other items to be discussed:
 - (a) Standing Committee—Prevention Through People
 - (b) STCW developments
 - (c) Other items brought up for discussion by the committee or the public

Procedural

Both meetings are open to the public. Please note that the meetings may adjourn early if all business is finished. At the Chair's discretion, members of the public may make oral presentations during the meetings. If you would like to make an oral presentation at a meeting, please notify the Executive Director no later than January 11, 2000. Written material for distribution at a meeting should also reach the Coast Guard no later than January 11, 2000. If you would like a copy of your material distributed to each member of the

committee or subcommittee in advance of a meeting, please submit 25 copies to the Executive Director no later than January 4, 2000.

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 the Executive Director as soon as possible.

Dated: December 21, 1999.

Joseph J. Angelo,

Director of Standards, Marine Safety and Environmental Protection.

[FR Doc. 00-248 Filed 1-5-00; 8:45 am]

BILLING CODE 4910-15-U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Acceptance of Noise Exposure Maps for Lanai Airport, Lanai City, HA

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces its determination that the noise exposure maps submitted by the State of Hawaii, Department of Transportation, for Lanai Airport under the provisions of Title I of the Aviation Safety and Noise Abatement Act of 1979 (Public Law 96-193) and 14 CFR Part 150 are in compliance with applicable requirements.

EFFECTIVE DATE: The effective date of the FAA's determination on the noise exposure maps is December 23, 1999.

FOR FURTHER INFORMATION CONTACT: David J. Welhouse, Airport Planner, Federal Aviation Administration, Honolulu Airports District Office, P.O. Box 50244, Honolulu, Hawaii 96850-0001, Telephone 808/541-1243, Street Address: Federal Building, 300 Ala Moana Boulevard, Room 7-128, Honolulu, Hawaii, 96813. Documents reflecting this FAA action may be reviewed at this same location.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA finds that the noise exposure maps submitted for Lanai Airport are in compliance with applicable requirements of Part 150, effective December 23, 1999.

Under section 103 of the Aviation Safety and Noise Abatement Act of 1979 (hereinafter referred to as "the Act"), an airport operator may submit to the FAA noise exposure maps which meet applicable regulations and which depict noncompatible land uses as of the date

of submission of such maps, a description of projected aircraft operations, and the ways in which such operations will affect such maps. The Act requires such maps to be developed in consultation with interested and affected parties in the local community, government agencies, and persons using the airport.

An airport operator who has submitted noise exposure maps that are found by FAA to be in compliance with the requirements of Federal Aviation Regulations (FAR) Part 150, promulgated pursuant to Title I of the Act, may submit a noise compatibility program for FAA approval which sets forth the measures the operator has taken or proposes for the reduction of existing noncompatible uses and for the prevention of the introduction of additional noncompatible uses.

The FAA has completed its review of the noise exposure maps and related descriptions submitted by the State of Hawaii, Department of Transportation. The specific maps under consideration are Figure 4-1, "Base Year (1999) Noise Exposure Map" and Figure 5-1, "5-Year (2004) Noise Exposure Map," in the submission. The FAA has determined that the maps for the Lanai Airport are in compliance with applicable requirements. This determination is effective on December 23, 1999. FAA's determination on an airport operator's noise exposure maps is limited to a finding that the maps were developed in accordance with the procedures contained in Appendix A of FAR Part 150. Such determination does not constitute approval of the applicant's data, information or plans, or a commitment to approve a noise compatibility program or to fund the implementation of that program.

If questions arise concerning the precise relationship of specific properties to noise exposure contours depicted on a noise exposure map submitted under section 103 of the Act, it should be noted that the FAA is not involved in any way in determining the relative locations of specific properties with regard to the depicted noise contours, or in interpreting the noise exposure maps to resolve questions concerning, for example, which properties should be covered by the provisions of section 107 of the Act. These functions are inseparable from the ultimate land use control and planning responsibilities of local government. These local responsibilities are not changed in any way under Part 150 or through FAA's review of noise exposure maps. Therefore, the responsibility for the detailed overlaying of noise exposure contours

onto the map depicting properties on the surface rests exclusively with the airport operator which submitted those maps, or with those public agencies and planning agencies with which consultation is required under section 103 of the Act. The FAA has relied on the certification by the airport operator, under section 150.16 of FAR Part 150, that the statutorily required consultation has been accomplished.

Copies of the noise exposure maps and of the FAA's evaluation of the maps are available for examination at the following locations:

Federal Aviation Administration, Community and Environmental Needs Division, APP-600, 800 Independence Avenue, SW, Washington, D.C. 20591.

Federal Aviation Administration, Western-Pacific Region, Airports Division, AWP-600, 15000 Aviation Boulevard, Room 3012, Hawthorne, California 90261

Federal Aviation Administration, Honolulu Airports District Office, Federal Building, 300 Ala Moana Boulevard, Room 7-128, Honolulu, Hawaii 96813

State of Hawaii, Department of Transportation, Airports Division, District Office Manager, Kahului Airport, Kahului, Maui, Hawaii 96732

Questions may be directed to the individual named above under the heading **FOR FURTHER INFORMATION CONTACT**.

Issued in Hawthorne, California on December 23, 1999.

Ellsworth L. Chan,

Acting Manager, Airports Division, AWP-600, Western-Pacific Region.

[FR Doc. 00-246 Filed 1-5-00; 8:45 am]

BILLING CODE 1410-13-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE-99-46]

Petitions for Exemption; Summary of Petitions Received; Dispositions of Petitions Issued

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petitions for exemption received and of dispositions of prior petitions.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for exemption (14 CFR Part 11), this notice contains a summary of certain petitions seeking relief from specified requirements of the Federal Aviation

Regulations (14 CFR Chapter I), dispositions of certain petitions previously received, and corrections. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

DATES: Comments on petitions received must identify the petition docket number involved and must be received on or before January 26, 2000.

ADDRESSES: Send comments on any petition in triplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attn: Rule Docket (AGC-200), Petition Docket No. _____, 800 Independence Avenue, SW., Washington, D.C. 20591.

Comments may also be sent electronically to the following internet address: 9_NPRM_cmstfaa.gov.

The petition, any comments received, and a copy of any final disposition are filed in the assigned regulatory docket and are available for examination in the Rules Docket (AGC-200), Room 915G, FAA Headquarters Building (FOB 10A), 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267-3132.

FOR FURTHER INFORMATION CONTACT: Cherie Jack (202) 267-7271 or Vanessa Wilkins (202) 267-8029 Office of Rulemaking (ARM-1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591.

This notice is published pursuant to paragraphs (c), (e), and (g) of § 11.27 of Part 11 of the Federal Aviation Regulations (14 CFR part 11).

Issued in Washington, DC, on December 30, 1999.

Donald P. Byrne,
Assistant Chief Counsel for Regulations.

Petitions for Exemption

Docket No.: 29644.

Petitioner: American Freightways, Inc. (AFI).

Section of the FAR Affected: 14 CFR 61.57(e)(3).

Description of Relief Sought: To permit AFI pilots to meet the night takeoff and landing recent experience requirements of § 61.57(b) for the Cessna Model 525 CitationJet by meeting the night takeoff and landing recent experience requirements for the Cessna Model 550 Citation II.

Docket No.: 29853.

Petitioner: JRG Design, Inc.

Section of the FAR Affected: 14 CFR 25.857(e).

Description of Relief Sought: To permit installation of a two-place courier seat for carriage of two non-crewmembers in McDonnell Douglas DC10-30F and -40F freighter airplanes.

Docket No.: 29788.

Petitioner: Brian W. Dodson, Ph.D.

Section of the FAR Affected: 14 CFR 103.1(e).

Description of Relief Sought: To permit Brian W. Dodson, Ph.D., to operate, under the other provisions of part 103, powered single-seat ultralight vehicles with a maximum empty weight of 496 pounds, a maximum fuel capacity of 10 gallons, a maximum power-off stall speed of 35 knots at mean sea level (MSL), and a maximum sustained level air speed of 75 knots at MSL.

Docket No.: 29796.

Petitioner: Save-A-Connie, Inc.

Section of the FAR Affected: 14 CFR 91.315.

Description of Relief Sought: To permit Save-A-Connie, Inc., to operate its Lockheed Super Constellation and its Martin 404 aircraft to carry passengers on local flights for compensation or hire on demonstration or promotional flights.

Docket No.: 29782.

Petitioner: Roy Earnest Duckworth.

Section of the FAR Affected: 14 CFR 61.129(c)(4)(ii).

Description of Relief Sought: To permit Mr. Roy Earnest Duckworth to obtain a commercial pilot certificate with a rotorcraft category and helicopter class rating without accomplishing the requirement for 5 hours of solo night flight.

Docket No.: 29773.

Petitioner: Experimental Aircraft Association, Inc., and the EAA Aviation Foundation, Inc. (Foundation).

Section of the FAR Affected: 14 CFR 119.5(g), 119.21(a), 135.251, and 135.255, and appendixes I and J to part 121.

Description of Relief Sought: To permit the Foundation to operate its Douglas DC-3, Ford Tri-Motor, and various single-engine aircraft, which are certificated in the standard category, for the purpose of carrying passengers for compensation or hire.

Docket No.: 29825.

Petitioner: Jamco America, Inc.

Section of the FAR Affected: 14 CFR 21.235(b)(3).

Description of Relief Sought: To permit the issuance of export airworthiness approvals for class II and class III products manufactured and located at Jamco Corporation's facilities in Tokyo, Japan.

Dispositions of Petitions

Docket No.: 22441.

Petitioner: United Airlines, Inc. (UAL).

Section of the FAR Affected: 14 CFR 121.433(c)(1)(iii), 121.440(a), and 121.441(a)(1) and (b)(1), appendix F to part 121, and Special Federal Aviation Regulation No. 58, paragraph 6(b)(3)(ii)(A).

Description of Relief Sought/

Disposition: To permit UAL to combine recurrent flight and ground training and proficiency checks for UAL's pilots in command, seconds in command, and flight engineers in a single annual training and proficiency evaluation program, that is, a single-visit training program.

GRANT, 12/7/99, Exemption No. 3451L

Docket No.: 29771.

Petitioner: John S. Grofcsik.

Section of the FAR Affected: 14 CFR 121.383(c).

Description of Relief Sought/

Disposition: To permit Mr. John S. Grofcsik to act as a pilot in operations conducted under part 121 after reaching your 60th birthday.

DENIAL, 12/7/99, Exemption No. 7083

Docket No.: 29749.

Petitioner: F.S. Air Service, Inc..

Section of the FAR Affected: 14 CFR 135.299(a).

Description of Relief Sought/

Disposition: To permit F.S. Air Service, Inc., pilots to accomplish a line operational evaluation in a Level C or Level D flight simulator in lieu of a line check in an aircraft.

DENIAL, 12/7/99, Exemption No. 7084

Docket No.: 29783.

Petitioner: Indianapolis Aviation, Inc.

Section of the FAR Affected: 14 CFR 135.143(c)(2).

Description of Relief Sought/

Disposition: To permit Indianapolis Aviation, Inc., to operate its Beechcraft Super King Air B200 (Registration No. N282CT, Serial No. BB-1002) under part 135 without a TSO-C112 (Mode S) transponder installed in the aircraft.

GRANT, 11/30/99, Exemption No. 7082

Docket No.: 29816.

Petitioner: Columbia Air L.L.C.

Section of the FAR Affected: 14 CFR 135.299(a).

Description of Relief Sought/

Disposition: To permit Columbia Air L.L.C. pilots to accomplish a line operational evaluation (LOE) in a Level C or Level D flight simulator in lieu of a line check in an aircraft.

DENIAL, 11/19/99, Exemption No. 7077

Docket No.: 26029.

Petitioner: ABX Air, Inc. (ABX).

Section of the FAR Affected: 14 CFR 121.503(b), 121.505(a), and 121.511(a).

Description of Relief Sought/

Disposition: To permit ABX's pilots and flight engineers to complete certain transcontinental flight schedules before being provided with at least 16 hours of rest.

GRANT, 11/19/99, Exemption No. 5167E

Docket No.: 29871.

Petitioner: Construcciones Aeronauticas, S.A. (CASA).

Section of the FAR Affected: 14 CFR 25.723.

Description of Relief Sought/

Disposition: To grant CASA a partial exemption from 25.723 to the extent necessary to permit type certification of the Model C-295 airplane.

PARTIAL GRANT, 12/17/99, Exemption No. 7088

Docket No.: 25863.

Petitioner: Department of Defense (DOD).

Section of the FAR Affected: 14 CFR 91.117(a) and (b), 91.159(a), and 91.209(a).

Description of Relief Sought/

Disposition: To permit the DOD to conduct air operations in support of drug law enforcement and traffic interdiction without meeting certain requirements pertaining to (1) aircraft speed, (2) cruising altitudes for flights conducted under visual flight rules, and (3) the use of aircraft position lights.

GRANT, 9/25/99, Exemption No. 5100E

Docket No.: 29751.

Petitioner: United Way of Northwest Illinois, Inc. (United Way), and the Freeport Pilots Association (FPA).

Section of the FAR Affected: 14 CFR 135.251, 135.255, and 135.353, and appendixes I and J to part 121.

Description of Relief Sought/

Disposition: To permit allow the FPA to conduct local sightseeing flights at Freeport Albertus Airport, for the United Way campaign kickoff hosted by the United Way on September 18, 1999, for compensation or hire, without complying with certain anti-drug and alcohol misuse prevention requirements of part 135.

GRANT, 9/17/99, Exemption No. 6996

Docket No.: 29682.

Petitioner: GE Engine Services—Corporate Aviation, Inc.

Section of the FAR Affected: 14 CFR 145.45(f).

Description of Relief Sought/

Disposition: To permit GE Engine Services—Corporate Aviation, Inc.,

doing business as Garrett Aviation Services, to place and maintain copies of its inspection procedures manual (IPM) in strategic locations throughout its maintenance facility rather than giving a copy of the IPM to each of its supervisory and inspection personnel.

GRANT, 12/16/99, Exemption No. 7089

Docket No.: 29792.

Petitioner: Tennessee Technical Services, L.L.C.

Section of the FAR Affected: 14 CFR 145.45(f).

Description of Relief Sought/

Disposition: To permit Tennessee Technical Services, L.L.C., to place copies of its inspection procedures manual (IPM) in strategic locations throughout its repair station rather than giving a copy of its IPM to each of its supervisory and inspection personnel.

GRANT, 12/23/99, Exemption No. 7092

Docket No.: 29234.

Petitioner: Cowboy Transportation Company.

Section of the FAR Affected: 14 CFR 135.163(f)(2), 135.411(c), and/or 135.421(c) and (d).

Description of Relief Sought/

Disposition: To permit Cowboy to conduct passenger-carrying operations under instrument flight rules (IFR) in its single-engine aircraft without complying with certain equipment and maintenance requirements of part 135.

DENIAL, 12/23/99, Exemption No. 7091

[FR Doc. 00-247 Filed 1-5-00; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Ex Parte No. 290 (Sub-No. 2) and (Sub-No. 5)]

Decision: Railroad Cost Recovery Procedures and Quarterly Rail Cost Adjustment Factor

Decided: December 29, 1999.

In this decision, we grant the request of Western Coal Traffic League (WCTL) to inspect all RCAF workpapers used in developing the Rail Cost Adjustment Factor (RCAF). We order the American Association of Railroads (AAR) to make available for inspection the confidential RCAF workpapers under the condition that the proprietary workpapers are subject to a standard protective order and treated as "Highly Confidential."

Background

Under the provisions of 49 U.S.C. 10708, the Board periodically issues the

RCAF, which is an index reflecting changes in railroad costs. The RCAF data are developed by the AAR, and are reviewed by Board staff and audited by an independent accounting firm.¹

In a filing transmitting to the Board its data for the fourth quarter 1999 RCAF, the AAR disclosed that the previous quarter's filing contained an error in the calculation of the weights for the Materials and Supplies component of the RCAF for the third quarter of 1999. The error, which was discovered by the AAR, was not of sufficient magnitude to alter the RCAF.

Nonetheless, in a letter dated September 13, 1999, WCTL asks the Board to direct the AAR to permit private parties to review the AAR's RCAF calculations. WCTL notes that shippers use the RCAF to periodically adjust many rail rates, and thus it asks that affected shippers be given the opportunity to review the accuracy of the underlying calculations. The AAR did not respond to WCTL's request.

Discussion and Conclusions

WCTL's request will be granted. Clearly, the accuracy of the RCAF is important, and although the data are already audited, mistakes are possible. Granting WCTL's request will enhance the accuracy of the data, and will also maintain shipper confidence in the RCAF process.

We recognize that, in 1990, our predecessor, the Interstate Commerce Commission (ICC), issued an order denying WCTL and its consultants access to the RCAF workpapers on the ground that the information is proprietary and commercially sensitive.² However, as WCTL notes, in various proceedings, the Board has authorized disclosure of commercially sensitive information provided the parties agreed to be bound by appropriate protective orders. Our experience has been that the protective orders and confidentiality agreements entered in recent Board proceedings have been effective.³ We see no reason

¹ The Board conducts regular staff reviews of the RCAF workpapers, and of the audits conducted by certified public accounting firms, whose audit plans are approved and monitored by Board staff.

² *Railroad Cost Recovery Procedures*, Ex Parte No. 290 (Sub-No. 2) (ICC served September 21, 1990).

³ For example, we protect the very sensitive STB Carload Waybill Sample data using confidentiality agreements. Protective orders were also successfully used to protect commercially sensitive information in STB Finance Docket 33388, *CSX Corporation and CSX Transportation, Inc., Norfolk Southern Corporation and Norfolk Southern Railway Company—Control and Operating Leases/Agreements—Conrail Inc. and Consolidated Rail Corporation*, and STB Docket No. 41989, *Potomac*

why the RCAF workpapers can not be similarly protected pursuant to an appropriate order. Therefore, we grant WCTL's request and order the AAR to make available for inspection the confidential RCAF workpapers under the condition that the proprietary workpapers are subject to a standard protective order and treated as "Highly Confidential."

It is ordered:

1. WCTL's request is granted.
2. AAR shall make available for inspection the confidential RCAF workpapers under the condition that the proprietary workpapers are subject to a standard protective order and treated as "Highly Confidential."

3. This decision is effective on January 5, 2000.

By the Board, Chairman Morgan, Vice Chairman Clyburn, and Commissioner Burkes.

Vernon A. Williams,

Secretary.

[FR Doc. 00-193 Filed 1-5-00; 8:45 am]

BILLING CODE 4915-00-P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

December 28, 1999.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104-13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

DATES: Written comments should be received on or before February 7, 2000, to be assured of consideration.

Financial Crimes Enforcement Network (FinCEN)

OMB Number: New (Formerly under 1515-0079).

Form Number: Customs Form 4790.

Type of Review: Extension.

Title: Report of International Transportation of Currency or Monetary Instruments (CMIR).

Description: Persons transporting into or out of the United States (and persons receiving in the United States) more

than \$10,000 in currency or monetary instruments must file a CMIR.

Respondents: Individuals or households, business or other for-profit.

Estimated Number of Respondents: 180,000.

Estimated Burden Hours Per

Respondent: 11 minutes.

Frequency of Response: On occasion.

Estimated Total Reporting Burden: 33,000 hours.

Clearance Officer: Lois K. Holland, (202) 622-1563, Departmental Offices, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

OMB Reviewer: Alexander T. Hunt, (202) 395-7860, Office of Management and Budget, Room 10202, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 00-283 Filed 1-5-00; 8:45 am]

BILLING CODE 4810-31-U

DEPARTMENT OF THE TREASURY

Customs Service

Extension of General Program Test; Quota Preprocessing

AGENCY: Customs Service, Treasury.

ACTION: General notice.

SUMMARY: This notice announces that the testing period for the quota preprocessing program, which allows for the electronic processing of quota-class apparel merchandise, is being extended through the year 2000. The test is being extended and not expanded at this time because of programming changes that will be made to the Automated Commercial System. When the programming changes which are scheduled to begin on March of 2000 have been completed, Customs will expand the program to all ports. Public comments concerning any aspect of the test are solicited.

DATES: The test is extended from January 1, 2000, until December 31, 2000, with evaluations of the test occurring periodically. Applications to participate in the test and comments concerning the test will continue to be accepted throughout the testing period.

ADDRESSES: Written comments regarding this notice or any aspect of this test should be addressed to Lori Bowers, U.S. Customs Service, QWG Team Leader, 1000 Second Ave., Suite 2100, Seattle, WA 98104-1020 or may be sent via e-mail to Lori.Bowers@customs.treas.gov. Applications should be sent to the prototype coordinator at any of the four

following port(s) where the applicant wishes to submit quota entries for preprocessing:

(1) Julian Velasquez, Port of Los Angeles, 300 S. Ferry St., Terminal Island, CA 90731;

(2) Tony Piscitelli, Los Angeles International Airport, 11099 S. La Cienega Blvd., Los Angeles, CA 90045;

(3) Barry Goldberg, JFK Airport, JFK Building 77, Jamaica, NY 11430; and

(4) John Lava, Ports of New York/Newark, 6 World Trade Center, New York, NY 10048.

FOR FURTHER INFORMATION CONTACT: Lori Bowers (206) 553-0452 or Cynthia Porter (202) 927-5399.

SUPPLEMENTARY INFORMATION: On July 24, 1998, Customs published a general notice in the *Federal Register* (63 FR 39929) announcing the limited testing, pursuant to the provisions of § 101.9(a) of the Customs Regulations (19 CFR 101.9(a)), of a new operational procedure regarding the electronic processing of quota-class apparel merchandise. The new procedure was designed to allow certain quota entries (merchandise classifiable in chapters 61 and 62 of the Harmonized Tariff Schedule of the United States (HTSUS)) to be processed prior to carrier arrival, thus, reducing the quota processing time. The test was to be conducted at only four ports located in New York/Newark and Los Angeles and was to commence no earlier than August 24, 1998, and run for approximately six months. The notice informed the public of the new procedure and eligibility requirements for participation in the test, and solicited comments concerning any aspect of the test. The initial testing of the quota preprocessing program did not begin until September 15, 1998. The six-month time period of the original test expired on March 14, 1999.

On March 25, 1999, Customs published a general notice in the *Federal Register* (64 FR 14499) announcing that the testing period for the quota preprocessing program was being extended through the remainder of 1999. The testing was extended so that Customs could further evaluate the program's effectiveness and determine whether the program should be extended to other ports. Again, the notice informed the public of the eligibility requirements for participation in the test, and solicited comments concerning any aspect of the test. The testing of the program is currently scheduled to expire on December 31, 1999.

In the future, Customs will be expanding the quota preprocessing program to all ports. However,

programming changes have to be made to the Automated Commercial System (ACS) which would have an impact on the expansion. These ACS programming changes are scheduled to begin in March of 2000.

This document announces that Customs is extending the test of the quota preprocessing prototype at the ports where testing is already underway until the end of 2000. Those ports are: the port of Los Angeles; the port of New York/Newark; JFK Airport; and Los Angeles International Airport. Anyone interested in participating in the test should refer to the test notice published in the July 24, 1998 **Federal Register** for eligibility and application information. Any expansion of the parameters of the test will be the subject of a future **Federal Register** notice.

Dated: January 3, 2000.

Elizabeth G. Durant,
Acting Assistant Commissioner, Office of
Field Operation.

[FR Doc. 00-266 Filed 1-5-00; 8:45 am]
BILLING CODE 4820-02-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request Forms 5310 and 6088

AGENCY: Internal Revenue Service (IRS), Treasury

ACTION: Notice and request for comments

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 5310, Application for Determination for Terminating Plan, and Form 6088, Distributable Benefits from Employee Pension Benefit Plans.

DATES: Written comments should be received on or before March 6, 2000 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 form(s) and instructions 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 5310, Application for Determination for Terminating Plan, and Form 6088, Distributable Benefits from Employee Pension Benefit Plans.

OMB Number: 1545-0202.

Form Number: Forms 5310 and 6088.

Abstract: Employers who have qualified deferred compensation plans can take an income tax deduction for contributions to their plans. Form 5310 is used to request an IRS determination letter about the plan's qualification status (qualified or non-qualified) under Internal Revenue Code section 401(a). Form 6088 is used to show the amounts of distributable benefits to participants in the plan.

Current Actions: There are no changes being made to the forms at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Responses: 30,000.

Estimated Time Per Response: 37 hours, 56 minutes.

Estimated Total Annual Burden Hours: 1,138,050.

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: December 28, 1999.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 00-276 Filed 1-5-00; 8:45 am]

BILLING CODE 4830-01-J

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8508

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8508, Request for Waiver From Filing Information Returns on Magnetic Media.

DATES: Written comments should be received on or before March 6, 2000 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 form(s) and instructions should be directed to Carol Savage, (202) 622-3945, Internal Revenue Service, room 5242, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Request for Waiver From Filing Information Returns on Magnetic Media.

OMB Number: 1545-0957.

Form Number: 8508.

Abstract: Certain filers of information returns are required by law to file on magnetic media. In some instances, waivers from this requirement are necessary and justified. Form 8508 is submitted by the filer and provides information on which the Internal Revenue Service will base its waiver determination.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, non-profit institutions, farms, the Federal government, and state, local or tribal governments.

Estimated Number of Respondents: 1,000.

Estimated Time Per Respondent: 45 minutes.

Estimated Total Annual Burden Hours: 750.

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: December 28, 1999.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 00-277 Filed 1-5-00; 8:45 am]

BILLING CODE 4830-01-U



Federal Register

Thursday
January 6, 2000

Part II

Department of Energy

18 CFR Part 35
Regional Transmission Organizations;
Final Rule

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission****18 CFR Part 35**

[Docket No. RM99-2-000; Order No. 2000]

Regional Transmission Organizations

Issued December 20, 1999.

AGENCY: Federal Energy Regulatory Commission**ACTION:** Final Rule.

SUMMARY: The Federal Energy Regulatory Commission (Commission) is amending its regulations under the Federal Power Act (FPA) to advance the formation of Regional Transmission Organizations (RTOs). The regulations require that each public utility that owns, operates, or controls facilities for the transmission of electric energy in interstate commerce make certain filings with respect to forming and participating in an RTO. The Commission also codifies minimum characteristics and functions that a transmission entity must satisfy in order to be considered an RTO. The Commission's goal is to promote efficiency in wholesale electricity markets and to ensure that electricity consumers pay the lowest price possible for reliable service.

EFFECTIVE DATE: This Final Rule will become effective March 6, 2000.

FOR FURTHER INFORMATION CONTACT:

Alan Haymes (Technical Information), Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, (202) 219-2919.

Brian R. Gish (Legal Information), Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, (202) 208-0996.

James Apperson (Collaborative Process), Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, (202) 219-2962.

SUPPLEMENTARY INFORMATION: In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through FERC's Home Page (<http://www.ferc.fed.us>) and in FERC's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street, NE, Room 2A, Washington, DC 20426.

From FERC's Home Page on the Internet, this information is available in

both the Commission Issuance Posting System (CIPS) and the Records and Information Management System (RIMS).

—CIPS provides access to the texts of formal documents issued by the Commission since November 14, 1994.

—CIPS can be accessed using the CIPS link or the Energy Information Online icon. The full text of this document will be available on CIPS in ASCII and WordPerfect 8.0 format for viewing, printing, and/or downloading.

—RIMS contains images of documents submitted to and issued by the Commission after November 16, 1981. Documents from November 1995 to the present can be viewed and printed from FERC's Home Page using the RIMS link or the Energy Information Online icon. Descriptions of documents back to November 16, 1981, are also available from RIMS-on-the-Web; requests for copies of these and other older documents should be submitted to the Public Reference Room.

User assistance is available for RIMS, CIPS, and the Website during normal business hours from our Help line at (202) 208-2222 (E-Mail to WebMaster@ferc.fed.us) or the Public Reference at (202) 208-1371 (E-Mail to public.referenceroom@ferc.fed.us).

During normal business hours, documents can also be viewed and/or printed in FERC's Public Reference Room, where RIMS, CIPS, and the FERC Website are available. User assistance is also available.

Table of Contents

I. Introduction and Summary

II. Background

- A. The Foundation for Competitive Markets: Order Nos. 888 and 889
- B. Developments Since Order Nos. 888 and 889

- 1. Industry Restructuring and New Stresses on the Transmission Grid
- 2. Successes, Failures and Haphazard Development of Regional Transmission Entities
- 3. The Commission's ISO and RTO Inquires; Conferences with Stakeholders and State Regulators

III. Discussion

- A. Existence of Barriers and Impediments to Achieving Fully Competitive Electricity Markets
- B. Benefits That RTOs Can Offer to Address Remaining Barriers and Impediments
- C. Commission's Approach to RTO Formation
 - 1. Voluntary Approach
 - 2. Organizational Form of an RTO
 - 3. Degree of Specificity in the Rule
 - 4. Legal Authority

D. Minimum Characteristics of an RTO

- 1. Independence (Characteristic 1)
- 2. Scope and Regional Configuration (Characteristic 2)
- 3. Operational Authority (Characteristic 3)
- 4. Short-Term Reliability (Characteristic 4)
- E. Minimum Functions of an RTO
 - 1. Tariff Administration and Design (Function 1)
 - 2. Congestion Management (Function 2)
 - 3. Parallel Path Flow (Function 3)
 - 4. Ancillary Services (Function 4)
 - 5. OASIS and Total Transmission Capability (TTC) and Available Transmission Capability (ATC) (Function 5)
 - 6. Market Monitoring (Function 6)
 - 7. Planning and Expansion (Function 7)
 - 8. Interregional Coordination (Function 8)
- F. Open Architecture
- G. Transmission Ratemaking Policy for RTOs

- 1. Pancaked Rates
- 2. Reciprocal Waiving of Access Charges Between RTOs
- 3. Uniform Access Charges
- 4. Congestion Pricing
- 5. Service to Transmission-Owning Utilities That Do Not Participate in an RTO
- 6. Performance-Based Rate Regulation
- 7. Other RTO Transmission Ratemaking Reforms
- 8. Additional Ratemaking Issues
- 9. Filing Procedures for Innovative Rate Proposals
- H. Other Issues

- 1. Public Power and Cooperative Participation in RTOs
- 2. Participation by Canadian and Mexican Entities
- 3. Existing Transmission Contracts
- 4. Power Exchanges (PXs)
- 5. Effect on Retail Markets and Retail Access
- 6. Effect on States with Low Cost Generation
- 7. States' Roles with Regard to RTOs
- 8. Accounting Issues
- 9. Market Design Lessons
- I. Collaborative Process
- J. Implementation Issues
 - 1. Filing Requirements
 - 2. Deadline for RTO Operation
 - 3. Commission Processing Procedures
 - 4. Other Implementation Issues
- IV. Environmental Statement
- V. Regulatory Flexibility Act Certification
- VI. Public Reporting Burden and Information Collection Statement
- VII. Effective Date and Congressional Notification
- VIII. Document Availability

Regulatory Text
Appendix

Before Commissioners: James J. Hoecker, Chairman; William L. Massey, Linda Breathitt, and Curt Hébert, Jr.

I. Introduction and Summary

In 1996 the Commission put in place the foundation necessary for competitive wholesale power markets in this country—open access

transmission.¹ Since that time, the industry has undergone sweeping restructuring activity, including a movement by many states to develop retail competition, the growing divestiture of generation plants by traditional electric utilities, a significant increase in the number of mergers among traditional electric utilities and among electric utilities and gas pipeline companies, large increases in the number of power marketers and independent generation facility developers entering the marketplace, and the establishment of independent system operators (ISOs) as managers of large parts of the transmission system. Trade in bulk power markets has continued to increase significantly and the Nation's transmission grid is being used more heavily and in new ways.

On May 13, 1999, the Commission proposed a rule on Regional Transmission Organizations (RTOs) that identified and discussed our concerns with the traditional means of grid management.² In that Notice of Proposed Rulemaking (NOPR), the Commission reviewed evidence that traditional management of the transmission grid by vertically integrated electric utilities was inadequate to support the efficient and reliable operation that is needed for the continued development of competitive electricity markets, and that continued discrimination in the provision of transmission services by vertically integrated utilities may also be impeding fully competitive electricity markets. These problems may be depriving the Nation of the benefits of lower prices and enhanced reliability. The comments on the NOPR overwhelmingly support the conclusion that independent regionally operated transmissions grids will enhance the benefits of competitive electricity markets. Competition in wholesale electricity markets is the best way to protect the public interest and ensure that electricity consumers pay the

lowest price possible for reliable service.

Regional institutions can address the operational and reliability issues now confronting the industry, and eliminate any residual discrimination in transmission services that can occur when the operation of the transmission system remains in the control of a vertically integrated utility. Appropriate regional transmission institutions could: (1) Improve efficiencies in transmission grid management;³ (2) improve grid reliability; (3) remove remaining opportunities for discriminatory transmission practices; (4) improve market performance; and (5) facilitate lighter handed regulation.

Thus, we believe that appropriate RTOs could successfully address the existing impediments to efficient grid operation and competition and could consequently benefit consumers through lower electricity rates resulting from a wider choice of services and service providers. In addition, substantial cost savings are likely to result from the formation of RTOs.

Based on careful consideration of the thoughtful comments submitted in response to the NOPR,⁴ the Commission adopts a final rule that generally follows the approach of the NOPR. Our objective is for all transmission-owning entities in the Nation, including non-public utility entities, to place their transmission facilities under the control of appropriate RTOs in a timely manner. Therefore, we are establishing in this rule minimum characteristics and functions for appropriate RTOs; a collaborative process by which public utilities and non-public utilities that own, operate or control interstate transmission facilities, in consultation with state officials as appropriate, will consider and develop RTOs; a proposal to consider transmission ratemaking reforms on a case-specific basis; an opportunity for non-monetary regulatory benefits, such as deference in dispute resolution and streamlined filing and approval procedures; and a time line for public utilities to make appropriate filings with the Commission to initiate operation of RTOs. As a result of this voluntary approach, we expect jurisdictional utilities to form RTOs. If

the industry fails to form RTOs under this approach, the Commission will reconsider what further regulatory steps are in the public interest.

Pursuant to our authority under section 205 of the Federal Power Act (FPA) to ensure that rates, terms and conditions of transmission and sales for resale in interstate commerce by public utilities are just, reasonable and not unduly discriminatory or preferential, and our authority under section 202(a) of the FPA to promote and encourage regional districts for the voluntary interconnection and coordination of transmission facilities by public utilities and non-public utilities for the purpose of assuring an abundant supply of electric energy throughout the United States with the greatest possible economy, this rule requires the following.

First, the Commission establishes minimum characteristics and functions that an RTO must satisfy in the following areas:

Minimum Characteristics:

1. Independence
2. Scope and Regional Configuration
3. Operational Authority
4. Short-term Reliability

Minimum Functions:

1. Tariff Administration and Design
2. Congestion Management
3. Parallel Path Flow
4. Ancillary Services
5. OASIS and Total Transmission Capability (TTC) and Available Transmission Capability (ATC)
6. Market Monitoring
7. Planning and Expansion
8. Interregional Coordination

Industry participants, however, retain flexibility in structuring RTOs that satisfy the minimum characteristics and functions. For example, we do not propose to require or prohibit any one form of organization for RTOs or require or prohibit RTO ownership of transmission facilities. The characteristics and functions could be satisfied by different organizational forms, such as ISOs, transcos, combinations of the two, or even new organizational forms not yet discussed in the industry or proposed to the Commission. Likewise, the Commission is not proposing a "cookie cutter" organizational format for regional transmission institutions or the establishment of fixed or specific regional boundaries under section 202(a) of the FPA.

We also establish an "open architecture" policy regarding RTOs, whereby all RTO proposals must allow the RTO and its members the flexibility to improve their organizations in the

¹ See Promoting Wholesale Competition Through Open Access Non-discriminatory Transmission Services by Public Utilities and Recovery of Stranded Costs by Public Utilities and Transmitting Utilities, Order No. 888, 61 FR 21,540 (May 10, 1996), FERC Stats. & Regs. ¶ 31,036 (1996) (Order No. 888), *order on reh'g*, Order No. 888-A, 62 FR 12,274 (March 14, 1997), FERC Stats. & Regs. ¶ 31,048 (1997) (Order No. 888-A), *order on reh'g*, Order No. 888-B, 81 FERC ¶ 61,248 (1997), *order on reh'g*, Order No. 888-C, 82 FERC ¶ 61,046 (1998), *appeal docketed*, Transmission Access Policy Study Group, *et al. v. FERC*, Nos. 97-1715 *et al.* (D.C. Cir.).

² Regional Transmission Organizations, Notice of Proposed Rulemaking, 64 FR 31,390 (June 10, 1999), FERC Stats. & Regs. ¶ 32,541 at 33,683-781 (1999).

³ As discussed more fully later, appropriate regional institutions could improve efficiencies in grid management through improved pricing, congestion management, more accurate estimates of Available Transmission Capability, improved parallel path flow management, more efficient planning, and increased coordination between regulatory agencies.

⁴ The Commission received 334 initial and reply comments in response to the NOPR. The commenters, and abbreviations for them as used herein, are listed in an Appendix to this Final Rule.

future in terms of structure, operations, market support and geographic scope to meet market needs. In turn, the Commission will provide the regulatory flexibility to accommodate such improvement.

Second, to facilitate RTO formation in all regions of the Nation, the Commission will sponsor and support a collaborative process to take place in the Spring of 2000. Under this process, we expect that public utilities and non-public utilities, in coordination with state officials, Commission staff, and all affected interest groups, will actively work toward the voluntary development of RTOs.

Third, we provide guidance on flexible transmission ratemaking that may be proposed by RTOs, including ratemaking treatments that will address congestion pricing and performance-based regulation. We also propose to consider on a case-by-case basis incentive pricing that may be appropriate for transmission facilities under RTO control.

Finally, all public utilities (with the exception of those participating in an approved regional transmission entity that conforms to the Commission's ISO principles) that own, operate or control interstate transmission facilities must file with the Commission by October 15, 2000, a proposal for an RTO with the minimum characteristics and functions to be operational by December 15, 2001,⁵ or, alternatively, a description of efforts to participate in an RTO, any existing obstacles to RTO participation, and any plans to work toward RTO participation. We expect that such proposals would include the transmission facilities of public utilities as well as transmission facilities of public power and other non-public utility entities to the extent possible. Through the required filings, public utilities will make known to the public any plans for RTO participation and any obstacles to RTO formation.

⁵ An RTO proposal includes a basic agreement filed under section 205 of the FPA setting out the rules, practices and procedures under which the RTO will be governed and operated, and requests by the public utility members of the RTO under section 203 of the FPA to transfer control of their jurisdictional transmission facilities from individual public utilities to the RTO. Most RTO proposals by public utilities are likely to involve one or more filings under FPA sections 203 and 205, but the number and types of filing may vary depending upon the type of RTO proposed and the number of public utilities involved in the proposal. Under the Rule, a utility may file a petition for a declaratory order asking, for example, whether a proposed transmission entity would qualify as an RTO or if a new or innovative method for pricing transmission service would be acceptable, to be followed by appropriate filings under sections 203 and 205.

A public utility that is a member of an existing transmission entity that has been approved by the Commission as in conformance with the eleven ISO principles set forth in Order No. 888 must make a filing no later than January 15, 2001. That filing must explain the extent to which the transmission entity in which it participates meets the minimum characteristics and functions for an RTO, and either propose to modify the existing institution to the extent necessary to become an RTO, or explain the efforts, obstacles and plans with respect to conforming to these characteristics and functions.

The goal of this rulemaking is to form RTOs voluntarily and in a timely manner. The alternative to a voluntary process is likely to be a lengthy process that is more likely to result in greater standardization of the Commission's RTO requirements among regions. Although the Commission has specific authorities and responsibilities under the FPA to protect against undue discrimination and remove impediments to wholesale competition, we find it appropriate in this instance to adopt an open collaborative process that relies on voluntary regional participation to design RTOs that can be tailored to specific needs of each region.

II. Background

In April 1996, in Order Nos. 888⁶ and 889,⁷ the Commission established the foundation necessary to develop competitive bulk power markets in the United States: non-discriminatory open access transmission services by public utilities and stranded cost recovery rules that would provide a fair transition to competitive markets. Order Nos. 888 and 889 were very successful in accomplishing much of what they set out to do. However, the orders were not intended to address all problems that might arise in the development of competitive power markets. Indeed, the nature of the emerging markets and the remaining impediments to full competition that became apparent in the nearly four years since the issuance of Order Nos. 888 and 889, and the insightful comments and information presented to us by a wide array of industry participants in this rulemaking proceeding have made clear that the Commission must take further action if

⁶ See *supra* note 1.

⁷ Open Access Same-Time Information System (Formerly Real-Time Information Networks) and Standards of Conduct, Order No. 889, 61 FR 21,737 (May 10, 1996), FERC Stats. & Regs. ¶ 31,035 (1996), *order on reh'g*, Order No. 889-A, 62 FR 12,484 (March 14, 1997), FERC Stats. & Regs. ¶ 31,049 (1997), *order on reh'g*, Order No. 889-B, 81 FERC ¶ 61,253 (1997).

we are to achieve the fully competitive power markets envisioned by those orders.

A. The Foundation for Competitive Markets: Order Nos. 888 and 889

In Order Nos. 888 and 889, the Commission found that unduly discriminatory and anticompetitive practices existed in the electric industry, and that transmission-owning utilities had discriminated against others seeking transmission access.⁸ The Commission stated that its goal was to ensure that customers have the benefits of competitively priced generation, and determined that non-discriminatory open access transmission services (including access to transmission information) and stranded cost recovery were the most critical components of a successful transition to competitive wholesale electricity markets.⁹

Accordingly, Order No. 888 required all public utilities that own, control or operate facilities used for transmitting electric energy in interstate commerce to (1) file open access non-discriminatory transmission tariffs containing, at a minimum, the non-price terms and conditions set forth in the Order, and (2) functionally unbundle wholesale power services. Under functional unbundling, the public utility must: (1) take transmission services under the same tariff of general applicability as do others; (2) state separate rates for wholesale generation, transmission, and ancillary services; and (3) rely on the same electronic information network that its transmission customers rely on to obtain information about its transmission system when buying or selling power.¹⁰ Order No. 889 required that all public utilities establish or participate in an Open Access Same-Time Information System (OASIS) that meets certain specifications, and comply with standards of conduct designed to prevent employees of a public utility (or any employees of its affiliates) engaged in wholesale power marketing functions from obtaining preferential access to pertinent transmission system information.

During the course of the Order No. 888 proceeding, the Commission received comments urging it to require generation divestiture or structural institutional arrangements such as regional independent system operators (ISOs) to better assure non-discrimination. The Commission responded that, while it believed that

⁸ Order No. 888, FERC Stats. & Regs. ¶ 31,036 at 31,682.

⁹ *Id.* at 31,652.

¹⁰ *Id.* at 31,654-55.

ISOs had the potential to provide significant benefits, efforts to remedy undue discrimination should begin by requiring the less intrusive functional unbundling approach. Subsequent to issuance of Order No. 888, it has become apparent that several types of regional transmission institutions, in addition to the kinds of ISOs approved to date, may also be able to provide the benefits attributed to ISOs in Order No. 888.

Order No. 888 set forth 11 principles for assessing ISO proposals submitted to the Commission.¹¹ Order No. 888 also stated:

[W]e see many benefits in ISOs, and encourage utilities to consider ISOs as a tool to meet the demands of the competitive marketplace. As a further precaution against discriminatory behavior, we will continue to monitor electricity markets to ensure that functional unbundling adequately protects transmission customers. At the same time, we will analyze all alternative proposals, including formation of ISOs, and, if it becomes apparent that functional unbundling is inadequate or unworkable in assuring non-discriminatory open access transmission, we will reevaluate our position and decide whether other mechanisms, such as ISOs, should be required.¹²

Below, we summarize our experiences with functional unbundling from the date of issuance of Order Nos. 888 and 889.

B. Developments Since Order Nos. 888 and 889

In the nearly four years since Order Nos. 888 and 889 were issued, numerous significant developments have occurred in the electric utility industry. Some of these reflect changes in governmental policies; others are strictly industry-driven. These activities have resulted in a considerably different industry landscape from the one faced at the time the Commission was developing Order No. 888, resulting in new regulatory and industry challenges.

Order Nos. 888 and 889 required a significant change to the way many public utilities have done business for most of this century, and most public utilities accepted these changes and made substantial good faith efforts to comply with the new requirements. Virtually all public utilities have filed tariffs stating rates, terms and conditions for comparable service to third-party users of their transmission systems. In addition, improved information about the transmission system is available to all participants in the market at the same time that it is

available to the public utility's merchant function and market affiliate as a result of utility compliance with the OASIS regulations.

The availability of tariffs and information about the transmission system has fostered a rapid growth in dependence on wholesale markets for acquisition of generation resources. Areas that have experienced generation shortages have seen rapid development of new generation resources. For example, in the Northeast Power Coordinating Council (NPCC) region (including New England, New York and parts of eastern Canada), where there was deep concern about adequacy of generation supply only three years ago, approximately 30,000 MW of generation is proposed or actually under construction.¹³ That response comes almost entirely from independent generating plants, which are able to sell power into the bulk power market through open access to the transmission system. Power resources are now acquired over increasingly large regional areas, and interregional transfers of electricity have increased. The very success of Order Nos. 888 and 889, and the initiative of some utilities that have pursued voluntary restructuring beyond the minimum open access requirements, have placed new stresses on regional transmission systems—stresses that call for regional solutions.

1. Industry Restructuring and New Stresses on the Transmission Grid

Open access transmission and the opening of wholesale competition in the electric industry have brought an array of changes in the past several years: Divestiture by many integrated utilities of some or all of their generating assets; significantly increased merger activity both between electric utilities and between electric and natural gas utilities; increases in the number of new participants in the industry in the form of both independent and affiliated power marketers and generators as well as independent power exchanges; increases in the volume of trade in the industry, particularly sales by marketers; state efforts to introduce retail competition; and new and different uses of the transmission grid.

With respect to divestiture, since August 1997, generating facilities representing approximately 50,000 MW of generating capacity have been sold (or are under contract to be sold) by utilities, and an additional 30,000 MW is currently for sale. In total, this represents more than ten percent of U.S.

generating capacity. In all, 27 utilities have sold all or some of their generating assets and seven others have assets for sale. Buyers of this generating capacity have included traditional utilities with specified service territories as well as independent power producers with no required service territory.

Since Order No. 888 was issued, more than 40 applications have been filed for Commission approval of proposed mergers involving public utilities.¹⁴ Most of these merger proposals involve electric utilities with contiguous service areas, although some of the proposed mergers have been between utilities with non-contiguous service areas. In addition, an increasing number of applications involve the combination of electric and natural gas assets.

There has been significant growth in the volume of trading, and particularly the number of marketers, in the wholesale electricity market. For example, in the first quarter of 1995, according to power marketer quarterly filings, marketer sales traded by only eight active power marketers, totaled 1.8 million MWh. By the first quarter of 1999, such sales escalated to over 400 million MWh, traded by over 100 power marketers.¹⁵

The Commission has granted market-based rate authority to more than 800 entities, of which nearly 500 are power marketers, (including over 100 marketers affiliated with investor-owned utilities). The remaining entities include approximately equal numbers of affiliated power producers, investor-owned utilities and other utilities.¹⁶

State commissions and legislatures have been active in the past few years studying competitive options at the retail level, setting up pilot retail access programs, and, in many states, implementing full scale retail access programs. As of November 1, 1999, twenty-one states had enacted electric restructuring legislation, three had issued comprehensive regulatory orders, and twenty-six states plus the District of Columbia had legislation or orders pending or investigations underway.¹⁷ Fifteen states had implemented full-

¹⁴ See Commission's website, www.ferc.fed.us/electric/mergers.

¹⁵ See Commission's website, www.ferc.fed.us/electric/PwrMkt. The Commission recognizes that a significant portion of the sales represent the retrading of power by a number of different market participants, such that there may be multiple resales of the same generation. Nonetheless, the volume of and intensity of trading continues to increase in the wholesale electricity market.

¹⁶ See Commission's website, www.ferc.fed.us/electric.

¹⁷ See the Energy Information Administration website, www.eia.doe.gov/cneaf/electricity/chg_str/regmap.html.

¹¹ Order No. 888, FERC Stats. & Regs. ¶ 31,036 at 31,730.

¹² *Id.* at 31,655.

¹³ Based on data supplied to the Commission by Resource Data International.

scale or pilot retail competition programs that offer a choice of suppliers to at least some retail customers. Eight states have initiated programs to offer access to retail customers by a date certain.

Because of the changes in the structure of the electric industry, the transmission grid is now being used more intensively and in different ways than in the past. The Commission is concerned that the traditional approaches to operating the grid are showing signs of strain. According to the North American Electric Reliability Council (NERC), "the adequacy of the bulk transmission system has been challenged to support the movement of power in unprecedented amounts and in unexpected directions."¹⁸ These changes in the use of the transmission system "will test the electric industry's ability to maintain system security in operating the transmission system under conditions for which it was not planned or designed."¹⁹ It should be noted that, despite the increased transmission system loadings, NERC believes that the "procedures and processes to mitigate potential reliability impacts appear to be working reliably for now," and that even though the system was particularly stressed during the summer of 1998, "the system performed reliably and firm demand was not interrupted due to transmission transfer limitations."²⁰

An indication that the increased and different use of the transmission system is stressing the grid is the increased use of transmission line loading relief (TLR) procedures.²¹ And, according to published reports, the incidence of TLRs is growing. While in all of 1998 over 300 TLRs were called, in the first ten months of 1999, over 400 TLRs have been called, resulting in over 8,000 MW of power curtailment in the three-month summer period beginning June 1999.²²

It appears that the planning and construction of transmission and transmission-related facilities may not be keeping up with increased requirements. According to NERC,

"business is increasing on the transmission system, but very little is being done to increase the load serving and transfer capability of the bulk transmission system."²³ The amount of new transmission capacity planned over the next ten years is significantly lower than the additions that had been planned five years ago, and most of the planned projects are for local system support.²⁴ NERC states that, "The close coordination of generation and transmission planning is diminishing as vertically integrated utilities divest their generation assets and most new generation is being proposed and developed by independent power producers."²⁵

The transition to new market structures has resulted in new challenges and circumstances. For example, during the week of June 22–26, 1998, the wholesale electric market in the Midwest experienced numerous events that led to unprecedented high spot market prices. Spot wholesale market prices for energy briefly rose as high as \$7,500 per MWh, compared with an average price for the summer of approximately \$40 per MWh in the Midwest if the pricing abnormalities are excluded.²⁶ This experience led to calls for price caps, allegations of market power, and a questioning of the effectiveness of transmission open access and wholesale electric competition.

The Commission staff undertook an investigation of the pricing abnormalities. Staff's report concluded that the unusually high price levels were caused by a combination of factors, particularly above-average generation outages, unseasonably hot temperatures, storm-related transmission outages, transmission constraints, poor communication of price signals, lowered confidence in the market due to a few contract defaults, and inexperience in dealing with competitive markets.²⁷

The Commission's staff found that the market institutions were not adequately prepared to deal with such a dramatic series of events. Regarding regional transmission entities, the staff report

observed: "The necessity for cooperation in meeting reliability concerns and the Commission's intent to foster competitive market conditions underscores the importance of better regional coordination in areas such as maintenance of transmission and generation systems and transmission planning and operation."²⁸ Support for this view comes from many sources. For example, the Public Utilities Commission of Ohio, in its own report on the high spot market prices, recommended that policy makers "take unambiguous action to require coordination of transmission system operations by regionwide Independent System Operators."²⁹

On September 29, 1998, the Secretary of Energy Advisory Board Task Force on Electric System Reliability published its final report.³⁰ The Task Force was convened in January 1997 to provide advice to the Department of Energy on critical institutional, technical, and policy issues that need to be addressed in order to maintain bulk power electric system reliability in a more competitive industry. The Task Force found that "the traditional reliability institutions and processes that have served the Nation well in the past need to be modified to ensure that reliability is maintained in a competitively neutral fashion;" that "grid reliability depends heavily on system operators who monitor and control the grid in real time;" and that "because bulk power systems are regional in nature, they can and should be operated more reliably and efficiently when coordinated over large geographic areas."³¹

The report noted that many regions of the United States are developing ISOs as a way to maintain electric system reliability as competitive markets develop. According to the Task Force, ISOs are significant institutions to assure both electric system reliability and competitive generation markets. The Task Force concluded that a large ISO would: (1) Be able to identify and address reliability issues most effectively; (2) internalize much of the loop flow caused by the growing number of transactions; (3) facilitate transmission access across a larger

¹⁸ Reliability Assessment 1998–2007, North American Electric Reliability Council (September 1998), at 26 (Reliability Assessment).

¹⁹ *Id.*

²⁰ *Id.*

²¹ The TLR procedures are designed to remedy overloads that result when a transmission line or other transmission equipment carries or will carry more power than its rating, which could result in either power outages or damage to property. The TLR procedures are designed to bring overloaded transmission equipment to within NERC's Operating Security Limits essentially by curtailing transactions contributing to the overload. See North American Electric Reliability Council, 85 FERC ¶ 61,353 (1998) (NERC).

²² *Power Markets Week*, November 8, 1999 at 1, citing NERC data.

²³ Reliability Assessment at 26.

²⁴ *Id.* at 7.

²⁵ *Id.*

²⁶ See *Staff Report to the Federal Energy Regulatory Commission on the Causes of Wholesale Electric Pricing Abnormalities in the Midwest During June 1998*, (Sept. 22, 1998) (Staff Price Spike Report) at 3–8 to 3–11. Unusually high spot market wholesale prices also occurred during the summer of 1999. The Commission is not aware that any formal evaluations of market data have been performed for that occurrence of price abnormalities.

²⁷ *Id.* at v.

²⁸ *Id.* at 5–8.

²⁹ Ohio's Electric Market, June 22–26, 1998, *What Happened and Why*, A Report to the Ohio General Assembly, at iii.

³⁰ *Maintaining Reliability in a Competitive U.S. Electricity Industry: Final Report of the Task Force on Electric System Reliability* (Sept. 29, 1998) (Task Force Report). The Task Force was comprised of 24 members representing all major segments of the electric industry, including private and public suppliers, power marketers, regulators, environmentalists, and academics.

³¹ Task Force Report at x-xi.

portion of the network, consequently improving market efficiencies and promoting greater competition; and (4) eliminate "pancaking" of transmission rates, thus allowing a greater range of economic energy trades across the network.³²

2. Successes, Failures, and Haphazard Development of Regional Transmission Entities

Since Order No. 888 was issued, there have been both successful and unsuccessful efforts to establish ISOs, and other efforts to form regional entities to operate the transmission facilities in various parts of the country. While we are encouraged by the success of some of these efforts, it is apparent that the results have been inconsistent, and much of the country's transmission facilities remain outside of an operational regional transmission institution.

Proposals for the establishment of five ISOs have been submitted to and approved, or conditionally approved, by the Commission. These are the California ISO,³³ PJM ISO,³⁴ ISO New England,³⁵ the New York ISO,³⁶ and the Midwest ISO.³⁷ In addition, the Texas Commission has ordered an ISO for the Electric Reliability Council of Texas (ERCOT).³⁸ Moreover, our international neighbors in Canada and Mexico are also pursuing electric restructuring efforts that include various forms of regional transmission entities.³⁹

The PJM, New England and New York ISOs were established on the platform of existing tight power pools. It appears

that the principal motivation for creating ISOs in these situations was the Order No. 888 requirement that there be a single systemwide transmission tariff for tight pools. In contrast, the establishment of the California ISO and the ERCOT ISO was the direct result of mandates by state governments. The Midwest ISO, which is not yet operational, is unique. It was neither required by government nor based on an existing institution. Two states in the region subsequently required utilities in their states to participate in either a Commission-approved ISO (Illinois and Wisconsin), or sell their transmission assets to an independent transmission company that would operate under a regional ISO (Wisconsin).

As part of general restructuring initiatives, several states now require independent grid management organizations. For example, an Illinois law required that its utilities become members of a FERC-approved regional ISO by March 31, 1999, and Wisconsin law gives its utilities the option of joining an ISO or selling their transmission assets to an independent transmission company by June 30, 2000. In both states, the backstop is a single-state organization if regional organizations are not developed. Recently, Virginia,⁴⁰ Arkansas⁴¹ and Ohio⁴² have also enacted legislation requiring their electric utilities to join or establish regional transmission entities.

The approved ISOs have similarities as well as differences. All five Commission-approved ISOs operate, or propose to operate, as non-profit organizations. All five ISOs include both public and non-public utility members. However, among the five, there is considerable variation in governance, operational responsibilities, geographic scope and market operations. Four of the ISOs rely on a two-tier form of governance with a non-stakeholder governing board on top that is advised, either formally or informally, by one or more stakeholder groups. In general, the final decision making authority rests with the independent non-stakeholder board. One ISO, the California ISO, uses a board consisting of stakeholders and non-stakeholders.

Four of the five ISOs operate a single control area, but the large Midwest ISO does not currently plan to operate a

single control area. Three are multi-state ISOs (New England, PJM and Midwest), while two ISOs (California and New York) currently operate within a single state. The current Midwest ISO members do not encompass one contiguous geographic area. The ISO New England administers a separate NEPOOL tariff, while the other four administer their own ISO transmission tariffs.

Three ISOs operate or propose to operate centralized power markets (New England, PJM and New York), and one ISO (California) relies on a separate power exchange (PX) to operate such a market.⁴³ The Midwest ISO has not proposed an ISO-related centralized market for its region.⁴⁴ In addition, at least one separate PX has begun to do business in California apart from the PX established through the restructuring legislation.⁴⁵

The existing ISOs are also evolving in terms of their governance structure and as a result of operating experience with the transmission systems and the various markets they operate. For example, the Commission rejected the original governance proposals for two ISOs: the New England ISO and New York ISO. In both cases, the Commission concluded that the vertically integrated utility members of the ISO would have too much voting power in the various advisory committees that provide advice and recommendations to the non-stakeholder Boards. The ISOs resubmitted governance proposals that gave balanced representation to the various sectors of stakeholders, and the Commission subsequently approved both revised governance structures.

In addition, the Commission has considered a number of significant modifications of market rules proposed by the existing ISOs in the seven months since issuance of the RTO

⁴³ The California PX offers day-ahead and hour-ahead markets and the ISO operates a real-time energy market. Participation in the PX market is voluntary except that the three traditional investor-owned utilities in California must bid their generation sales and purchases through the PX for the first five years. New York will offer day-ahead and real-time energy markets that will be operated by the ISO. PJM and New England offer only real-time energy markets, although PJM has proposed to operate a day-ahead market. The ERCOT ISO is the only other ISO that does not currently operate a PX.

⁴⁴ There are indications, however, that the Midwest ISO is considering the formation of a power exchange. See Joint Committee for the Development of a Midwest Independent Power Exchange, "Solicitation of Interest-Creation of an Independent Power Exchange for the U.S. Midwest," February 5, 1999.

⁴⁵ See Automated Power Exchange, Inc., 82 FERC ¶ 61,287, *reh'g denied*, 84 FERC ¶ 61,020 (1998), *appeals docketed*, No. 98-1415 (D.C. Cir. Sept. 14, 1998) and No. 98-1419 (D.C. Cir. Sept. 14, 1998).

³² *Id.* at 76.

³³ Pacific Gas & Electric Company, *et al.*, 77 FERC ¶ 61,204 (1996), *order on reh'g*, 81 FERC ¶ 61,122 (1997) (*Pacific Gas & Electric*).

³⁴ Pennsylvania-New Jersey-Maryland Interconnection, *et al.*, 81 FERC ¶ 61,257 (1997), *order on reh'g*, 82 FERC ¶ 61,047 (1998) (*PJM*).

³⁵ New England Power Pool, 79 FERC ¶ 61,374 (1997), *order on reh'g*, 85 FERC ¶ 61,242 (1998) (*NEPOOL*).

³⁶ Central Hudson Gas & Electric Corporation, *et al.*, 83 FERC ¶ 61,352 (1998), *order on reh'g*, 87 FERC ¶ 61,135 (1999) (*Central Hudson*).

³⁷ Midwest Independent Transmission System Operator, *et al.*, 84 FERC ¶ 61,231, *order on reconsideration*, 85 FERC ¶ 61,250, *order on reh'g*, 85 FERC ¶ 61,372 (1998) (*Midwest ISO*).

³⁸ See 16 Texas Administrative Code § 23.67(p). Furthermore, on June 18, 1999, S.B. 7 was enacted to restructure the Texas electric industry allowing retail competition. The bill requires retail competition to begin by January 2002. Rates will be frozen for three years, and then a six percent reduction will be required for residential and small commercial consumers.

³⁹ See Policy Proposal for Structural Reform of the Mexican Electricity Industry, Secretary of Energy, Mexico (Feb. 1999); Third Interim Report of the Ontario Market Design Committee (Oct. 1998); TransAlta Enterprises Corporation, 75 FERC ¶ 61,268 at 61,875 (1996) (recognition of the restructuring in the Province of Alberta, Canada to create a Grid Company of Alberta).

⁴⁰ See Virginia Electric Utility Restructuring Act, S1269 (Mar. 25, 1999). In Virginia, electric utilities are required by January 2001, to join or establish regional transmission entities.

⁴¹ See The Arkansas Electric Consumer Choice Act of 1999, Act 1, 82nd General Assembly (Apr. 1999).

⁴² See Amended Substitute Senate Bill No. 3, 123rd General Assembly (July 6, 1999).

NOPR. In particular, a number of rules for the California ISO and New England ISO have been modified, affecting the products traded in, and the timing of, the markets for energy, ancillary services, balancing services and transmission.

An additional few transmission restructuring proposals that were pending as of the date of issuance of the RTO NOPR have been approved by the Commission, and others have been filed since that date. In July 1999, the Commission granted a petition for declaratory order filed by Entergy Services Inc., in which the majority concluded that passive ownership of a transmission entity by a generating company or other market participant could meet the ISO principles contained in Order No. 888. The order stated, however, that the passive ownership must be properly designed, such that the transmission entity is truly independent of the market participants.⁴⁶ Another filing that was pending when the NOPR was issued was the request by FirstEnergy to sell its transmission assets to a newly-formed affiliate. The Commission approved the disposition of jurisdictional facilities, noting that the proposed action would not adversely affect competition, rates or regulation. In addition, the Commission noted that the creation of the transmission-owning affiliate would facilitate the subsequent transfer of FirstEnergy's transmission facilities to an RTO, which FirstEnergy pledged to do within two years of Commission approval of the disposition of facilities to its affiliate.⁴⁷

Since issuance of the RTO NOPR, the Alliance Companies filed a proposal to create an RTO. Applicants suggest that the RTO could take one of two forms, either an ISO or a transco, but note that they prefer a transco configuration in which, at least initially, the five transmission-owning participants could hold five percent ownership stakes in the transco.⁴⁸

Not all efforts to create ISOs have been successful. For example, after more than two years of effort, the proponents of the IndeGO (*Independent Grid Operator*) ISO in the Pacific Northwest and Rocky Mountain regions ended

their efforts to create an ISO.⁴⁹ More recently, members of the Mid-American Power Pool (MAPP), an existing power pool that covers six U.S. states and two Canadian provinces, failed to achieve consensus for establishing a long-planned ISO.⁵⁰ In the Southwest, proponents of the Desert STAR ISO have not been able to reach agreement to date on a formal proposal after more than two years of discussion.⁵¹ In the interim period, some of the participants in the Desert STAR ISO have filed at the Commission a proposal to create the Mountain West Independent Scheduling Administrator, which would oversee the scheduling of transmission service within Nevada.⁵²

Various reasons have been advanced to explain the difficulty in forming a voluntary, multi-state ISO. Reasons include: "cost shifting," which involves increases in transmission rates for some parties; disagreements about sharing of ISO transmission revenues among transmission owners; difficulties in obtaining the participation of publicly-owned transmission facilities; concerns about the loss of transmission rights and prices embedded in existing transmission agreements; and the preference of certain transmission owners to sell or transfer their transmission assets to a for-profit transmission company in lieu of handing over control to a non-profit ISO.

3. The Commission's ISO and RTO Inquiries; Conferences With Stakeholders and State Regulators

In light of the various restructuring activities occurring throughout the United States, the Commission has held 11 public conferences in nine different cities across the country to hear the views of industry, consumers, and state regulators with respect to the need for RTOs and their appropriate roles and responsibilities.

The Commission initiated an inquiry in March 1998 pertaining to its policies on ISOs. A notice establishing procedures for a conference gave the following rationale:

⁴⁹ Recently, however, parties in the Pacific Northwest have resumed RTO discussions.

⁵⁰ However, trade press reports suggest that while MAPP members continue to try to reach consensus, the Midwest ISO is in discussion with MAPP members to join the Midwest ISO. See *Inside FERC*, July 26, 1999; *The Energy Report*, Nov. 1, 1999 at 931.

⁵¹ Recent press reports, however, indicate that Desert STAR has incorporated as a non-profit organization, a first step toward the launch of an ISO. See *Energy Daily*, Nov. 5, 1999 at 2.

⁵² See Application of Mountain West Independent Transmission Administrator in Docket No. ER99-3719-000 (filed July 23, 1999).

In Order Nos. 888 and 889 and their progeny, the Commission established the fundamental principles of non-discriminatory open access transmission services. Nevertheless, many issues remain to be addressed if the Nation is to fully realize the benefits of open access and more competitive electric markets.

* * * * *

Given the dramatic changes taking place in both wholesale and retail electric markets and the many proposals under consideration with respect to the creation of ISOs or other transmission entities, such as transmission-only utilities, it is time for the Commission to take stock of its policies in order to determine whether they appropriately support our dual goals of eliminating undue discrimination and promoting competition in electric power markets.⁵³

Accordingly, the Commission held a series of eight conferences in 1998 to gain insight into participants' views on the formation and role of ISOs in the electric utility industry. The first conference was held in April 1998 at the Commission's offices in Washington, D.C. Between May 28 and June 8, 1998, the Commission held seven regional conferences in Phoenix, Kansas City, New Orleans, Indianapolis, Portland, Richmond and Orlando. As a result of these conferences, the Commission heard approximately 145 oral presentations and received a large number of written comments on the appropriate size, scope, organization and functions of regional transmission institutions. A number of different viewpoints were expressed.⁵⁴

On October 1, 1998, the Secretary of Energy delegated his authority under section 202(a) of the FPA to the Commission. In doing so, the Secretary stated that section 202(a) "provides DOE with sufficient authority to establish boundaries for Independent System Operators (ISOs) or other appropriate transmission entities."⁵⁵ The Secretary also stated: "FERC is also increasingly faced with reliability-related issues. Providing FERC with the authority to establish boundaries for ISOs or other appropriate transmission entities could aid in the orderly formation of properly-sized transmission institutions and in addressing reliability-related issues, thereby increasing the reliability of the transmission system."

On November 24, 1998, we gave notice in this docket of our intent to initiate a consultation process with State commissions pursuant to section

⁵³ Inquiry Concerning the Commission's Policy on Independent System Operators, Notice of Conference, Docket No. PL98-5-000, at 1-2 (March 13, 1998).

⁵⁴ A summary of those views was included as Appendix A to the NOPR in this docket.

⁵⁵ 63 FR 53,889 (Oct. 7, 1998).

⁴⁶ See Entergy Services, Inc., 88 FERC ¶ 61,149 (1999) (Commissioner Massey dissented from this order).

⁴⁷ See FirstEnergy Operating Companies, et al., 89 FERC ¶ 61,090 (1999).

⁴⁸ See Application of Alliance Companies in Docket No. ER99-3144-000 (filed June 3, 1999). The Commission issued an order on this application concurrently with the issuance of this Final Rule. See Alliance Companies, 89 FERC ¶ (1999) (*Alliance Companies*).

202(a).⁵⁶ The purpose of the consultations was to afford State commissions a reasonable opportunity to present their views with respect to appropriate boundaries for regional transmission institutions and other issues relating to RTOs. Conferences with State commissioners were held in St. Louis, Missouri, on February 11, 1999; in Las Vegas, Nevada, on February 12, 1999; and in Washington, D.C., on February 17, 1999. In all, we heard oral presentations by representatives of 41 state commissions during these consultations, with others monitoring or providing written comments.⁵⁷ During these sessions, we received much valuable advice. Furthermore, we have had additional consultations since issuance of the RTO NOPR in May 1999.

III. Discussion

A. Existing Barriers and Impediments To Achieving Fully Competitive Electricity Markets

In the NOPR, the Commission expressed its belief that there remain important transmission-related impediments to a competitive wholesale electric market. The Commission grouped these remaining impediments into two broad categories: (1) The engineering and economic inefficiencies inherent in the current operation and expansion of the transmission grid, and (2) continuing opportunities for transmission owners to unduly discriminate in the operation of their transmission systems so as to favor their own or their affiliates' power marketing activities.⁵⁸

With respect to engineering and economic inefficiencies, the NOPR noted that the transmission facilities of any one utility in a region are part of a larger, integrated transmission system which, from an electrical engineering perspective, operates as a single machine.⁵⁹ Engineering and economic inefficiencies occur because each separate operator usually makes independent decisions about the use, limitations and expansion of its piece of the interconnected grid based on incomplete information, even though any action taken by one transmission provider can have major and instantaneous effects on the transmission facilities of all other transmission providers. The Commission noted that, while this was

not a new phenomenon, the demands placed on the transmission grid had changed in recent years due to (1) increases in bulk power trade, (2) large shifts in power flows, and (3) an increasingly de-integrated and decentralized competitive power industry.⁶⁰ As a consequence of these changes in trade patterns and industry structure, certain operational problems had become more significant and difficult to resolve.

Engineering and Economic Inefficiencies. The NOPR identified a number of specific economic and engineering inefficiencies. First, the NOPR noted that the reliability of the nation's bulk power system was being stressed in ways that have never been experienced before, and questioned the continued feasibility of one-on-one coordination of an interconnected transmission grid encompassing more than 100 transmission owners and 140 separate control areas.⁶¹ Second, the NOPR observed that there were increasing difficulties in accurately computing Total Transmission Capacity (TTC) and Available Transmission Capacity (ATC), assessments that require reliable and timely information about load, generation, facility outages and transactions on neighboring systems, as well as consistency in methodologies among systems.⁶² Third, the NOPR noted that efficient congestion management required regional actions, and that the current methods for managing congestion (e.g., Transmission Line Loading Relief procedures in the Eastern Interconnection), which do not attempt to optimize regional congestion relief, were cumbersome, inefficient and disruptive to bulk power markets.⁶³ Fourth, the NOPR expressed concern that the uncertainty associated with transmission planning and expansion had increased with the increasing number and distance of unbundled transactions and the wider variation in generation dispatch patterns. The NOPR pointed to a noticeable decline in planned transmission investments and expressed concern that, without a regional approach to planning and expansion, it would be difficult to address complex and controversial issues that arise when the benefits of an expansion do not necessarily accrue to the transmission system that must undertake the expansion.⁶⁴ Finally, the NOPR explained that pancaked

transmission rates (where a separate access charge is assessed every time the transaction contract path crosses the boundary of another transmission owner) restrict the size of regional power markets. The Commission added that the balkanization of electricity markets hurts consumers who pay higher transmission rates and have access to fewer generation options.⁶⁵

Continuing Opportunities for Undue Discrimination. With respect to continuing opportunities for undue discrimination, the NOPR observed that, when utilities control monopoly transmission facilities and also have power marketing interests, they have poor incentives to provide equal quality transmission service to their power marketing competitors.⁶⁶ The NOPR explained that the Commission had made this point in Order No. 888:

It is in the economic self-interest of transmission monopolists, particularly those with high-cost generation assets, to deny transmission or to offer transmission on a basis that is inferior to that which they provide themselves. The inherent characteristics of monopolists make it inevitable that they will act in their own self-interest to the detriment of others by refusing transmission and/or providing inferior transmission to competitors in the bulk power markets to favor their own generation, and it is our duty to eradicate unduly discriminatory practices.⁶⁷

In the NOPR, the Commission noted that functional unbundling does not change the incentives of vertically integrated utilities to use their transmission assets to favor their own generation, but instead attempt to reduce the ability of utilities to act on those incentives.⁶⁸

The NOPR expressed concern about continuing indications that transmission service problems related to discriminatory conduct remain and concluded that these problems are impeding competitive wholesale power markets.⁶⁹ The NOPR also noted that

⁵⁶ *Id.* at 33,703.

⁵⁷ *Id.* at 33,704.

⁵⁸ Order No. 888, FERC Stats. & Regs. ¶ 31,036 at 31,682.

⁵⁹ As noted in the NOPR, in Order No. 888, the Commission received and considered numerous comments that functional unbundling was unlikely to work, and that more drastic restructuring, such as corporate unbundling, was needed. For example, the Federal Trade Commission advised the Commission that a functional unbundling approach " * * * would leave in place the incentive and opportunity for some utilities to exercise market power in the regulated system. Preventing them from doing so by enforcing regulations to control their behavior may prove difficult." However, the Commission decided at the time to adopt the less intrusive and less costly remedy of functional unbundling. FERC Stats. & Regs. ¶ 32,541 at 33,707.

⁶⁰ The NOPR described specific examples of undue discrimination that had been brought to its

Continued

⁵⁶ Regional Transmission Organizations, Notice of Intent to Consult with State Commission, 63 FR 66,158 (Dec. 1, 1998), FERC Stats. & Regs. ¶ 35,534 (1998).

⁵⁷ See Appendix for a list of commenters.

⁵⁸ FERC Stats. & Regs. ¶ 32,541 at 33,696.

⁵⁹ *Id.* at 33,697.

⁶⁰ *See id.*

⁶¹ *See id.* at 33,699.

⁶² *Id.* at 33,700.

⁶³ *Id.* at 33,701-02.

⁶⁴ *See id.* at 33,702-03.

instances of actual discrimination may be undetectable in a non-transparent market and, in any event, it is often hard to determine, on an after-the-fact basis, whether an action was motivated by an intent to favor affiliates or simply reflected the impartial application of operating or technical requirement. The NOPR added that, while continued discrimination may be deliberate, it could also result from the failure to make sufficient efforts to change the way integrated utilities have done business for many years. The Commission expressed concern that the difficulty in determining whether there has been compliance with our regulations raises the question as to whether functional unbundling is an appropriate long-term regulatory solution.

The NOPR explained that the Commission considers allegations of discrimination, even if not reduced to formal findings, to be a serious concern for two reasons. First, this can be indicative of additional, unreported, discriminatory actions, because there are significant disincentives to filing and pursuing formal complaints that would result in definitive findings.⁷⁰ The NOPR expressed a concern that actual problems with functional unbundling may be more pervasive than formally adjudicated complaints would suggest. Second, the NOPR explained that allegations of discrimination are serious because, if nothing else, they represent a perception by market participants that the market is not working fairly. If market participants perceive that other participants have an unfair advantage through their ownership or control of transmission facilities, it can inhibit their willingness to participate in the market, thus thwarting the development of robust

attention through formal complaints, informal complaints made to the Commission's enforcement hotline, oral and written comments made in conjunction with public conferences held by the Commission, and pleadings filed with the Commission in various dockets. The complaints generally involved: (1) Calculation and posting of ATC in a manner favorable to the transmission provider; (2) standards of conduct violations; (3) line loading relief and congestion management, and (4) OASIS sites that are difficult to use. *See id.* at 33,707-13.

⁷⁰ As noted in the NOPR, transmission customers are reluctant to make even informal complaints because they fear retribution by their transmission supplier; the complaint process is costly and time-consuming; the Commission's remedies for violations do not impose sufficient financial consequences on the transmission provider to act as a significant deterrent; and, in the fast-paced business of power marketing, there may be no adequate remedy for the lost short-term sales opportunities in after-the-fact enforcement. *See* FERC Stats. & Regs. ¶ 32,541 at 33,706.

competition. The NOPR added that such mistrust can also harm reliability.⁷¹

The NOPR explained the potential for undue discrimination increases in a competitive environment unless the market can be made structurally efficient and transparent with respect to information, and equitable in its treatment of competing participants. Also, a system that attempts to control behavior that is motivated by economic self-interest through the use of standards of conduct will require constant and extensive policing and requires the Commission to regulate detailed aspects of internal company policy and communication. The NOPR added that functional unbundling does not necessarily promote light-handed regulation and undoubtedly imposes a cost on those entities that have to comply with the standards of conduct and abide by rules that limit the flexibility of their internal management activities. The NOPR stated that the perception that many entities that operate the transmission system cannot be trusted is not a good foundation on which to build a competitive power market, and it created needless uncertainty and risk for new investments in generation.⁷²

Comments. Engineering and Economic Inefficiencies. Virtually all commenters support the NOPR's premise that engineering and economic inefficiencies exist in the operation, planning and expansion of the regional transmission grid and that these inefficiencies hinder electric system reliability and a fully competitive bulk power market.⁷³ Many commenters state further that, in the new industry structure, coordinated regional transmission planning has become a thing of the past and new transmission additions that will benefit reliable grid operations are being delayed.⁷⁴

FMPA states that grid fragmentation harms reliability.⁷⁵ NU and EPRI note that recent demand growth has meant new stresses on grid reliability and there is less coordination of generation and transmission planning. TXU Electric states that, as the shift from regulation to competition accelerates, and restructuring efforts proliferate, the

⁷¹ *Id.*

⁷² *See id.* at 33,714.

⁷³ *See, e.g.,* Duquesne, Entergy, Florida Power Corp., NU, Kentucky Commission, NECPUC, Ohio Commission, Texas Commission, DOE, American Forest, Arkansas Cities, East Texas Cooperatives, EPSA, First Rochdale, FMPA, Oglethorpe, PNGG, Powerex, Public Citizen, SoCal Cities, Sonat, Williams.

⁷⁴ *See, e.g.,* EPRI, Florida Power Corp., Duquesne, Entergy, SoCal Cities, Merrill Energy, TAPS, IPCE, Powerex.

⁷⁵ FMPA at 24.

regional transmission grid is being exposed to stresses that cannot be alleviated without regional solutions.

WPPI describes a situation in 1997 in which the 345-kV transmission facility between MAPP and MAIN was overloaded as a result of transactions scheduled within MAPP, and Wisconsin operators became aware of the problem only when the constrained 345-kV facility automatically separated in response to the overload. WPPI explains that, with the 345-kV facility shut down, other transmission facilities in the region overloaded, causing the transmission system over a large region to come perilously close to a blackout. WPPI adds that, because transmission providers do not have information about their neighbors' on-system transactions to serve native load, they are unable to predict the impact of potential TLR events. WPPI says that, in the face of this uncertainty, transmission providers have to make overly conservative, but inaccurate assumptions which unnecessarily reduce the amount of transmission capacity available to the market.

TAPS states that, when the owners of a constrained interface between MAPP and MAIN tried to remove the line for service for maintenance, they found that 500 MW of flow remained on the line even after all scheduled transactions were terminated. TAPS explains that there were so many transactions in the region at the time that transmission operators could not determine the source of this 500 MW loop flow and were unable to ask other parties to cut their schedules to permit the necessary maintenance.⁷⁶ TAPS asserts that transmission owners have engaged in "creative" concepts such as CBM to reduce ATC and argues that price spikes are exacerbated, if not caused by the failure to have regional transmission information and control in one place.⁷⁷

TDU Systems complaint that the current system balkanizes regions into a series of submarkets, each with its own dominant incumbent transmission owner/generator that collects its own transmission toll.

EPRI contends that the current off-line ATC calculations result in inconsistencies of ATC values. Entergy argues that the accuracy of ATC will continue to be a problem as long as contract path pricing is used.⁷⁸

Minnesota Power notes that reliability across the broader region suffers simply because of different standards for ATC calculations within and across NERC

⁷⁶ TAPS, Appendix A, at 8

⁷⁷ TAPS, Appendix A at 2-5.

⁷⁸ Entergy at 8.

regions and, indeed, different terminology and operating practices. Minnesota Power states that: the market currently suffers as participants attempt to deal with multiple OASIS sites; existing tagging and reservation practices that limit transactions due to the complexity of arrangements; its transactions are subject to curtailment pursuant to two different procedures, NERC TLR and MAPP LLR; and congestion management alternatives to line loading relief have not succeeded because they lack regional coordination. Minnesota Power argues that energy price volatility will continue to increase unless there is a viable process, supported by transmission rights and secondary transfer markets, where a participant can secure transmission daily, or as needed, to bring the least cost supply to its customers.

EPSA asserts that one of the major impediments to robust competitive bulk power markets is the current balkanization of the system with dozens of individual utilities, NERC Regional Councils, and security coordinators, and state laws and regulations imposing a patchwork of often inconsistent and incompatible rules for the use of the interstate transmission system. EPSA argues that the operational and economic inefficiencies detailed in the NOPR are not unique to certain region as and may be most pronounced in those regions where competition has yet to take hold.⁷⁹

SoCal Edison states that existing transmission systems were designed to serve native load customers in a defined area, in the most efficient manner possible, in conjunction with the generation that it owned and operated, and were not designed to function as common carriers. SoCal Edison concludes that that radical changes in downstream generation markets are having, and will continue to have, significant and largely adverse effects of transmission systems. Consumers Energy echoes this concern, noting that it should be obvious that the current transmission system was designed to deliver locally generated power to local markets with interfaces used primarily for reliability purposes. Consumers Energy states that the system is simply

⁷⁹ EPSA specifically points to the SERC as a region where "state commissions and utilities may be arguing that they don't 'need' RTOs to promote competitive markets," at a time when Southeastern markets trail the rest of the nation in proposed merchant plant development and power trading, "both hallmarks of robust wholesale competition and workable open access policies." EPSA notes that SERC is the largest NERC region, both in load and peak demand, yet SERC and FRCC together constitute only 5.2 percent of the wholesale power trades nationwide.

not engineered to move large quantities of power from many distant generation sources to millions of end users.

Williams concludes that problems with congestion management, pancaked transmission rates, parallel path or loop flows, inaccurate ATC postings, and transmission facilities management and expansion planning continue to impede the development of robust, competitive wholesale electric markets in the United States.

PECO states that current TLR procedures allow one entity to cause the curtailment of numerous third party transactions on a regular basis to preserve power delivery in its single control area, regardless of the impact on other control areas. PECO argues that, while physical operation of the grid is maintained under these TLR procedures, reliable, inter-control area power delivery is not assured and market participants are denied fair access to the grid.

Tampa Electric states that, within peninsular Florida, transmission users must often go to several individual transmission providers and OASIS nodes, sign multiple agreements with various providers and attempt to piece together and navigate through various partial paths to connect a power sale to a buyer. Tampa Electric concludes that access to transmission services within this region is not as open as it could be to facilitate an efficient, robust wholesale market.

AEP states that coordination that previously existed in a fully integrated electric system of the construction of new generation and transmission facilities has eroded due to the separation of these functions. AEP states that congestion constraints could potentially inhibit the development of additional generation capacity or provide a disincentive to add generating capacity where needed. AEP also notes that the priorities of state regulatory agencies sometimes favor the needs of native load customers that can create conflicts among competing interest at the regional level. AEP also states that developers of new merchant generation plants have become less willing to share their long-term planning goals with transmission owners due to the business strategies that accompany a more competitive power market. However, AEP argues that removal of pancaking is not consistent with economic efficiency and may distort future transmission expansion because the cost of transmission should be based on distance and location.⁸⁰

⁸⁰ AEP at 1, and Attachment to AEP's comments (Statement of Paul Moul). As discussed in the

Several commenters state that needed transmission expansion is not taking place because of a lack of pricing incentives to build new transmission.⁸¹ EPRI states that failure to satisfy grid expansion needs is resulting in increasing frequency and duration of power disturbances and outages costing \$50 billion per year.

WPPI points out that transmission planning must be undertaken on a regional, not a state basis, noting that import capability from MAPP into Wisconsin is sometimes constrained by facilities located outside of Wisconsin, e.g., transformers and lines located in Illinois and Minnesota. On the other hand, Allegheny asserts that the industry has not failed to plan and coordinate on a regional basis and cites examples of study groups and planning committees, such as VEM (Virginia-ECAR-MAAC) and GAPP (General Agreement on Parallel Paths).

Most commenters assert that pancaked transmission access charges prevent efficient access to regional markets and distort the generation market.⁸² A few commenters, however, question the benefits associated with eliminating rate pancaking. Southern Company observes that the severity of pancaking effects may vary from region to region.⁸³

Continuing Opportunities for Undue Discrimination. Comments dealing with continuing opportunities for undue discrimination fall generally into two camps. On the one side, transmission customers and some transmission providers agree with the NOPR's premise that opportunities for discrimination exist, that perceptions of discrimination are also a serious impediment to competitive bulk power markets, and that functional unbundling does not reflect the optimal long-term regulatory solution.⁸⁴ On the other side,

Transmission Ratemaking section (Section G), elimination of pancaked rates (multiple access charges assessed only because the transaction crosses a corporate boundary) does not constitute a prohibition on distance sensitive rates.

⁸¹ See, e.g., Transmission ISO Participants, H.Q. Energy Services, Powerex.

⁸² See, e.g., FMPA, IMEA, NECPUC, Ohio Commission, Texas Commission, American Forest, Arkansas Cities, East Texas Cooperatives, Oglethorpe, PNGC, Powerex, Williams, WPSC.

⁸³ For illustration, Southern Company points out that a customer in its service area can transmit power 500 miles away for \$3/MWh whereas a customer wanting to transmit power from Boston to Washington, DC (also a distance of 500 miles) will have to go through the three PJM, New England and NY ISOs and pay a total of approximately \$14/MWh.

⁸⁴ E.g., American Forest, Los Angeles, TAPS, UAMPS, Steel Dynamics, Turlock, Cinergy, Statoil, WPPI, NJBUS, MidAmerican, LG&E, Clarksdale, Michigan Commission, New Smyrna Beach,

a number of transmission providers disagree with these premises.⁸⁵

Comments Asserting That Discrimination Still Exists. AMP-Ohio points to an event last summer when it was unable to transmit power from a generator on AEP's system to a load on the FirstEnergy system and was forced to purchase power from FirstEnergy at \$4000/MWh. AMP-Ohio contends that AEP and FirstEnergy were simultaneously reporting zero ATC during the hour, *i.e.*, an event that cannot be rationalized by AMP-Ohio (*i.e.*, an interface that is fully loaded in both directions at the same time would, in AMP-Ohio's view, cancel out).

UAMPS argues that three transmission owners that jointly own segments of a single transmission line have avoided releasing the capacity of this line under their open access tariffs through a series of contractual arrangements that distributes transmission rights directly to each of their merchant functions. As a result, only the transmission owners' merchant functions have the ability to schedule transmission service over the line. UAMPS contends that this example, and others, confirm the Commission's perception that the remedies mandated in Order No. 888 have not eliminated discrimination. UAMPS states that it is intuitively obvious that when the transmission function and merchant function ultimately serve the same master, neither can be truly independent.

Hogan contends that, without an efficient regional spot market and its ease of access, the problems of discrimination will persist. FTC concludes that several years of industry experience confirm the concern that discrimination remains in the provision of transmission services by utilities that continue to own both generation and transmission. FTC concludes that reliance on behavioral rules have proved to be less than ideal.

Cinergy contends that reliance on CBM by some transmission providers this summer provided their native load an unfair operational edge over network service in the import of power through interconnects that were the subject of TLR orders. Cinergy argues that the

more severe impact on market efficiency is caused by the lack of information underlying the transmission provider's implementation of TLRs, and raises significant opportunities for transmission providers to use alleged reliability reasons to hide conduct actually motivated to protect their own or their affiliate's own power market. Cinergy concludes that market participants will never know the real answer because it may be impossible to prove abuse of the TLR procedures with access to information on the nature and cause of constraints and the lack of consistency in implementing TLRs across the regions. Cinergy adds that, even where there may be sufficient evidence to prove discrimination, potential complainants may fear retribution by the transmission provider, and may also be hesitant to file complaints because of the litigation costs of the complaint process and the lack of remedy for lost short-term market opportunities.

Enron/APX/Coral Power state that the following types of relatively overt, although difficult to detect, discrimination occur: (1) Offers of attractive transmission service to a transmission owner's affiliate or merchant function that are not similarly offered to others; (2) advance notification to the affiliate or merchant function of the availability of transmission service or the availability of a new service; and (3) changes in procedures, such as scheduling deadlines, for obtaining transmission service in ways that benefit the affiliate or merchant function. Enron/APX/Coral Power (as well as CCEM/ELCON, UtiliCorp and EPSA) also argue that a "principal form of discrimination grows out of the exemption from the *pro forma* OATT and OASIS that is enjoyed by transmission bundled with service to captive 'native-load' customers." Enron/APX/Coral Power believes that, if the Commission were to conduct an investigation of compliance with the Commission's open access requirements and the uses of their own transmission system during periods of extreme peak loads and volatile prices during the past summer, the Commission would uncover evidence of widespread abuses. According to Enron/APX/Coral Power, these abuses would include instances where the transmission provider imported power on a network basis, as if it were intended to service captive, native load customers, only to turn around and sell that power competitively, off-system; where scheduling requirements or deadlines were changed without adequate notice

to third parties; and where ATC amounts that either were not posted or were posted in an untimely manner.

NASUCA concludes that, despite Order No. 888, there is still reason for concern that continued discrimination in the provision of transmission services by vertically integrated utilities may be impeding competitive electric markets.

EPSA states that the prospect of real competition continues to be threatened by (1) arbitrary and discriminatory curtailment and line loading relief policies, and (2) needlessly complex and overly restrictive transmission planning, expansion and interconnection practices.

TAPS argues that the anticompetitive effects of allowing a subset of competitors to control essential facilities have been long recognized.⁸⁶ TAPS provides specific examples that it claims show that discrimination exists: (1) The price spikes in June 1998 and Summer of 1999 where the asserted ATC was inadequate to allow external generation resources to meet the needs of the market; (2) failure of a transmission owner to provide necessary upgrades; and (3) a transmission owner taking negotiating positions contrary to a clear provision of the Open Access Transmission Tariff (OATT). In its reply comments, TAPS describes a recent situation where AEP, acting in its role as the NERC Security Coordinator, informed IMPA that it had implemented a TLR seven minutes earlier, too late for IMPA to replace the curtailed schedule with another transaction at market prices, which were \$35/MWh. TAPS contends that IMPA had no effective choice but to make up the shortfall by purchasing emergency energy from AEP at \$100/MWh. In following hours that day, IMPA elected to purchase power from AEP at \$35/MWh rather than continue its other purchase options (at \$17/MWh) and risk further curtailments. TAPS observes that AEP substantially profited from delayed communication of the TLR, by selling power to IMPA at nearly three times the then-market price. TAPS states that, even assuming AEP was acting properly on this occasion, this example illustrates the inherent conflict of interest in combining security coordinator functions with that of market participant. TAPS argues that this diminishes the faith in the market place and breeds mistrust. Based on the examples it provides and on the evidence reviewed in the NOPR, TAPS

⁸⁶ TAPS cites to a 1912 Supreme Court case involving the control of a railway terminal by several railroads which their competitors were required to use. See *United States v. Terminal RR Ass'n*, 224 U.S. 383, 397 (1912).

Industrial Consumers, IMPA, First Rochdale, East Texas Cooperatives, FMPA, TDU Systems, Canada DNR, Allegheny, IMEA, Sonat, Public Citizen, EPSA, CCEM/ELCON, UtiliCorp and FTC.
[85]: United Illuminating, Southern Company, MidAmerican, Duke, PSE&G, FP&L, Entergy, FirstEnergy, Alliance Companies, Lenard and Florida Power Corp.

⁸⁵ United Illuminating, Southern Company, MidAmerican, Duke, PSE&G, FP&L, Entergy, FirstEnergy, Alliance Companies, Lenard and Florida Power Corp.

recommends that the Final Rule make formal findings that undue discrimination remains widespread throughout the industry.

Steel Dynamics states that the Commission needs to build confidence that transmission customers will not be victimized when markets get tight and claims the Commission's record to date has been uneven. Steel Dynamics cites a case in which the Commission determined that Niagara Mohawk Power Corporation had committed several violations of the OASIS posting requirements and standards of conduct in order to favor its marketing affiliate over a third-party user.

Clarksdale states that it has experienced problems with the posting of ATC by Entergy on the OASIS. Clarksdale states that on July 21, 1999, it attempted to purchase from Cajun Electric Cooperative 20 MW of power for whatever length of time that Cajun would have had it available up to one week. Entergy denied the transaction on the basis that the ATC between Entergy and Cajun was zero. Clarksdale complained and the next day the ATC for this interface was shown to be 1,700 megawatts; however, by that time Cajun had sold the power to another entity and it was no longer available for Clarksdale. Clarksdale submits that the incident, along with others Clarksdale reported, compels the conclusion that the function of security coordination should be entirely separate from the transmission owner and from the generation owner and that participation in an absolutely independent RTO should be mandated by the Commission in the final rule.

FMPA states that, whether because of discriminatory motivations or simply because of balkanized perspectives (or both), there have been numerous instances of Florida's dominant transmission owners falling short on the transmission planning performance. According to FMPA, Florida's dominant transmission owners have failed to promptly address regionally significant constraints (until addressing them became advantageous for their own merchant function), and have continued to impose discriminatory transmission-related construction requirements. FMPA claims that relying on functional separation rules to curb the self interest of market-interested transmitters when huge sums of money are at stake is like "relying on words to hold back the tide."⁸⁷

WPPI states that it routinely experiences and observes subtle and difficult to detect problems in the

marketplace. WPPI states that, because they are subtle and difficult to detect, they are not susceptible to any prompt and effective regulatory remedy. WPPI adds that prosecution of complaints is expensive and time consuming and customers do not have the ability to prosecute each such incident.

WPPI contends that transmission owners are able to dispatch their resources in order to manipulate their exposure to TLRs, while customers cannot. WPPI characterizes this tactic as a "shell game" because it is purportedly accomplished by designating fictional sources and sinks and treating one transaction as two separate transactions. WPPI contends that these actions leave other transmission users to bear the costs of curtailments and denials of service. WPPI argues that these manipulations of TLRs are "rampant."

WPPI states that during summer peak periods, when it claims power prices exceeded \$5,000/MWh in the Eastern Interconnection, at least one Midwestern transmission-owning utility appears to have been able to abuse its control-area operator authority to gain a market advantage. According to WPPI, as a control-area operator, the transmission owner at issue declared that power shortages had created an emergency situation which allowed it to relax the transmission limitations that it had imposed on other market participants, enabling the transmission owner to acquire less expensive power from the MAPP region. WPPI claims that the transmission owner thereby gained a market advantage, at a time when market advantages were worth huge sums. WPPI claims that most if not all other control-area operators in the region played by the rules and did not abuse the system to access less expensive power for which ATC ostensibly was not available. WPPI asserts that utilities that are not control-area operators had no choice other than to buy high cost, locally generated power, and that they "lack not only the right, but also the might"⁸⁸ to declare an emergency or to recalculate ATC to help themselves. WPPI and Cinergy maintain that this recent event provides a clear example of the continuing potential, under present industry structure, for vertically integrated utilities to abuse their transmission control to gain market advantages and for that reason, among others, the Commission should mandate that entities under its jurisdiction participate in RTOs.

TDU Systems provide a number of examples which raise their concerns

about undue discrimination, including: (1) Failure of an incumbent IOU to reduce its own out-of-region power sales during a period when the system was experiencing overloads and the transactions of other transmission users were jeopardized; (2) overly aggressive and selective enforcement of tariff requirements on transmission customers than are imposed on the transmission providers' own merchant function; (3) selectively targeting generating units that are jointly owned by competitors when redispatch of the transmission system is required to relieve line loading; (4) self-serving ATC calculations in circumstances when transmission customers have no way of knowing whether access is being denied legitimately or through manipulation for competitive gain; and (5) onerous and lengthy negotiations to obtain system studies. TDU Systems contend that there is a fire under the smoke of allegations of discrimination, and those complaining of the anecdotal nature of its information haven't provided any evidence to show that discrimination is not occurring.

TXU Electric states that, if a truly successful, restructured competitive electric industry is to achieve its full potential, it is incumbent of all concerned, transmission providers, users and regulators alike, to move beyond the impediments of the past, including hidden motivations on the part of some, unfounded fears of hidden motivations on the part of others, and a general environment of distrust. TXU Electric adds that, transmission users and regulators must have confidence that the transmission grid is truly an open, non-discriminatory and robust commercial highway and transmission providers must inspire that confidence. TXU Electric concludes that the Commission's voluntary collaborative approach is an important step in the right direction.

LG&E states that, under the current system, transmission owners' operational decisions, even if well intentioned, are surrounded by a cloud of suspicion that, acting in the name of reliability, the transmission owner has enhanced its position in the generation market. LG&E agrees that this perception that the transmission system is not being operated in an even handed manner undermines confidence in the non-discriminatory open access implemented under Order No. 888.

Virginia Commission agrees that allegations of discrimination represent only known problems, and there may be many unknown ones remaining given that it is difficult for transmission users

⁸⁷ FMPA at 23-24.

⁸⁸ WPPI at 31.

to identify and demonstrate instances of discrimination.

Canada DNR states that discriminatory behavior by transmission operators, identified in the NOPR as the second significant driver for establishment of RTOs, is not perceived as a key impediment to the evolution of efficient bulk power markets in Canada.

Dynegy argues that transmission provides have the incentive and ability to discriminate in today's markets due to the combination of control over transmission with participation in power markets and the existing regulatory structure that exempts transmission providers from the open access rules of Order Nos. 888 and 889 for its bundled, native load customers. Dynegy argues that the "native load" exemption can be and is often manipulated to favor the transmission providers' own or affiliated merchant functions.

PECO notes that, in their capacity as vertically integrated utilities, transmission providers have access to critical market sensitive information with respect to each transaction (e.g., source, sink), at a time when they are in direct competition in the same markets and with the same transmission customers whose market information they have. PECO argues that, in spite of the existence of functional unbundling and codes of conduct, the serious potential for conflicts of interest and abuse inherent in the current structure cannot be ignored.

Comments Asserting That Discrimination Is Not a Problem. A number of commenters, mostly transmission owners, do not believe that significant discrimination problems remain with respect to wholesale transmission access pursuant to Order No. 888. As a general matter, those transmission owners whose actions are cited in other pleadings as examples of undue discrimination disagree with those characterizations of the cited events and declare that they provide non-discriminatory transmission service under their OATT. These transmission owners contend that the disputes cited in the pleadings are not the result of discriminatory practices; rather, they are the result of the priority accorded native load customers under the OATT, and good faith errors on the part of the transmission provider trying to administer complex rules and tariff changes that have necessitated fundamental changes to the structure of companies and the way they do business.

EEL contends that many of the difficulties transmission customers encounter in obtaining price,

availability and transmission service result in a technology gap that can be, and often is, interpreted as discriminatory behavior. EEL also contends that many allegations of discrimination are "rooted at their heart" on the scarcity of transmission resources and not overt attempts to discriminate against specific customers.

PSE&G argues that supposition and anecdotal evidence of alleged abuses by transmission owners does not justify a radical change in the existing regulatory scheme. PSE&G contends that, while the incentive to maximize shareholder value is certainly a powerful force in the marketplace, the requirements of law, such as Order Nos. 888 and 889, will prevail.

Duke argues that mere anecdotes of discrimination, involving unnamed parties and without reference to specific facts, are not evidence of anything, let alone discrimination, and cannot form the basis of a reasoned decision. Duke also lists a number of formal complaint proceedings where the Commission found the transmission provider to have acted properly. Entergy argues that those alleging discrimination, as competitors of transmission providers, have an economic incentive to make their own allegations. Entergy adds that, if perceptions of discrimination were impeding competitive markets, there would not be 20,000 MW of generation investment proposed in its region.

United Illuminating complains that many of the allegations of undue discrimination presuppose that all utilities are the same, i.e., vertically integrated transmission, distribution and generation companies, and do not recognize that a number of utilities are divesting their generation business.

Southern Company states that the goal of non-discriminatory transmission service is already being satisfied in the Southeast. Southern Company asserts that it has separated its transmission and reliability functions from its wholesale merchant function up to the level of "very senior management." Southern Company submits that it is unaware of any pending allegations of discrimination against it. Southern Company adds that the Southeast is characterized by large transmission systems such as Southern Company, Tennessee Valley Authority, and Entergy and that these transmission systems are already planned and operated on a regional basis. Southern Company also points out that it alone covers a region as large as (if not larger than) many ISOs currently in existence. Under these circumstances, Southern Company believes that the Commission's open access initiatives

have worked in the Southeast and that additional steps are not required to ensure non-discriminatory transmission service.

MidAmerican asserts that complaints received by the Commission about alleged discrimination should not be the primary basis for determining if the market is successful. According to MidAmerican, if it is assumed that an adequate number of parties are competing successfully, it could be concluded that the complaints may be indications of ill-defined problems not yet resolved, isolated market flaws, or indications of a successful market with somewhat inadequate tools.

Duke believes that its transmission organization is meeting the needs of its customers as evidenced by the very few and relatively insignificant complaints Duke has received regarding the administration of its OATT. Duke believes that Order No. 888 has been quite successful and, although it agrees with the Commission that elimination of balkanized transmission operations through the formation of larger, regional operations is ultimately preferred, Duke does not believe Order No. 888 should be abandoned hastily.

Duke argues that disputes are primarily the result of the complexity of the priority scheme in the Commission's *pro forma* tariff, the rules for which are still being developed; the inherent tension between the Commission's comparability requirement and the requirements of state-regulated native load customers; and the obligation to ensure reliability of the transmission grid on a real time basis. Duke asserts that the vast majority of transactions occurring as a result of Order No. 888 do not produce transmission disputes and, to the extent that isolated instances of discrimination have occurred, the Commission has adequate authority to address the problem.

Duke also maintains that a major source of confusion involves the rights of native load customers versus wholesale transmission users under the *pro forma* tariff and that this issue remains subject to disagreement and needs further clarification. Duke says its conclusion is reinforced by its experience as a market participant in areas where there are ISOs. Duke asserts that the establishment of ISOs in California, NEPOOL and PJM has not resulted in the elimination of disputes over tariff ambiguities. Duke questions the assertion that disagreements between customers and individual transmission owners are indicative of significant ongoing discrimination.

Florida Power Corp. and FP&L's comments are similar to Duke's. Florida

Power Corp. and FP&L state that they have not received any formal complaints alleging undue discrimination with regard to their OATT. Florida Power Corp. and FP&L agree that the increasing number of transactions has led to a concomitant increase in transmission disputes; however, they characterize the disputes as legitimate disagreements over policy or meaning of the *pro forma* tariff as opposed to true allegations of discriminatory conduct. Like Duke, Florida Power Corp. and FP&L believe that many of the allegations of potentially discriminatory conduct are attributable to two primary areas: (1) Rights of native load customers versus wholesale wheeling customers; and (2) disputes arising from the complex priority scheme in the *pro forma* tariff. According to FP&L, disputes will still occur until the issues relating to priority rights are resolved. FP&L argues that the Commission cannot expect that any remedy will eliminate discrimination claims in light of the Eighth Circuit Court's decision in *Northern States Power Co. v. FERC*.⁸⁹

FPL and Florida Power Corp. argue that unsubstantiated allegations do not constitute evidence of discrimination and should be characterized as legitimate disputes over tariff interpretation, while EEI describes some of the allegations as "one-sided characterizations of cases now being litigated." FPL also contends that some intervenors adopt the stance that, whenever the transmission provider and customer are in disagreement, it evidences discrimination. Florida Power Corp. states that, if undue discrimination exists outside of Florida, it is a function of the newness of the Commission's open access rules, and it is far too soon to declare functional unbundling ineffective. Florida Power Corp. agrees with the Commission's statement that it may be impossible to distinguish an inaccurate ATC presented in good faith from an inaccurate ATC posted for the purpose of favoring the transmission provider's marketing interests, but concludes that, once technical issues have been resolved about ATC calculations, the volume of disputes will be greatly diminished. Florida Power Corp. adds

that there is no evidence of a pattern of industry-wide undue discrimination, and concludes that mere perceptions cannot provide a justification for generic remedial action.

Entergy, FirstEnergy, Alliance Companies and Lenard argue that there is no credible or substantial evidence in the record that transmission owners have been engaging in discriminatory practices in providing transmission services under Order Nos. 888 and 889 and, therefore, the Commission should not, and lawfully cannot, rely on mere allegations of discriminatory conduct. FirstEnergy states that it has doubled its control area reservation and back office staff to handle the five percent of its transmission business that is wholesale related and still is having difficulty keeping pace with OASIS and tagging administrative processes. FirstEnergy asserts that due to relatively new processes associated with open access transmission, there are often good faith disputes over the proper interpretation of the Commission's requirements and these disputes should not be mischaracterized as continued discrimination.

Commission Conclusion. Engineering and Economic Inefficiencies. In this Final Rule, we affirm our preliminary determination that the engineering and economic inefficiencies identified in the NOPR⁹⁰ are present in the operation, planning and expansion of regional transmission grids, and that they may affect electric system reliability and impede the growth of fully competitive bulk power markets. The sources of these inefficiencies involve: difficulty determining ATC; parallel path flows; the limited scope of available information and the use of non-market approaches to managing transmission congestion; planning and investing in new transmission facilities; pancaking of transmission access charges; the absence of clear transmission rights; the absence of secondary markets in transmission service; and the possible disincentives created by the level and structure of transmission rates. Virtually all commenters agree that at least some of these inefficiencies exist. There is substantial agreement among commenters that most of the engineering and economic obstacles identified by the NOPR arise from the current industry structure and can be rectified through development of regional transmission entities.

As noted by Allegheny, the industry historically has done an excellent job of regional coordination in implementing voluntary standards to maintain the

security of the transmission system through various study groups and planning committees. However, virtually all commenters agree that new competitive pressures are interfering with the use of traditional methods of coordinated regional transmission planning. As a result, new transmission additions that will benefit reliable grid operations are being delayed. Some commenters state that the increasing frequency and duration of power outages have cost the economy billions of dollars, and they predict that unless this problem is addressed now the reliability of power supply will worsen. The traditional use of regional coordination through study groups and planning committees is no longer effective because these entities are usually not vested with the broad decisionmaking authority needed to address larger issues that affect an entire region, including managing congestion, planning and investing in new transmission facilities, pancaking of transmission access charges, the absence of secondary markets in transmission service, and the possible disincentives created by the level and structure of transmission rates.

We recognize, as some commenters point out, that the degree to which these inefficiencies act as obstacles to electric competition and reliability varies from system to system. However, we believe it is clear that such inefficiencies exist and are sufficiently widespread that they must be addressed to prevent them from interfering with reliability and competitive electricity markets.

Continuing Opportunities for Undue Discrimination. As noted, many transmission customers and some transmission providers argue that there are continuing opportunities for undue discrimination under the existing functional unbundling approach. A number of the commenters provide examples of events that, in their view, indicate that transmission owners are engaging in undue discrimination. These commenters also generally believe that even the perception of undue discrimination is a significant impediment to the evolution of competitive electricity markets. A number of transmission providers challenge the relevancy of these examples, characterizing them as unsubstantiated or anecdotal allegations that do not rise to the level of evidence of undue discrimination necessary to support generic action. These transmission providers further contend that many disputes simply reflect good faith efforts of transmission providers to interpret the Commission's *pro forma* tariff and standards of conduct. These

⁸⁹ See *Northern States Power Co. (Minnesota)* and *Northern States Power Co. (Wisconsin)*, 83 FERC ¶ 61,098, *clarified*, 83 FERC ¶ 61,338, *reh'g, clarification and stay denied*, 84 FERC ¶ 61,128 (1998), *remanded*, *Northern States Power Co., et al. v. FERC*, 176 F.3d 1090 (8th Cir. 1999), *reh'g denied* (unpublished order dated Sept. 1, 1999), *order on remand*, 89 FERC ¶ 61,178 (1999) (request to withdraw curtailment procedures pending) (*Northern States*).

⁹⁰ FERC Stats. & Regs. ¶ 32,541 at 33,697.

commenters also generally share the view that the Commission should not base its decisions in this rule on mere perceptions that may be prevalent in the industry.

For the most part, the challenges mounted by these commenters are focused against a determination by the Commission that it should mandate participation in RTOs in this Rule. As noted in Section C.1 of this Rule, we have also determined that a measured and appropriate response to the evidence presented and concerns raised is to adopt a voluntary approach to the formation of RTOs. However, as discussed below, we do conclude that opportunities for undue discrimination continue to exist that may not be remedied adequately by functional unbundling. We further conclude that perceptions of undue discrimination can also impede the development of efficient and competitive electric markets. These concerns, in addition to the economic and engineering impediments affecting reliability, operational efficiency and competition, provide the basis for issuing this Final Rule.

At the outset, it is important to note that the conclusion that there are continuing opportunities for undue discrimination should not be construed as a finding that particular utilities, or individuals within those utilities, are acting in bad faith or deliberately violating our open access requirements or standards of conduct. However, we cannot ignore the fact that the vertically integrated structure reflected in the industry today was created to support the business objectives of a franchised monopoly service provider that owned and operated generation, transmission and distribution facilities primarily to serve requirements customers at wholesale and retail in a non-competitive environment. Clearly, there are aspects of this vertically integrated structure that are difficult to transition into a competitive market. As we noted in the NOPR and Order No. 888, vertically integrated utilities have the incentive and the opportunity to favor their generation interests over those of their competitors. If a transmission provider's marketing interests have favorable access to transmission system information or receive more favorable treatment of their transmission requests, this obviously creates a disadvantage for market competitors.

While we have attempted to rely on functional unbundling to address our concerns about undue discrimination, there are indications that this is difficult for transmission providers to implement and difficult for the market and the

Commission to monitor and police. In cases in which the Commission has issued formal orders, we have found serious concerns with functional separation and improper information sharing with respect to at least four public utilities.⁹¹ In addition, our enforcement staff is receiving an increasing number of telephone calls about standards of conduct issues, ranging from simple questions about what is permissible conduct to more serious complaints alleging actual violations of the standards of conduct. In a number of cases, our staff has verified non-compliance with the standards of conduct.⁹² The petitioners for rulemaking in Docket No. RM98-5-000 allege that there are common instances of "unauthorized exchanges of competitively valuable information on reservations and schedules between transmission system operators and their own or affiliated merchant operation employees."⁹³ They also cite OASIS data showing an instance where a transmission provider quickly confirmed requests for firm transmission service by an affiliate, while service requests from independent marketers took much longer to approve. We believe that some of the identified standards of conduct violations are transitional issues resulting from a new way of doing business, and we acknowledge that many utilities are making good-faith efforts to properly implement standards of conduct. However, we also believe that there is great potential for standards of conduct violations that will never even be reported or detected. Moreover, as we stated in the NOPR,⁹⁴ we are increasingly concerned about the extensive regulatory oversight and administrative burdens that have resulted from policing compliance with

standards of conduct. The use of standards of conduct is not the best way to correct vertical integration problems. Their use may be unnecessary in a better structured market where operational control and responsibility for the transmission system is structurally separated from the merchant generation function of owners of transmission.

We also cannot dismiss the significance of reports of undue discrimination simply because they are not reduced to formal complaints. As many intervenors have asserted, the cost and time required to pursue legal channels to prove discrimination will often provide an inadequate remedy because, among other things, the competition may have already been lost.⁹⁵ The fact that evidence of discrimination in the fast-paced marketplace is not systematic or complete is not unexpected. The fact remains that claims of undue discrimination have not diminished, and there is no evidence that discrimination is becoming a non-issue.

Finally, we continue to believe that perceptions of discrimination are significant impediments to competitive markets. Efficient and competitive markets will develop only if market participants have confidence that the system is administered fairly.⁹⁶ Lack of market confidence resulting from the perception of discrimination is not mere rhetoric. It has real-world consequences for market participants and consumers. As stated by NERC, there is a reluctance on the part of market participants to share operational real-time and planning data with transmission providers because of the suspicion that they could be providing an advantage to their affiliated marketing groups,⁹⁷ and this can, in turn, impair the reliability

⁹¹ See *Wisconsin Public Power Inc. SYSTEM v. Wisconsin Public Service Corporation*, 83 FERC ¶ 61,198 at 61,855, 61,860, order on reh'g, 84 FERC ¶ 61,120 (1998) (WPSC's actions raised "serious concerns" as to functional separation; WP&L's actions demonstrated that it provided unduly preferential treatment to its merchant function); *Washington Water Power Co.*, 83 FERC ¶ 61,097 at 61,463, further order, 83 FERC ¶ 61,282 (1998) (utility found to have violated standards in connection with its marketing affiliate); *Utah Associated Municipal Power Systems v. PacifiCorp*, 87 FERC ¶ 61,044 (1999) (finding that PacifiCorp had failed to maintain functional separation between merchant and transmission functions).

⁹² See, e.g., *Communications of Market Information Between Affiliates*, Docket No. IN99-2-000, 87 FERC ¶ 61,012 (1999) (Commission issued declaratory order based on hotline complaint clarifying that it is an undue preference in violation of section 205 of the FPA for a public utility to tell an affiliate to look for a marketing offer prior to posting the offer publicly).

⁹³ Petition at 15.

⁹⁴ FERC Stats. & Regs. ¶ 32,541 at 33,711-12.

⁹⁵ For example, EPSA has told us: "Furthermore, even if the exercise of such discrimination could be adequately documented and packaged in the form of a complaint under section 206 of the Federal Power Act under a more streamlined complaint process contemplated by the Commission, it would still be extremely costly and inefficient to deal with such complaints on a case-by-case basis. More than likely, the potential power transactions for which transmission principally was sought would disappear by the time a Commission ruling was obtained. Motion to Intervene and Comments of Electric Power Supply Association in Support of Petition for Rulemaking, Docket No. RM98-5-000 (filed Sept. 21, 1998), at 3."

⁹⁶ For example, a representative of Blue Ridge told us: "There simply is no shaking the notion that integrated generation and transmission-owning utilities have strategic and competitive interests to consider when addressing transmission constraints. Functional unbundling and enforcement of [standard of] conduct standards require Herculean policing efforts, and they are not practical." Regional ISO Conference (Richmond), Transcript at 20.

⁹⁷ NERC Reliability Assessment 1998-2007, at 39.

of the nation's electric systems. Lack of market confidence may deter generation expansion, leading to higher consumer prices. Fears of discriminatory curtailment may deter access to existing generation or deter entry by new sources of generation that would otherwise mitigate price spikes of the type that have been experienced during peak periods in the last two summer peak periods. Mistrust of ATC calculations will cause transactions involving regional markets to be viewed as more risky and will unnecessarily constrain the market area, thereby reducing competition and raising prices for consumers. The perception that a transmission provider's power sales are more reliable may provide subtle competitive advantages in wholesale markets, e.g., purchasers may favor sales by the transmission provider or its affiliate, expecting greater transmission service reliability. We believe that the potential for such problems increases in a competitive environment unless the market can be made structurally efficient and transparent with respect to information, and equitable in its treatment of competing participants.

In summary, we affirm our conclusion in the NOPR that economic and engineering inefficiencies and the continuing opportunity for undue discrimination are impeding competitive markets. As noted below, we conclude that RTOs will remedy these impediments and that it is essential for the Commission to issue this Final Rule.

B. Benefits That RTOs Can Offer to Address Remaining Barriers and Impediments

In the NOPR the Commission explained how the use of independent RTOs could help eliminate the opportunity for unduly discriminatory practices by transmission providers, restore the trust among competitors that all are playing by the same rules, and reduce the need for overly intrusive regulatory oversight.⁹⁸ The Commission further identified a number of significant benefits of establishing RTOs: (1) RTOs would improve efficiencies in the management of the transmission grid;⁹⁹ (2) RTOs would improve grid reliability; (3) RTOs would remove opportunities for discriminatory transmission practices; (4) RTOs would result in improved market performance;

⁹⁸ FERC Stats. & Regs. ¶ 32,541 at 33,714.

⁹⁹ These efficiencies include, among other things, regional transmission pricing, improved congestion management of the grid, more accurate ATC calculations, more effective management of parallel path flows, reduced transaction costs, and facilitation of state retail access programs.

and (5) RTOs would facilitate lighter-handed governmental regulation.¹⁰⁰ The Commission requested comments on the benefits of RTOs and the magnitude of these benefits.

Comments. Description of Benefits. Many commenters support the establishment of RTOs throughout the United States to effectively remove the remaining impediments to competition in the power markets.¹⁰¹ Illinois Commission states that the pursuit of competition as the driving force for markets in the electric industry requires developing new institutions and accepting new practices, and RTOs are the logical next organizational step in the electric industry restructuring process. Entergy agrees that significant benefits can be achieved by the creation of properly-structured, large RTOs and that the Commission has accurately described many of those benefits in the NOPR. Ohio Commission believes that a properly structured RTO will facilitate efficient regional generation markets, while preventing incumbent holding companies from improperly exercising their market power.

PG&E acknowledges that the benefits of Order No. 888 have been largely reaped, and still significant impediments to an efficient competitive marketplace remain in place where RTOs are not yet operational. Moreover, industry restructuring has led to new and complex operational issues that were unanticipated at the time Order No. 888 was issued. RTOs represent the most promising and efficient regulatory method for the Commission to address these issues. Without RTOs, it would be incumbent on the Commission to take very detailed and intrusive actions because the transmission grid cannot operate reliably and efficiently unless the competitive and operational issues are resolved.

Ontario Power agrees that the electric power industry should now move beyond the functional unbundling approach prescribed in Order Nos. 888 and 889. TDU Systems asserts that wholesale electric markets will benefit immensely if RTOs can simply provide transmission service on an unbiased basis, treating all customers fairly, and take the lead role in regional transmission planning.

On the other hand, a number of vertically integrated utilities do not support government action to form RTOs. For example, Duke recognizes that there may be transmission functions performed today within individual company control centers,

within existing control areas, or within existing reliability councils that may be better and/or more efficiently performed by a regional transmission organization. However, Duke also believes that the industry is voluntarily working to identify such functions or processes and is effecting meaningful changes and improvements in a timely manner. Accordingly, Duke believes that this progress should not be pre-empted by regulatory mandates, and that there are insufficient data, at this time, to draw meaningful conclusions regarding the magnitude of benefits that will result from RTO formation.

Similarly, MidAmerican argues that benefits of RTOs can be realized without RTOs. MidAmerican claims that existing regional organizations, such as MAPP, are capable of meeting the Commission's concerns about eliminating existing impediments to an efficient competitive marketplace. FP&L states that the NOPR does not attempt to quantify any of the claimed benefits of RTOs. FP&L is unaware of any data that specifically and objectively show that ISOs have saved ratepayers money in those areas where ISOs have been established. Nor is it aware of any specific quantification of any other actual or projected benefits of ISOs.

Some commenters contend that the costs of establishing RTOs must not exceed the benefits. Cal DWR argues that significant start-up costs and costs associated with duplicative efforts have been higher than the NOPR appears to recognize. These costs entail not only costs of the new organization itself, but also market participants' costs in travel, staffing, and other expenses and investments necessary to participate or operate in new structures. Other commenters suggest that each proposal contained in the NOPR should be carefully evaluated for its cost consequences.¹⁰²

Seattle notes that its region has the lowest cost electricity in the Nation and an already thriving wholesale market with little price volatility. Assuming that an RTO is projected to result in additional transmission costs, Northwest consumers will be less willing to incur these costs than consumers in regions where power costs are high and wholesale prices are extremely volatile. Snohomish and Aluminum Companies assert that one of fatal flaws of the IndeGO proposal¹⁰³ was that its demonstrable benefits did

¹⁰² See, e.g., Cal DWR, California Board, Southern Company, Aluminum Companies.

¹⁰³ IndeGO is an independent grid operator proposal that has been discussed for the Pacific Northwest and Rocky Mountain area.

¹⁰⁰ FERC Stats. & Regs. ¶ 32,541 at 33,716-20.

¹⁰¹ See, e.g., PJM, DOE, Illinois Commission.

not clearly outweigh the costs of its start-up and operation. Snohomish requests that the Commission not impose an RTO with similar flaws upon the Northwest. A number of commenters also urge the Commission to reject any RTO filing for the Northwest or other regions that fails to provide a strong demonstration that its benefits will substantially outweigh its projected costs.¹⁰⁴

To ensure that RTOs are formed in a cost effective and efficient manner, SRP proposes a phased approach to RTO development that would allow RTOs to gradually take on new functions and responsibilities in response to the needs to the market. In addition, the Commission should require RTOs to establish criteria against which they will measure cost effectiveness and efficient performance and to make adjustments where criteria are not being met.

Canada DNR states that structural differences between the Canadian and American electric power industries mean that there may be fewer potential benefits from the formation of RTOs in Canada than those identified by the Commission for the United States. Consequently, it believes that Canadian jurisdiction should be able to assess the costs and benefits of RTO proposals. In addition, it notes that some may find that, although the benefits do warrant the associated costs, they may address impediments to efficient electricity markets through other means.

Comments on RTOs Improving Efficiencies in the Management of the Transmission Grid.¹⁰⁵ PJM agrees with the Commission that placing as many grid management functions as possible under an RTO is the best means of bringing the benefits of RTOs to the marketplace. A number of commenters address specific RTO actions as examples of grid management efficiencies, including use of regional transmission pricing, accurate estimation of ATC, efficient planning for grid expansion, and facilitating state retail access programs.

FMPA claims that a just and reasonable RTO transmission rate, with a unified regional loss factor or factors, would provide a regionally rational approach, which is not provided by the

existing fragmented regime. Pancaking has long prevented FMPA and its members located on the Florida Power Corp. transmission system from economically delivering the output from their portions of the St. Lucie nuclear plant to their loads. Similarly, WPSC notes that without an RTO that encompasses the Midwest region, unjustified pancaked transmission rates may inhibit the efficient flow of power across the region.

PacifiCorp supports the Commission goal of eliminating transmission pancaking, to the extent practical. PacifiCorp maintains that such a goal could be furthered by the creation of the most geographically expansive RTOs that are technically workable. The goal also could be met, however, if multiple RTOs within the western United States agree to reciprocally eliminate charges in connection with the "export" or "import" of power from one RTO to another. In the western United States, such "reciprocity" agreements may be preferable to the creation of a single RTO that otherwise is too large to be efficient, safe and reliable, or of a single RTO for which operating principles must be unreasonably compromised to attract all necessary transmission owners.

Allegheny asserts that even with an RTO, grid inefficiencies such as rate pancaking and congestion will continue unless an appropriate pricing mechanism is adopted. The various RTO structures, regardless of size and number, would still need to work cooperatively to ensure that the various interfaces are sufficient to maintain the reliable operation of the system. The formation of an RTO, by itself, does not bring a particular benefit.

Rochdale asserts that a properly structured independent RTO, with a broad geographic scope, could eliminate incorrect calculations of ATC and TTC. Furthermore, the motive for discrimination and possible manipulation that exists where transmission owners with affiliated power marketers are responsible for reporting ATC and TTC would become moot. FMPA contends that, without an RTO, most market participants would remain unable to replicate or trust the transmission owners' ATC calculations. FMPA indicates that customers and regulators cannot properly review transmission providers' ATC accounting without access to their TTC starting points; however, existing Florida OASIS sites do not provide TTC information. In addition, ATC calculations require extensive application of engineering judgment. FMPA questions whether market-interested transmission

providers can be trusted to exercise such judgment disinterestedly. Consequently, FMPA believes that an RTO could provide unbiased ATC information.

Many commenters believe that RTOs would provide more efficient planning for transmission and generation investments.¹⁰⁶ For example, Entergy agrees that the creation of RTOs can lead to more efficient and effective planning and expansion of the transmission system. However, to ensure efficient investment in the transmission system, Entergy proposes that the Commission encourage innovative pricing policies to replace traditional cost-of-service ratemaking in certain respects. Minnesota Power also agrees that an RTO would help identify the best place on the grid to locate new generation. It believes that the centralization of regional reliability planning is a big step forward for enabling independent power producers to build projects and also is a significant benefit to each transmission owner who deals with requests from generation groups.

Illinois Commission and Texas Commission state that electricity consumers in states adopting retail direct access can directly and fully benefit from the operation of properly constituted RTOs and their concomitant improvements in system efficiency, reliability and market competition.

Comments on RTOs Improving Grid Reliability. Many commenters agree that an RTO could provide improved reliability.¹⁰⁷ Minnesota Power supports the formation of a single regional body that operates the regional grid and enforces reliability rules for the entire region. It suggests that a non-profit RTO can be expected to enforce reliability rules fairly and aggressively and, thus, require minimal Commission oversight. On the other hand, a for-profit RTO may be perceived as biased towards making a profit at the expense of reliability and may require additional scrutiny by the Commission.

Michigan Commission strongly supports creating an RTO for the Midwest that is large enough to ensure reliability. It is very concerned that splitting the Midwest region into improperly sized competing ISOs, RTOs, and/or Transcos will affect regional reliability and delay the benefits of competition. Also, splitting a region into multiple RTOs reduces

¹⁰⁴ See, e.g., Big Rivers, Chelan, California Board, Industrial Customers, Arizona Commission, EEI, Idaho Commission, Washington Commission.

¹⁰⁵ As noted earlier, many of the principal benefits of RTOs (e.g., congestion management, improved reliability, parallel path flow resolution) are discussed in greater detail later as RTO minimum characteristics and functions; however, some of the commenters cited here mention these benefits as part of their overall discussion of RTOs improving efficiencies in the management of the transmission grid.

¹⁰⁶ Comments are addressed in greater detail in the discussion of planning and expansion as an RTO minimum function.

¹⁰⁷ Comments are addressed in greater detail in the discussion of short-term reliability as an RTO minimum characteristic.

access to economic generation due to increased transmission charges. Michigan Commission believes competition and reliability within the region will be served best if the Transmission Alliance and Midwest ISO are joined.

Comments on RTOs Removing Opportunities for Discriminatory Transmission Practices. Many commenters, mostly transmission customers, agree that RTOs will remedy continuing opportunities for undue discrimination.¹⁰⁸

As both a buyer and seller of wholesale electricity, Oglethorpe supports the evolution of competitive markets for generation service. To ensure that competitive markets evolve and perform in a workable manner, market participants should be assured access to the transmission system on a fair and comparable basis, without regard to transmission ownership. It believes that true competition can occur only with widespread, open and nondiscriminatory access to the transmission system. UtiliCorp claims that removing control over access to transmission from the remaining large transmission-owning utilities and placing such control in properly structured RTOs will go a long way toward eliminating the remaining obstructions to effective competition in wholesale markets for electric power.

Virginia Commission agrees that discrimination exists and that RTOs can help facilitate competition and police non-competitive activities. However, Virginia Commission believes that it is premature to conclude that there is no role for rigorous governmental regulation. Virginia Commission urges that the Commission not rely exclusively on RTOs to detect, prevent and penalize violations of the FPA and should itself provide for expedited handling of allegations regarding discrimination and market power abuses.

On the other hand, a number of commenters, mostly transmission owners, do not believe that RTOs are needed to address undue discrimination because they do not believe that significant discrimination problems remain with respect to wholesale transmission access pursuant to Order No. 888.¹⁰⁹ PSE&G argues that, if a

misperception exists in the marketplace as to the trustworthiness or incentives of transmission owners as a whole, it may signal a need for an industry-wide educational campaign that discusses transmission operation and system reliability. However, such a misperception does not, in and of itself, warrant altering the structure of the industry.

Comments on RTOs Resulting in Improved Market Performance. DOE asserts that open and comparable transmission access can reduce both concentration in generation markets (by expanding the boundaries of the relevant market) and the potential to discriminate through vertical control but cannot, in its view, eliminate all market power. The establishment of an independent RTO can and should substantially mitigate the potential exercise of market power through vertical control, because dispatch and related transmission services will be provided by an independent entity with no financial interest in wholesale market participants. Furthermore, the expected contribution of an RTO in reducing the risk of horizontal market power will be realized only if RTOs have sufficient "critical mass." Appropriately sized RTOs are necessary to assure a transparent and fair marketplace for all generation.

EPA notes that RTOs can play an important role in the development of environmentally preferred or "green" electricity products for use by states that are implementing retail electricity competition. As the operator of the transmission system, an RTO will have access to detailed information on the operations of individual generators as well as fuel type and air emissions, even where such information is considered confidential. RTOs are uniquely situated to assemble the information necessary to determine environmental attributes of specific retail electricity products for purposes of consumer information disclosure. EPA notes that this is already occurring in New England, where ISO-NE has agreed to provide the states with information on environmental attributes and resource mix for individual generators. In addition to facilitating consumer information disclosure, EPA notes that this information will support other state policies, such as renewable portfolio standards and generation performance standards.

Comments on RTOs Facilitating Lighter-Handed Governmental Regulation. Although most commenters agree that properly-designed RTOs can be self-governing to a certain extent, the vast majority of commenters believe that

the Commission has either overstated the reliance it should place on self-governance or has reached this conclusion prematurely. Most of these commenters suggest that there is insufficient evidence at this time to reach the conclusion that RTO formation would necessarily result in lighter-handed regulation. A number of commenters also caution that the Commission should not significantly reduce its oversight of RTOs until they are proven to be effective. British Columbia Ministry states that the structure of future RTOs should minimize additional layers of administration and oversight. However, at least one commenter, Cal DWR, noting that RTOs are themselves transmission monopolies subject to the FPA, argues that the Commission should continue its course of regulating RTOs to ensure compliance with legal and policy requirements.

PJM generally supports the Commission's conclusion regarding light-handed regulation. It notes that, where ISOs' decisions are independent and conducted through an extensive stakeholder processes to produce collaborative solutions to market issues, the Commission can defer confidently to those decisions. Under such circumstances, the Commission can be assured that ISO proposals to changes market rules and procedures would promote competitive markets and are not designed to favor any one group of market participants.

PJM argues further that the Commission accord greater flexibility to properly structured RTOs to change market rules and procedures without Commission filings. An RTO with an established stakeholder process could publish some changes in market rules on its internet site, without requiring prior Commission approval. In the event that a market participant objected, it could file a complaint with the Commission. PJM says the benefit is that the market would not be hindered by delay in implementing new rules. Other rules could be permitted to go into effect upon filing, rather than at the end of the Commission review process.

Some commenters suggest that the Commission be particularly deferential to decisions that result from ADR processes. For example, PNGC supports strong and broad dispute resolution power in an RTO. It argues that many small transmission users currently have no effective way to be heard regarding service complaints, outage restoration, and adequacy of equipment or maintenance because of the high cost of bringing such a dispute to the Commission. In addition, Desert STAR

¹⁰⁸ See, e.g., American Forest, TDU Systems, WPPI, Sonat, Illinois Commission, Arizona Commission, FMPA, Tampa Electric, Advisory Committee ISO-NE. Comments are addressed in more detail later in the discussion of existing discriminatory conduct.

¹⁰⁹ See, e.g., United Illuminating, Southern Company, MidAmerican, Duke, PSE&G, FP&L, Entergy, FirstEnergy, Alliance Companies, Lenard, Florida Power Corp.

asserts that where the Commission has approved the charter governance and ADR processes of an RTO as being sufficiently broad-based and independent, the Commission should give some deference to decisions reached through the RTO's ADR processes. However, deference in dispute resolution to an RTO should not impair a transmission user's fundamental rights under section 211 of the FPA. Because the RTO will be a jurisdictional entity, the Commission is an appropriate appeals forum. Similarly, Seattle supports the Commission proposal to defer to RTOs on matters involving commercial, operating and planning practices, as well as to resolve disputes, but argues that it is too early to tell whether ISOs transcos or other forms of RTOs can be deferred to in lieu of regulatory filings.

MidAmerican welcomes the Commission's proposed lighter-handed approach to regulation, but questions whether lighter-handed regulation, in fact, will be derived from the proposed rule. MidAmerican proposes that the Commission issue a policy statement to provide general guidance on how it intends to give deference to RTOs. For example, the policy should outline that, if a transmission owner follows RTO directives, it will be presumed that the transmission owner does not have transmission market power and that it is not capable of transmission market discrimination. The Commission should give deference to RTOs to design tariffs that include rate incentives and should permit returns on equity that compensate transmission owners for additional risks and for competitive market development.

A number of commenters argue that there is as yet no evidence to support the conclusion that RTO formation should lead to lighter-handed regulation. Duke and Entergy argue that each of the existing ISOs has been mired in significant litigation with market participants, and the Commission's dockets are loaded with cases arising out of decisions made by ISOs. They and NECPUC suggest that this raises the possibility that RTOs represent a new layer of regulatory oversight of market activities, supplementing rather than replacing federal and state regulation. FP&L states that the independence and objectivity of the Florida Public Service Commission make it unnecessary to create a formal (and costly) separate entity to operate and oversee the Florida grid as an RTO.

Other commenters suggest that the probability that RTOs can be self-regulating may be overstated. APPA argues that existing ISOs still represent

the interests of the transmission owners that formed these ISOs. In addition, it argues that each ISO is a market participant because its revenue recovery is affected by the performance of transmission, ancillary services, and energy imbalance spot markets. It suggests that the right to self-regulation must be earned in the marketplace, not bestowed by regulators in advance.

NECPUC argues that not only must an RTO be properly structured to be self-regulating, so must the utilities involved, or the RTO will constantly be involved in the business of dispute resolution. It suggests that during a transition phase, a certain level of active regulation may be inescapable. For example, it notes that the Commission stepped in quite definitively in developing the governance of the New England Power Pool. NECPUC believes that strong intervention by the Commission was effective at achieving progress when the parties in New England stalemated.

PG&E claims that an RTO is uniquely situated to handle a number of responsibilities, including reliability enforcement and sanctions, market monitoring, and reporting non-reliability market-related violations. However, a single entity, no matter how well-structured and independent, cannot successfully fulfill several competing roles simultaneously, *i.e.*, serve as judge, jury and advocate. While the RTO can do much to create region-specific processes that meet the needs of market participants, the Commission must retain ultimate oversight. The RTO is not a substitute for this function. With the tremendous volume of transactions flowing through an RTO, even small errors in energy or financial accounting can lead to huge cost shifts. Market participants need to have a remedy at the Commission if issues are not resolved adequately by the RTO.

Other commenters believe that the Commission may have to play a strong role in ADR. Arizona Commission urges the Commission to give respect rather than deference to decisions reached through an RTO's ADR processes. TDU Systems state that the ability of an RTO transmission customer to obtain ultimate Commission review of a dispute with the RTO (or another RTO customer) should not be cut off. RTO tariffs should contain ADR provisions that allow for mediation or other low-cost forms of ADR so disputes can, if possible, be resolved without resort to the Commission. If this is not possible, the Commission should consider any dispute that comes to it after the conclusion of ADR at an RTO on a *de novo* basis.

In dealing with disputes between RTOs and their customers, TDU Systems suggests that the Commission be sensitive to the issue of "minority rights." The Commission should ensure that transmission customers with complaints against their RTOs get due process and a full and fair opportunity to air their concerns. Just because a customer may take a position in a dispute not shared by many others does not mean that it is automatically wrong.

Moreover, TDU Systems believe that the Commission, in considering the ADR issue, should make a distinction between ISOs or other RTOs that are not-for-profit or quasi-governmental in nature and for-profit RTOs. For-profit RTOs may not necessarily be well suited to be the arbiters of disputes, especially where they are an involved party. It would be inappropriate for the Commission simply to "off load" dispute resolution duties to a private for-profit entity, especially if the entity is an interested party in the dispute. ISOs, on the other hand, are more quasi-governmental in nature, and if fully independent, may be in a better position to attempt to resolve a dispute, subject to Commission review.

Duke asserts that streamlined filings and approval procedures could reduce costs that would otherwise be borne by market participants. Reducing regulatory burdens could constitute one form of incentive to encourage RTO participation. The policy could be applied equally for non-profit and for-profit RTOs. On the other hand, TDU Systems argues that opportunities for streamlined RTO filings could set a very dangerous precedent, especially if applied to incentive rate filings of for-profit RTOs. RTOs will still be monopolies (although hopefully large horizontal ones, rather than smaller, vertically integrated ones). The norm for RTO filings should still be full Commission scrutiny. Entergy argues that the Commission should encourage proposals submitted by RTOs designed to increase regulatory efficiencies and reduce regulatory burdens imposed on RTOs. The Commission should specifically declare its willingness to entertain proposals to streamline filing requirements. The Commission could encourage innovative ways to reduce regulatory costs by authorizing performance-based rates that reward RTOs for reducing regulatory costs.

Commission Conclusion. We conclude that properly structured RTOs throughout the United States can provide significant benefits in the operation of the transmission grid. The comments received reinforce our preliminary determination in the NOPR

that RTOs can effectively remove existing impediments to competition in the power markets.

Description of Benefits. We conclude that RTOs will provide the benefits that we described in detail in the NOPR, and others that commenters mention.¹¹⁰ While we acknowledge that the level of RTO benefits may vary from region to region depending on the current transparency and efficiency of markets, the Commission believes that benefits from RTO's would be universal. These benefits will include: increased efficiency through regional transmission pricing and the elimination of rate pancaking; improved congestion management; more accurate estimates of ATC; more effective management of parallel path flows; more efficient planning for transmission and generation investments; increased coordination among state regulatory agencies; reduced transaction costs; facilitation of the success of state retail access programs; facilitation of the development of environmentally preferred generation in states with retail access programs; improved grid reliability; and fewer opportunities for discriminatory transmission practices.¹¹¹ All of these improvements to the efficiencies in the transmission grid will help improve power market performance, which will ultimately result in lower prices to the Nation's electricity consumers.

As stated in the NOPR, we expect that RTOs can reduce opportunities for unduly discriminatory conduct by cleanly separating the control of transmission from power market participants. An RTO would have no financial interests in any power market participant, and no power market participant would be able to control an RTO. This separation will eliminate the economic incentive and ability for the transmission provider to act in a way that favors or disfavors any market participant in the provision of transmission services.

Most commenters support the premise that RTOs can be beneficial in addressing the remaining transmission-related impediments to full competition in the electricity markets. Although we recognize certain differences in perspective about the existence of, or potential for, widespread discrimination by current transmission owners, no one

seriously disputes the benefits of a marketplace where service quality and availability are uniform, where users of the network are treated equally, and where commercially important data are readily available to all. Although some commenters support the NOPR proposal only if the costs of establishing RTOs do not exceed the benefits, a subject discussed further below, most believe that the benefits listed in the NOPR are accurate and can be achieved through an RTO.

We recognize that some commenters believe that either RTOs alone will not solve all of the identified problems, or individual benefits can be achieved in ways other than creating RTOs. Both of these observations may have some merit. However, we believe that the creation of RTOs is one action that can address all of the identified impediments to competition and provide all or most of the identified benefits.

We also recognize that there are those who worry that the costs of establishing an RTO will outweigh the benefits. We believe this concern fails to account for the flexibility we have built into this rule. While many look at the high costs involved with respect to establishing some existing ISOs and PXs, this rule does not require an RTO to follow any specific approach. For example, this rule does not require the consolidation of control areas nor does it require the establishment of a PX. We are allowing significant flexibility with respect to how and, in some cases, when the minimum characteristics and functions are satisfied. Accordingly, we do not believe it will be necessary to expend the same level of resources that were expended, e.g., in California, to create an RTO satisfying our minimum characteristics and functions. We therefore conclude that the flexibility built into the Final Rule will allow RTOs to create streamlined organizational structures that are not overly costly. Moreover, with five ISOs now operating in the United States, there is considerable experience available regarding what works and what does not with respect to regional transmission entities. This experience should make it somewhat easier, and more cost efficient, to create new RTOs.

As we stated in the NOPR, by improving efficiencies in the management of the grid, improving grid reliability, and removing any remaining opportunities for discriminatory transmission practices, the widespread development of RTOs will improve the performance of electricity markets in several ways and consequently lower prices to the Nation's electricity

consumers. To the extent that RTOs foster fully competitive wholesale markets, the incentives to operate generating plants efficiently are bolstered. The evidence is clear that market incentives can lead to highly efficient plant operations. The incentives for more efficient plant operation can also affect existing generation facilities. Especially noteworthy is the recent experience that indicates improvements in the generation sector in regions with ISOs. Regions that have ISOs in place are undergoing dramatic shifts in the ownership of generating facilities. Large-scale divestiture and high levels of new entry in California and the Northeast are changing the ownership structure of these regions' generators. Access to customers and the presence of competing suppliers are creating the incentives for better-performing plants.

By improving competition, RTOs also will reduce the potential for market power abuse. As discussed earlier, eliminating pancaked transmission prices will expand the scope of markets and bring more players into the markets. By eliminating the mistrust in the current grid management, entry by new generation into the market will become more likely as new entrants will perceive the market as more fair and attractive for investment. And with more players, the market becomes deeper and more fluid, allowing for more sophisticated forms of transacting and better matching of buyers and sellers.

Estimation of Benefits. The full value of the benefits of RTOs to improve market performance cannot be known with precision before their development, and we do not yet have a sufficiently long track record with existing institutions with which to measure. The Commission staff has estimated a subset of the potential cost savings from RTOs as part of its National Environmental Policy Act analysis. In the Environmental Assessment (EA) for this rulemaking, three scenarios were developed to estimate potential economic and environmental effects of the rulemaking.¹¹² The scenario analysis was conducted using a computer simulation model of the continental U.S. electric power system over the

¹¹⁰ The benefits described in this section are not intended to include all benefits that RTOs could provide. Some of the principal benefits of RTOs (e.g., more effective management of parallel path flows, improved congestion management) are addressed in later discussions of RTO minimum characteristics and functions.

¹¹¹ FERC Stats. & Regs. ¶ 32,541 at 33,716-20.

¹¹² One of these scenarios assessed transmission effects only, the second assessed generation efficiencies in addition to transmission effects, and the third posited increased entry of new supply and demand choices.

period 1997 to 2015.¹¹³ The Commission adopts staff's analysis.

The results of the EA modeling present a range of potential cost savings resulting from the changes in modeling assumptions in each scenario. Although this Final Rule does not mandate RTO formation, full development of RTOs as envisioned by the Commission in this rule could offer substantial economic benefits. The EA scenarios modeled resulted in average annual savings of up to \$5.1 billion per year over the 2000–2015 period. Based upon review of the EA scenarios and comparison with other existing analyses of competitive electric power markets, the best estimate from the EA analysis of annual benefits that could result from RTO formation is \$2.4 billion per year. This estimate results from a scenario in which the modeling assumptions for transmission and generation efficiency are selected for consistency with other economic analyses of competitive power markets, including the Order No. 888 Environmental Impact Statement analysis conducted by Commission staff in 1996.¹¹⁴

These estimates do not represent a complete economic analysis of the rulemaking because the EA analysis addressed only factors that may change the dispatch of power plants or future generating capacity decisions. The model accounts for production costs (capital additions, operations and maintenance expenses, and fuel) equal to roughly one-third of the annual sales revenue now passing through the industry, and does not include such cost categories as existing (sunk) capital, the distribution system, and end user charges such as taxes. If other cost savings were realized, for example, from merger-like consolidation savings in the transmission grid, these savings would be additional to those estimated in the EA. Benefits from elimination of market power and improved intra-regional congestion management are also not included in the calculation and could represent significant additional savings.

The costs of RTO formation are not explicitly captured in the EA analysis, nor are any potential costs associated with the provision of incentives for RTO formation or operation. Costs of RTO formation cannot be well estimated because of the wide range of design choices that the rule allows for a new

RTO. For instance, the choice of building a dedicated telecommunications and data infrastructure, as opposed to relying on existing infrastructures, can have a large effect on the initial cost of an RTO.¹¹⁵

Based on review of cost studies for existing ISOs, it appears unlikely that the costs of RTO formation will exceed RTO cost savings on an annualized basis over time. This is because most of the costs are capital investments that occur at the beginning of the RTO's operation. But whether the costs in the initial period are under \$10 million or up to several hundred million dollars (and more likely between these two figures) for an RTO, they are small in comparison with the ongoing annual savings that RTOs may provide.

As discussed above, our best estimate of cost savings from RTO formation is \$2.4 billion annually, with potential cost savings estimated to be as high as \$5.1 billion annually. This represents about 1.1 to 2.4 percent of the current total costs of the U.S. electric power industry.¹¹⁶ Such savings can be considered in the context of recent analysis of the economic benefits of further industry restructuring.¹¹⁷ The wholesale cost savings the Commission is anticipating from the formation of RTOs are properly viewed as distinct from the larger savings that may result from competitive retail power markets. However, RTOs can also help achieve retail access and its associated benefits by creating a robust wholesale power market. In this sense the cost savings from retail access depend on the Commission fulfilling its RTO objectives.¹¹⁸

Light-Handed Regulation. One of the benefits of RTOs that we identified in the NOPR was that the existence of a properly structured RTO would reduce the need for Commission oversight and scrutiny, which would benefit both the Commission and the industry. We stated that to the extent an RTO is independent of power marketing interests, there would be no need for the Commission to monitor and attempt to

enforce compliance with the standards of conduct designed to unbundle a utility's transmission and generation functions. We also stated that an independent RTO with an impartial dispute resolution mechanism could resolve disputes without resort to the Commission complaint process, and that it is generally more efficient for these organizations to resolve many disputes internally rather than bringing every dispute to the Commission. Further, we noted that the Commission has in the past indicated its willingness to grant more latitude to transmission pricing proposals from appropriately constituted regional groups¹¹⁹ and, to the extent that RTOs increase market size and decrease market concentration, the competitive consequences of proposed mergers would become less problematic and thereby help further streamline the Commission's merger decision-making process.

We continue to believe that the types of reduced regulatory scrutiny mentioned in the NOPR, and summarized above, are possible and appropriate for RTOs. A number of commenters, however, have expressed concern that it is premature to reduce regulation of RTOs, and that RTOs will be monopolies that will require continued regulation. We believe that this concern stems from a misunderstanding of our concept of light-handed regulation. Admittedly, this concept is subject to varying interpretations.

We clarify that we will continue to apply the level of regulation and scrutiny that is necessary to ensure that public utilities comply with the FPA and our regulations. Only when we determine that a different form of regulation will adequately protect the public interest, we will allow a reduced oversight role for the Commission.

Furthermore, our encouragement of the use of ADR by participants in RTOs to resolve disputes without resort to formal complaint proceedings is not new. In our RTG Policy Statement, we encouraged RTGs to develop alternative dispute resolution procedures for resolving transmission issues, particularly technical and reliability issues. We also stated that we would be willing to entertain proposals for some degree of deference to decisions rendered pursuant to an ADR process, pursuant to procedures that are specified in an agreement and assure

¹¹³The Integrated Planning Model (IPM) was developed for the U.S. Environmental Protection Agency by ICF Inc. See 3.3.1 of the Commission Staff's Environmental Assessment in this proceeding.

¹¹⁴Order No. 888, *Final Environmental Impact Statement*, FERC/EIS-0096, FERC Stats. & Regs. ¶ 31,036 at 31,860–96.

¹¹⁵See, e.g., California ISO, *Cost Performance Benchmarking Study of Independent System Operators*, revised version of Feb. 17, 1999.

¹¹⁶Defined as revenue from sales to ultimate users, which were reported as \$215 billion in 1997. See Energy Information Administration, *Annual Energy Review 1997*, DOE/EIA-0384(97) (July 1998).

¹¹⁷See, e.g., Department of Energy, *Supporting Analysis for the Comprehensive Electricity Competition Act*, DOE-PO-0059 (May 1999).

¹¹⁸DOE's Economic Analysis of the Comprehensive Electricity Competition Act shows an estimated cost savings from a national policy of retail access to be \$20 to \$32 billion per year. See *id.*

¹¹⁹Inquiry Concerning the Commission's Pricing Policy for Transmission Services Provided by Public Utilities Under the Federal Power Act, 59 FR 55031 (Nov. 3, 1994), FERC Stats. & Regs. ¶ 31,005, at 31,140, 31,145, 31,148 (1994) (Transmission Pricing Policy Statement).

due process for all participants.¹²⁰ We stated there, and we reaffirm here, that while the Commission cannot delegate its authority, it can give deference to resolutions that meet the standards of the FPA.

We reiterated this concept in the eleven ISO principles we set forth in Order No. 888. We stated there that an ISO should provide for a voluntary dispute resolution process that allows parties to resolve technical, financial, and other issues without resort to filing complaints at the Commission.¹²¹ We have also expressed our willingness to grant some deference to changes to an open access tariff by an ISO concerning a regional solution to an identified regional problem based on what we understand is a broad consensus.¹²²

Accordingly, we believe that some degree of deference can be granted on certain issues to independent RTOs that have appropriate procedural mechanisms in place to ensure fair representation of viewpoints. We cannot delineate here precisely the degree of deference that is appropriate, or on what issues. To the extent some issues can be fairly resolved within a region without formal Commission procedures, a benefit accrues to both the parties and the Commission.

In addition, we note that some of the innovative ratemaking policies discussed later in this Final Rule are consistent with light-handed regulation, since we expect that these policies may result in reduced levels of regulatory scrutiny. We emphasize, however, that we will not delegate or fail to exercise our regulatory responsibilities. We also recognize that the degree of deference and reduced regulatory scrutiny accorded to an RTO may necessarily depend on the ability of the RTO to reach consensus solutions to regional issues.

C. Commission's Approach to RTO Formation

The NOPR proposed an approach to RTO formation that embraces several general principles: first, as a matter of policy, we should strongly encourage transmission owners to participate voluntarily in RTOs; second, we should be neutral as to organizational form (e.g., ISO or transco) of an RTO as long as it satisfies our minimum characteristics and functions; and third,

we should provide maximum flexibility as to the specifics of how an RTO can satisfy the minimum characteristics and functions. We sought comment on these principles and specifically asked whether we should generically mandate RTO participation¹²³ or whether market-based rates or merger approvals should be conditioned on RTO participation.¹²⁴

Based on the wide array of comments received, which we discuss next, and the voluminous record compiled in this rulemaking proceeding, we conclude that a voluntary approach to RTO formation represents a measured and appropriate response to the technical impediments to competition that have been identified as well as the lingering discrimination concerns that have been raised. We believe that voluntary formation of RTOs will address the fundamental economic and engineering issues which confront the industry and the Commission, and will help eliminate any actual or perceived discriminatory conduct by entities that continue to control both generation and transmission facilities.¹²⁵ Further, we believe that the voluntary process adopted in this rule, in conjunction with the innovative transmission pricing reforms that we will permit RTOs to seek, will be successful in achieving widespread formation of RTOs in a timely manner. Our adoption of a voluntary approach to RTO formation in this Final Rule does not in any way preclude the exercise of any of our authorities under the FPA to order remedies to address undue discrimination or the exercise of market power, including the remedy of requiring participation in an RTO, where supported by the record.

1. Voluntary Approach

Comments. Comments as to whether the Commission should require formation of and/or participation in RTOs break down into five main categories: (1) The Commission should require formation of and participation in RTOs; (2) formation of and participation in RTOs should be voluntary; (3) the Commission should encourage voluntary RTOs, but with strong enforcement mechanisms; (4) RTOs should be voluntary, but if they do not form or if utilities do not participate, the Commission should mandate them; and (5) RTOs should be voluntary, but the

requirements of the NOPR effectively create a mandate.

Most investor-owned utilities argue that RTOs should be voluntary. Most municipal utilities, customer groups, consumer advocates, and marketers argue that the Commission should require RTOs. State commissions and cooperatives are more evenly split. These characterizations, however, are broad generalizations, and there are strong exceptions to each statement.

Comments That the Commission Should Require Formation of and Participation in RTOs. The most extensive argument for mandating RTOs comes from TAPS and is representative of the positions of a number of public power utilities and other transmission customers.¹²⁶ TAPS argues that the non-mandatory approach leaves the keys to reform in the hands of the wrong people—the monopolists who have market power—and that the voluntary creation of RTOs will give opportunities for monopolists to maintain their market power. TAPS presents extensive arguments as to the Commission's authority to mandate and its obligation under the FPA to do so. They state:

Only by mandating that jurisdictional utilities participate in * * * RTOs will the Commission protect against * * * utilities' inclinations to form alternative RTOs that are structured to perpetuate or enhance their competitive position. Compelling such participation is also the only way for the Commission to satisfy its statutory obligations to eradicate undue discrimination and protect against unjust and unreasonable pricing of both transmission service and wholesale generation sales.

TAPS further argues that past attempts to allow voluntary formation of RTOs have not been successful. Only where states have required ISOs or where the Commission has required them as part of a merger proceeding have effective ISOs been formed.

TDU Systems also presents extensive arguments for a mandate. It argues that the need for a national system of RTOs is urgent; that the Commission cannot rely purely on voluntary actions of transmission owners; that only a mandate will create RTOs in a timely fashion; and that inducements are counterproductive. WPPI states that the financial incentive to protect a transmission owner's generation investment is much stronger than any transmission incentive FERC can give to induce RTO participation. First Rochdale argues that voluntary RTOs will create too great an emphasis on forcing parties to litigation and other

¹²⁰ Policy Statement Regarding Regional Transmission Groups, 58 FR 41626 (Aug. 5, 1993), FERC Stats. & Regs. ¶ 30,976 (1993) (RTG Policy Statement).

¹²¹ Order No. 888, FERC Stats. & Regs. ¶ 31,036 at 31,732.

¹²² See PJM Interconnection, L.L.C., 84 FERC ¶ 61,212 (1998).

¹²³ FERC Stats. & Regs. ¶ 32,541 at 33,762.

¹²⁴ *Id.*

¹²⁵ These engineering, economic and discrimination issues are discussed in Section III.A above.

¹²⁶ E.g., APPA, Empire District, FMPA, Great River, Lincoln, UAMPS, UMPA.

costly, time consuming dispute resolution.

Some investor-owned utilities support a mandate.¹²⁷ For example, Cinergy presents arguments similar to those of TAPS, and believes that "all jurisdictional utilities must be required to transfer control of their transmission facilities to a qualified ISO, which shall integrate those facilities into an RTO approved by the Commission."

A number of marketers believe that RTOs must be mandated. Sonat is not convinced that incentives alone are sufficient to persuade transmission providers to follow through with RTO formation. NEMA believes that participation by all transmission owners should be mandatory, but that the form of the RTO should be allowed to evolve.

Many industrial customers agree that RTOs must be required. PJM/NEPOOL Customers argue that the goals of the Commission cannot be achieved without mandatory participation by all transmission owners in RTOs. They go further to state that experience from both the Midwest ISO/Alliance debate over formation of ISOs and from the natural gas industry demonstrates monopolists will not act effectively to eliminate discrimination without strong mandates attached to strong penalties.

Residential consumer advocates and environmental organizations concur. Public Citizen says that the Commission should order the creation of three non-profit public transmission companies (one each for the Eastern, Western, and ERCOT interconnections) and order each public transco to purchase all of the transmission facilities needed to provide customers with transmission service.

Project Groups recommends that the final rule be strengthened to require that if owners do not voluntarily transfer control of facilities to an approved RTO by a date certain, the Commission will either order the transfer (in the case of jurisdictional utilities) or take other actions designed to minimize the opportunities for resisting owners to use their facilities in anti-competitive ways.

A number of state commissions support a mandatory RTO regime imposed by the Commission. Illinois Commission does not believe that the voluntary approach set out in the NOPR is likely to obtain its objectives and especially not in a timely manner, noting that voluntary efforts "for more than six years" have failed and that the encouragements and incentives contained in the NOPR are unlikely to change the situation. Indiana Commission points to its experience

with the Midwest ISO/Alliance debates as indicating that the Commission must take a more assertive role. Montana Commission agrees, pointing to unwillingness of transmission owners to give up control and to concerns about cost-shifting. It recommends that the Commission strengthen the NOPR to ensure the prompt formation of RTOs using all the tools at its disposal. Pennsylvania Commission argues that in order to be stable, both as to their authority and with respect to membership participation, RTOs must be mandatory. Virginia Commission argues that the goal of independence is in conflict with a voluntary approach.

Wisconsin Commission argues that the Commission should move forward quickly and require all transmission facilities to be placed under the control of an RTO. In the absence of any action from FERC to require utility membership, it states, it is unclear how any effort to resolve the "Swiss cheese" problems already experienced in the Midwest can succeed. Ohio Commission argues that it continues to believe that the mandatory participation and boundary drawing approach is more appropriate.

Comments That Formation of and Participation in RTOs Should Be Voluntary. The most extensive presentation of the argument that RTOs should and must be voluntary comes from Indianapolis P&L and FP&L, which make mostly legal arguments that are addressed below. Southern Company argues that a voluntary, flexible RTO policy is consistent with desires of the states as reflected in statements given at the consultations with the states held by the Commission. It also avers that an RTO is not required to achieve the goals of the NOPR. Alliance Companies and Trans-Elect argue that voluntary formation is the key to RTO success, noting that the Commission's voluntary approach of encouraging regionalization of the transmission grid has been successful and there is no reason to doubt its continued success.

EEL suggests that the voluntary approach is working well, indicating that five ISOs have been approved serving 46 percent of U.S. customers and 38 percent of total MWh sales. They state that four other regions have proposed or are about to propose RTOs which will result, within three years since the issuance of Order No. 888, in nearly 63 percent of the nation's electricity customers being served by regional transmission entities. They go on to argue that a mandate could

stimulate litigation that would slow this voluntary development.¹²⁸

A number of public power entities, including municipal utilities, cooperative utilities, Federal Power Marketing Administrations, and others, also support a voluntary approach. TVA argues that FERC's proposal to make RTO participation voluntary is a wise one, that as RTOs demonstrate their effectiveness and the benefits of RTOs become more evident, transmission owners likely will be persuaded to participate and the holes in the RTOs should disappear. CMUA argues that mandatory RTOs are not likely to be formed through collaborative processes and therefore are not likely to take into account broad stakeholder input. Tacoma Power supports voluntary formation because some utilities may not find that the cost savings are sufficient to warrant the expenditure necessary. Also, it states that public power utilities may face legal obligations or restrictions that inhibit their participation and that such utilities should not face penalties or sanctions for not participating.¹²⁹

A number of state commissions support voluntary formation of RTOs. Alabama Commission argues that the Commission does not have authority to mandate RTOs. Florida Commission agrees and states that any action by the Commission must be on a case-by-case basis, and the Commission should defer to states in developing regional approaches. Michigan Commission believes that there is a solution short of mandating RTO formation, but that uses FERC's unique national perspective and authority to facilitate larger RTO formation. Wyoming Commission urges the Commission not to codify or mandate anything other than the general framework for RTOs and thereby allow the voluntary process an opportunity to work.¹³⁰

Comments That the Commission Should Encourage Voluntary RTOs But With Strong Enforcement Mechanisms. The Justice Department argues that the

¹²⁸ Other transmission-owning utilities supporting voluntary development and opposing mandates are Detroit Edison, Duke, Entergy, Florida Power Corp., SCE&G, Metropolitan, MidAmerican, NEPCO *et al.*, NU, NSP, Montana-Dakota, Tampa Electric, TXU Electric, United Illuminating, CP&L, Central Maine and Virginia Power.

¹²⁹ Other public power and cooperative entities supporting voluntary formation of RTOs include Big Rivers, East Kentucky, Georgia Transmission, South Carolina Authority, SMUD, Seattle, JEA, LPPC, NRECA, Los Angeles, MEAG, Oglethorpe, Platte River, NPRB, NPPD, RUS and Tri-State.

¹³⁰ Other state commissions supporting voluntary formation include South Carolina, Iowa, New York, and Washington. Other entities supporting voluntary formation of RTOs include NYPP, SRP and Cal ISO.

¹²⁷ E.g., Minnesota Power, WEPCO, PG&E, PECCO.

NOPR makes a strong case for mandating RTOs. It recommends that a regime of "carrots and sticks" be carefully designed to reasonably guarantee complete voluntary compliance, rather than merely promote greater voluntary compliance.

Enron/APX/Coral Power argue that the Commission should take steps to induce transmission owners to participate in RTOs.¹³¹ They doubt, however, that performance-based ratemaking alone will be a sufficient inducement and recommend Commission procedures to prevent transmission owners that fail to participate in RTOs from misusing their transmission systems to favor their own or affiliated uses of their systems. These could include regional proceedings to impose added safeguards against violations, presumptions of ineligibility for market-based rates, and presumptions that mergers are inconsistent with public interest absent membership in an RTO.

Comments That RTOs Should Be Voluntary, But if They Do Not Form, the Commission Should Mandate Them. PNGC argues that if a voluntary RTO encompassing the Pacific Northwest does not come about in a reasonably short time, the Commission should explore its authority or seek new authority to mandate participation in RTOs. Fertilizer Institute believes that the Commission has sufficient authority to mandate RTOs but would likely be bogged down in endless litigation should it do so, and so recommends that the Commission pursue a voluntary approach, but, should that not work, proceed with a requirement. WPSC argues that encouraging voluntary participation in RTOs is the appropriate starting place. However, the Commission must be prepared to take more direct action, including increased legislative authority, to ensure the participation of utilities that do not voluntarily choose to join an RTO.

Comments That RTOs Should Be Voluntary, But the Requirements of the NOPR Effectively Create a Mandate. Puget states that if the Final Rule continues to reflect a position that nonparticipation in the RTO will result in negative regulatory consequences for the nonparticipant, then the RTO proposal cannot really be said to be voluntary. CP&L argues that mandatory filings, coupled with threats of withholding benefits and/or leveling penalties for those that do not choose to "voluntarily" join and RTO, do not

present a picture of a truly voluntary process.

Comments on Sanctions for Non-Participation. Most vertically integrated public utilities oppose conditioning market-based rates and merger approval on RTO participation, while most transmission customers favor the Commission using conditioning authority. A number of utilities express concern that the Commission may be exceeding its legal authority, and that conditioning would undermine the voluntary nature of the RTO initiative. Florida Power Corp. argues that the Commission cannot impose penalties for failure to participate voluntarily in an RTO in contravention of the FPA. Puget contends that the possibility of penalties for non-participation means that no provision is made for participation to be truly voluntary. Duke expresses concern that potential revocation of market-based rate authorization and refusal to find a merger in the public interest are actions that make it legally or economically impossible for any public utility not to participate in an RTO. EEI observes that such linkage would change settled law requiring reasoned analysis or factual findings. Similarly, Consumers Energy submits that summary withdrawal of existing market-based rate authorization must be justified by substantial evidence of changed circumstances. CP&L claims that the Commission cannot impose RTO participation conditions on a proposed merger that go beyond the consistency with the public interest standard under the FPA.

Two commenters suggest that the Commission must proceed on a case-by-case basis. MidAmerican contends that there is no clear indication that the number of parties competing in generation markets is so small to cause inadequate levels of competition. Since changes to restructure the industry into RTOs will be costly and difficult for all parties, mandates or sanctions should be based only on willful violations of Commission policy. LG&E concurs that only where the record supports a case-specific finding that a transmission owner's failure to participate in an RTO will result in undue discrimination or the ability to exercise market power should the Commission take remedial steps to address the situation so that the Commission is on firm legal grounds.

On the other hand, a number of commenters believe the Commission must require RTO participation as a condition of future market-based rate transactions and authorizations. TAPS notes that this is necessary for the Commission to meet its obligation to protect consumers from unjust and

unreasonable rates if it intends to pursue a lighter-handed regulatory approach, adding that only RTOs of appropriate size and structure will be able to meet fully the Commission's statutory obligation to protect consumers. Oneok and New Smyrna Beach argue that manipulation and undetectable anticompetitive conduct for which there is no practical after-the-fact remedy are concerns that could be alleviated by an RTO and that, accordingly, denial of merger approval or market-based rate authorization is well within the Commission's authority when anticompetitive factors have not been mitigated.

PJM/NEPOOL Customers, Great River, East Texas Cooperatives and PNGC support revoking market-based rate authorization to remedy inherent discrimination resulting from non-participation and also using non-participation as a factor in merger analysis. APPA favors imposing the merger condition in the form of an immediate requirement to participate given the Commission's prior experience with conditioning mergers with commitments to join an ISO. American Forest supports conditioning all future market-based rate transactions on participation. H.Q. Energy Services encourages the Commission to explore the full extent of its authority under the FPA to compel participation in RTOs.

Enron/APX/Coral Power recommend that the Commission create a rebuttable presumption that RTO participation is required for approval of market-based pricing or a transfer of facilities under section 203 of the FPA. For market-based rate authorizations, the Commission should establish a presumption that a decision by a transmission owner not to participate in an RTO is evidence that it is misusing its transmission facilities to advantage its merchant function. This presumption could be rebutted through a demonstration that stand-alone operation of the non-participant's grid serves the public interest as well as or better than participating in an RTO. They suggest that utilities currently with market-based rate authorizations should be ordered to show cause by the December 15, 2001, implementation deadline why their market rate authorizations should not be revoked. Enron/APX/Coral Power also recommend that all sales, leases, mergers and consolidations of transmission systems be conditioned on RTO participation based on a presumption that it is inconsistent with the public interest to dispose of transmission facilities without eliminating the incentive to

¹³¹ Concurring are H.Q. Energy Services, Midwest Energy and Oregon Office.

discriminate by committing the operation of those facilities to an RTO.

Industrial Consumers believes that the engineering and economic efficiencies of RTO participation loom so large that the Commission is justified in adopting a presumption that a decision by a transmission owner not to participate in an RTO is evidence that it is misusing its transmission facilities. Industrial Consumers recommends that the Commission assert jurisdiction over the transmission component of bundled sales, and order that the rates, terms and conditions offered under the OATT apply to all eligible customers. This would deprive vertically-integrated utilities of the incentive to resist RTO participation.

State commission commenters tend to favor the Commission using conditioning authority, but some are not sure this will necessarily encourage participation in RTOs. Oregon Commission comments that unless a utility can demonstrate that it cannot manipulate the transmission system to its advantage or that an RTO is impossible, the Commission should revoke its ability to sell at market-based rates. Complaints of unfair practices without credible reasons should be prima facie evidence of market power. Pennsylvania Commission recommends that the Commission revisit previously granted market-based rate authorizations. Indiana Commission cautions, however, that a recalcitrant utility that does not join an RTO may not perceive loss of market-based pricing authorization as detrimental. Illinois Commission does not oppose conditioning merger and market-based rate approvals on RTO participation, but it also believes that the threat of these penalties may be inadequate to induce RTO participation.

Comments on Consequences for Failure to File, or Filing Alternative Explanation. The majority of comments on this issue support the Commission taking additional action if adequate RTOs do not form. PJM/NEPOOL Customers suggests that strict penalties must be assessed against actions inconsistent with RTO formation. Oneok suggests that certain benefits that are within the Commission's authority and discretion to grant or deny should be withheld from utilities unwilling to participate. Project Groups recommend that the Final Rule provide that the Commission itself create RTOs if the stakeholders are unable or unwilling voluntarily to do so by a reasonable date certain. PNGC suggests that if RTOs do not form within a reasonable time, the Commission should explore its

authority or seek new authority to mandate participation by all utilities.

On the other hand, Duke is concerned that the Commission may not accept valid reasons for nonparticipation and use the October 15, 2000, alternative filings as vehicles to mandate RTO membership. Duke offers that the Commission cannot consider imposing penalties for non-participation while simultaneously claiming that its policy on participation is voluntary. Seattle cautions that the Commission should exercise care not to unfairly sanction transmission-owning utilities that cannot participate in an RTO (e.g., where good cause is shown that participation would violate state and local legal obligation, or the costs of RTO participation outweighs the benefits).

Commission Conclusion. Based on the record before us with respect to undue discrimination and market power, as well as with respect to economic and engineering issues affecting reliability, operational efficiency, and competition in the electric industry, it is clear that RTOs are needed to resolve impediments to fully competitive markets. However, we continue to believe, as we proposed in the NOPR, that at this time we should pursue a voluntary approach to participation in RTOs.

We acknowledge that there are many commenters who are skeptical that a voluntary approach will be able to accomplish our stated objective, which, as we stated in the NOPR,¹³² is for all transmission-owning entities to place their transmission facilities under the control of RTOs in a timely manner. In general, they argue that those with a market advantage will not easily give it up, and that voluntary efforts to date have not been very successful in creating effective regional entities.

However, we believe that a voluntary approach as we have structured it, with guidance and encouragement from the Commission, is most appropriate at this time. Given the rapidly evolving state of the electric industry, we want to allow involved participants the flexibility to develop mutually agreeable regional arrangements with respect to RTO formation and coordination. Further, we want the industry to focus its efforts on the potential benefits of RTO formation and how best to achieve them, rather than on a non-productive challenge to our legal authority to mandate RTO participation.

We believe the voluntary approach to RTO formation can be more successful now than in the past for several reasons.

The pace of industry restructuring is accelerating. Many formerly vertically integrated utilities have recently recognized the strategic benefits to them of concentrating solely in one of the traditional utility areas (generation, transmission, or distribution). Moreover, the NOPR has focused industry attention on RTOs and their benefits. Further, this Final Rule is providing clear rules and guidance on what is necessary to form an RTO. Through this Final Rule, we are also committing the Commission to act as a catalyst in RTO discussions by initiating and encouraging a collaborative process. Finally, we have provided in this Final Rule for certain favorable ratemaking treatments for those who assume the risks of the transition to a new structure, which should, at a minimum, eliminate any rate disincentives to RTO formation.

We are not adopting as a generic policy in this Final Rule either that RTO participation is required in order to retain or obtain market-based rate authorization for wholesale power sales, or that RTO participation is required for a disposition of jurisdictional facilities to be in the public interest. However, in response to those who argue that the Commission has a statutory responsibility to remedy undue discrimination and anticompetitive effects when evaluating market-based rate and merger requests, we recognize that we may have to consider, in individual cases, issues that arise as to whether market power has been mitigated in the absence of RTO participation or as to whether a merger would be in the public interest without RTO participation.

While we have concluded on this record that it is in the public interest to provide for a voluntary approach to RTO formation that relies upon encouragement, guidance, and support from the Commission, this does not mean that all aspects of this Rule are voluntary. The filing requirements set forth in section 35.34(c) of the new regulations are mandatory. In other words, public utilities must file either an RTO proposal or a report on the impediments to RTO participation. In addition, to qualify as an RTO, an applicant must comply with the minimum characteristics and functions and other specific RTO requirements set forth in the new regulations. We will also expect that all transmission owners will participate in good faith in the collaborative process that we are establishing herein.

2. Organizational Form of an RTO

Comments. A number of commenters address the proposal to allow flexibility

¹³²FERC Stats. and Regs. ¶ 32.541 at 33.685.

in the type of structure allowed for RTOs. Several of those commenting recommend maintaining the NOPR's flexibility and that the Commission not prescribe either a transco, ISO or some other structure.¹³³ FirstEnergy advocates flexibility and says that no one knows today what the best structure will be for the future so, therefore, the Commission should allow customization reflecting regional needs. Several commenters, such as APPA, argue that the Commission's flexibility on type of organization should go beyond the standard ISO and transco structures and include gridcos, wirecos, not-for-profit and for-profit forms of each organization, and hybrid organizations.

Numerous commenters state a preference in favor of for-profit transcos although many of these commenters still recommend that other structures be allowed at each region's option.¹³⁴ In favoring transcos, commenters cite the greater efficiency due to a transco's profit motive.¹³⁵ Commenters further argue that for-profit transcos can better serve the goal of independence because the transco would make all business decisions,¹³⁶ can more cleanly divide Commission-regulated transmission from state-regulated distribution,¹³⁷ and can operate more efficiently by integrating investment decisions, facility design, construction and O&M into a unified strategy.¹³⁸ A few additional supporters of transcos prefer that they be not-for-profit.¹³⁹ Gainesville recommends further that transcos in Florida become an instrumentality of the state.

In contrast to the above, ISOs are preferred by a number of commenters.¹⁴⁰ PJM argues that ISOs are necessary to ensure independence, provide more independent market monitoring and have a fiduciary duty to the public interest. PJM also notes that ISOs can meet the Commission's objectives more quickly than transcos. NASUCA reports that some of its members oppose for-profit transcos because of their "natural incentive to extract monopoly rents from consumers."¹⁴¹ Some of those who prefer ISOs contend that transcos would

favor transmission solutions over generation solutions to congestion.¹⁴² This argument is contested in the reply comments of Trans-Elect and others. NEPCO *et al.* maintains that the alleged bias in favor of transmission solutions can be overcome by using performance-based rates to replace standard rate base regulation.

Some commenters favor a hybrid involving an ISO with a gridco or with another type of organization.¹⁴³ As noted above, many commenters recommend flexibility and believe that either an ISO or transco would satisfy the needs of an RTO if designed properly.

Several commenters cited problems that need to be worked out for both transcos and ISOs. Professor Joskow notes that ISOs would suffer efficiency losses from the separation between ownership and operation of transmission assets. This separation makes it harder to apply incentive regulation because it divides decisions that affect the costs of transmission between two organizations. On the other hand, Professor Joskow says that an ISO may be superior to a transco where transmission ownership is presently so balkanized that loop flow and congestion cannot be managed, but he asserts that this advantage may decline over time as the industry changes. Southern Company says that while some see ISOs as ineffective bureaucracies which add to transmission risk, the creation of transcos presents substantial tax and financial problems.

A few commenters contend that the NOPR's provisions produce a bias in favor of ISOs even though this intent is not noted.¹⁴⁴ For example, Duke argues that the NOPR provisions for stakeholder participation in formation, governance and market monitoring functions seem more geared toward the ISO form of organization. These commenters recommend that the Final Rule not include such a bias.

A number of commenters suggest multi-layered structural alternatives. For example, ISO-NE proposes an ISO and gridco operating in tandem. A non-profit ISO would direct the operation of the transmission system and run day-ahead and real-time power markets coupled with a grid entity that owns and maintains the transmission in the area operated by the ISO. This, they claim, would require a final rule that defines an RTO as an entity, or a

combination of entities working in collaboration, that satisfies the minimum characteristics set forth in the NOPR. Under the model discussed by ISO-NE, the ISO would have responsibility for assuring open transmission access, operating the regional transmission assets (including provision of switching orders to the gridco), monitoring power markets, serving as a clearing agent and possibly serving as a clearinghouse, and maintaining short-term reliability. The gridco would own and maintain transmission assets, operate transmission assets in response to ISO directions consistent with safety requirements, and build new transmission facilities (including licensing, permitting and siting responsibilities). Joint responsibilities would include planning upgrades to transmission system.

ISO-NE argues that ISOs alone would have disadvantages in the realm of transmission expansion due to fragmentation of transmission ownership. A gridco, however, could raise investment capital, bring parallel and complementary strengths to an ISO, and should bring crisp and decisive implementation of transmission planning and expansion decisions. Pairing an ISO with a gridco, ISO-NE argues, would eliminate the problems inherent in a transco by separating transmission ownership from market administration and market monitoring.

Midwest ISO suggests a structure that it believes could meld the best of both ISOs and transcos, *i.e.*, an ISO that would allow an independent transmission company to operate under the Midwest ISO. This model would not require that all transmission be owned by a single gridco—transmission owners could decide whether to operate directly through the ISO, or spin assets off to a gridco that would operate under the ISO. Midwest ISO argues that this proposal overcomes the problems encountered in expecting all transmission owners to divest their transmission assets to separate companies.

PGE points out that, "for an RTO to achieve * * * critical mass in the near term, it must be capable of managing a regional transmission market in which a variety of subsidiary transmission structures will be in place. Such subsidiary structures may include single-company and sub-regional ITCs, integrated utilities located in states that already have restructured their retail electric markets, integrated utilities located in states that have not yet restructured, and publicly-owned and federal utilities." PJM argues that ISOs

¹³³ See, e.g., EEI, Lincoln, LG&E, SERC and Washington Commission.

¹³⁴ See, e.g., Allegheny, Entergy, INCAA and Trans-Elect.

¹³⁵ See, e.g., Sierra Pacific, H.Q. Energy Services and Detroit Edison.

¹³⁶ MidAmerican.

¹³⁷ CTA.

¹³⁸ Duke.

¹³⁹ LPPC, Los Angeles, Gainesville and Public Citizen.

¹⁴⁰ See, e.g., NASUCA, PJM and ICUA.

¹⁴¹ NASUCA at 20.

¹⁴² See, e.g., PJM and ISO-NE.

¹⁴³ See, e.g., ISO-NE.

¹⁴⁴ See, e.g., Sierra Pacific, Duke and Enron/APX/ Coral Power.

should be present even in regions that form separate transmission-owning companies to avoid continued conflict regarding the neutrality and commercial consequences of grid management decisions.

Professor Hogan states that it is very unlikely that a pure transco model is viable at all. He further indicates that, "the advantages of an independent transmission company can be pursued through the gridco model with an accompanying ISO." He suggests that this approach is already well advanced in the United States and elsewhere, and that by separating ownership of the wires from control of system operations, it would be easy to accommodate a complex pattern of ownership.

ComEd says that characteristics and functions should be performed by two linked organizations that make up a binary RTO: a for-profit ITC under the oversight of an independent not-for-profit regional transmission board.

Michigan Commission believes that wirecos, transcos and ISOs are all interim transitional organizations along the path toward very large RTO-like organizations. Even if vestiges of the smaller interim organizations continue to exist, they should operate under some kind of RTO umbrella to assure appropriate regional control. Missouri Commission proposes a zonal model in which the zones are areas where generation is integrated through the transmission grid in such a way as to minimize restrictions on sources of generation used in the area. In the future, independent transmission companies may form with the possibility that adjacent control areas will join to form larger zones. In such a case, an RTO is a collection of zones for purposes of administering the regional gatekeeper function and providing markets for transmission congestion. Each zone would be responsible for maintaining its transmission facilities and coordinating both the use and expansion of those facilities with the RTO.

WEPCO proposes that each RTO should be composed of two parallel organizations to serve the same region under a common, independent board: a Regional Reliability Council to develop regional reliability rules and a not-for-profit ISO that operates under those regional rules.

Cal DWR suggests a three-tiered structure that builds on existing organizations. Existing NERC regional councils should set broad governing criteria for ISO reliability issues, parallel path flow issues, and for regional planning. More than one ISO may be located in each NERC region.

These should control area reliability, administer transmission terms and conditions, and create market mechanisms to manage congestion, among other functions. Transmission owners should support, but not duplicate the roles of NERC regional councils.

Commission Conclusion. We will not limit the flexibility of proposed structures or forms of organization for RTOs. We are prepared to accept a transco, ISO, hybrid form, or other form as long as the RTO meets our minimum characteristics and functions and other requirements.

Some of the commenters argue that the NOPR's requirements either favor one form of organization over others or make one or the other forms very difficult to construct. It is not our intention to favor or disfavor transcos, ISOs, or other organizational form. We acknowledge that some of our minimum requirements might affect transcos and ISOs differently, but there also may be different acceptable ways for an ISO or transco to satisfy the minimum requirements. However, we designed this Final Rule to be neutral as to organizational form, and we do not believe that the requirements for forming an RTO in this Final Rule favor any particular RTO structure.

Arguments are made that an ISO is the better form of RTO because an ISO has no incentive either to favor transmission solutions to solve congestion constraints or to perpetuate congestion. ISOs are easier to form, in most cases, because there are fewer tax and mortgage consequences as there is no actual transfer of ownership.

On the other hand, some argue that transcos are preferable because they introduce a profit motive for efficient operation and expansion. Performance-based rates are normally considered more effective with transcos than with ISOs. Advantages are cited for having the same entity both propose and carry out transmission expansion and maintenance.

The transco and ISO forms of organization each has its advantages and disadvantages as do combination forms and other forms that have been suggested. In many cases, the situation facing transmission owners in a particular region may influence the appropriate form of organization to propose. In other cases it may be a matter of preference for how the participants wish to do business. Some may propose to start operation in one form and transform to another form at a future date. Tax consequences, public ownership, bond indentures and current organization will each have an impact

on the decision of what form of organization a particular RTO will propose.

This Rule does not necessarily require that a single organization perform all of the functions itself. To mention but a few examples, we specifically clarify in other parts of this Final Rule that the security coordinator function and the OASIS function could be shared with another RTO or contracted out, and that appropriate scope may be achieved in creative ways. We will entertain appropriate tiered or other structures. We require only that the RTO be responsible for ensuring that the requirements are met in a way that satisfies our Rule.

Because of the differing conditions facing various regions, we offer flexibility in form of organization. We welcome innovative structures and forms that meet the needs of the market participants while satisfying the minimum requirements of this Rule.

3. Degree of Specificity in the Rule

Comments. Many commenters believe that our proposed flexible approach is either still too rigid, or that it should provide clearer guidance. INGAA argues for less specificity in the Final Rule. INGAA points to the success of Order No. 636, wherein the Commission required open access, functional unbundling, and a new rate design, and it established specific requirements for operational control and pipeline capacity trading, all without having to specify the structure of the conforming gas transmission entity. NU similarly points to the precedent of the restructured gas industry. It states that the Commission should avoid the perils of imposing a rigid system pursuant to the mistaken belief that it can be easily and swiftly changed later to respond to future needs of the marketplace. CP&L also cautions that the principle of flexibility could prove illusory in practice and that there is a danger that, if guidance from the Commission takes the form of overly restrictive rules, it will stifle the development of innovative proposals. PG&E submits that the Commission should simply define a broad standard that provides for independence and evaluate particular RTO proposals on a case-by-case basis. South Carolina Commission also counsels that the Commission should not attempt to mandate a particular form of RTO, or establish its size or region, because this will not ensure that an efficient market will develop. It posits that any RTO policy should be flexible enough and dynamic enough to allow for both regional and

organizational differences and for growth and changes in the future.

SCE&G claims that the NOPR is overly prescriptive with respect to both scope and timing. TXU Electric submits that the NOPR's approach to reliance on minimum characteristics and functions seems to reflect a significant number of fundamental policy decisions that have already been made without the benefit of any of the very experimentation the NOPR extols. Southern Company argues that the Commission should recast the characteristics and functions as voluntary guidelines at this early stage in the development of RTOs, since it is unclear what the best form of RTO will be.

ISO supporters, such as NYPP and Central Maine, recommend that the Commission reject proposals to impose rigid and inflexible rules on RTOs and remain flexible especially with regard to existing ISOs and RTO pricing. ISO-NE counsels that tolerance for a diversity of approaches is essential, as well as politically pragmatic, due to the fact that different regions will have different histories, industry elements, and local regulatory policies that need to be accommodated.

FirstEnergy supports the NOPR's flexibility because there is no best model to deal with regional variations. Alliance Companies and Washington Commission also recommend that the Commission adhere to a flexible RTO policy, open to voluntary regional experimentation in the design of RTO structures. In addition, both Southern Company and Trans-Elect recommend that the Commission maintain flexibility toward transcos. And while a transco supporter, Entergy, sees the NOPR as properly flexible in regard to for-profit and not-for-profit RTOs. Finally, Duke agrees that RTOs should satisfy key principles, as long as they are not so prescriptive as to promote only one type of RTO.

On the other hand, Illinois Commission submits that the NOPR's minimalist approach will lead to creation of lowest common denominator RTOs that minimally comply with the characteristics and functions and general guidance as to geographic scope and membership. Project Groups suggests that the Commission expand and strengthen the minimum characteristics. TDU Systems recommends that the Commission resist calls to water down its Final Rule and urges more substance. TAPS claims that calls for more flexibility are really a cover for diluted, ineffective RTOs that will lack the scope, independence and authority to get the job done.

Commission Conclusion. While many commenters think that our proposal to rely on guidance and flexibility to promote establishment of appropriate RTOs is either too rigid or too non-specific, we conclude that we struck an appropriate balance in the NOPR.

Although we and the electric industry see many problems associated with the operation of the Nation's transmission systems and we see a general need for regional transmission solutions, we cannot at this time foresee the best organizational means to resolve every problem. Given this situation, we believe that the right balance is a minimally intrusive, solution-oriented approach that provides guidance and specifies only the fundamental RTO characteristics and functions.

We do not agree with those commenters who contend that the NOPR approach adopted herein is either overly or insufficiently prescriptive. Certainly the minimum characteristics and functions do reflect a number of threshold requirements, but collectively, these requirements serve to define the minimum necessary to improve the operation of the Nation's transmission systems. While we agree that there is no best answer and we encourage regional innovation, we cannot simply define a standard of independence and nothing else. This would leave the industry without direction and provides no guidance on how we would evaluate the various RTO proposals.

Finally, we do not agree with those who suggest that our electric regulation must follow our natural gas pipeline industry Order No. 636 model, where the Commission did not attempt structural unbundling of the pipeline industry but simply relied on more limited, functional unbundling. The situations in the two industries are different regarding the need for regional entities. Most importantly, there was not in the gas industry the degree of vertical integration of production, transmission, and distribution that historically existed in the electric industry. In addition, the gas industry has no analog to loop flow, transmission loading relief, the need for large regional calculations of ATC, or the use of generation energy and reactive power output to manipulate transmission flow, among other reasons.

4. Legal Authority

In the NOPR, we noted that sections 205 and 206 of the FPA, 16 U.S.C. 824d and 824e, give the Commission both the authority and responsibility to ensure that the rates, charges, classifications, and services of public utilities (and any rule, regulation, practice, or contract affecting any of these) are just and

reasonable and not unduly discriminatory, and to remedy undue discrimination in the provision of such services. We stated that in fulfilling its responsibilities under FPA sections 205 and 206, the Commission is required to address, and has the authority to remedy, undue discrimination and anticompetitive effects.¹⁴⁵ We also noted that the Commission has the authority and responsibility under section 203 of the FPA to review mergers and other transactions involving public utilities, including dispositions of jurisdictional facilities by public utilities, and that the Commission may grant an application under section 203 upon such terms and conditions as it finds necessary to secure the maintenance of adequate service and the coordination in the public interest of jurisdictional facilities.

Further, we noted that section 202(a) of the FPA authorizes and directs the Commission "to divide the country into regional districts for the voluntary interconnection and coordination of facilities for the generation, transmission, and sale of electric energy." The purpose of this division into regional districts is for "assuring an abundant supply of electric energy throughout the United States with the greatest possible economy and with regard to the proper utilization and conservation of natural resources." Section 202(a) states that it is "the duty of the Commission to promote and encourage such interconnection and coordination within each such district and between such districts."

We solicited comments on whether the Commission should generically mandate RTO participation by all public utilities to remedy undue discrimination under sections 205 and 206 of the FPA, whether market-based rates for generation services could continue to be justified for a public utility that does not participate in an RTO, whether a merger involving a public utility that is not a member of an RTO would be consistent with the public interest, whether non-participants that own transmission facilities should be allowed to use the non-pancaked transmission rates of the RTO participants in that region, whether transmission services provided by a transmitting utility need to be under RTO control to satisfy the discrimination standards of sections 211 and 212 of the FPA, and whether a public utility's lack of participation

¹⁴⁵FERC Stats. & Regs. ¶ 32.541 at 33.695.

would otherwise be in violation of the FPA.¹⁴⁶

Comments. The comments on the Commission's legal authority to mandate participation in RTOs span the spectrum from those asserting that we clearly have that authority to those asserting that we clearly do not, with others taking a less definitive position in between.

Supporting Commission's Authority to Mandate RTO Participation. Representative of those asserting that the Commission has the authority to mandate RTO participation are the joint comments filed by APPA, ELCON, TAPS, and TDU Systems ("APPA *et al.* (WP)"). These parties argue that the FPA as presently constituted gives the Commission "ample" legal authority to require participation by public utilities in properly structured and configured RTOs. APPA *et al.* assert that section 202(a) permits the Commission to determine rational and efficient regional boundaries; section 203 provides authority to require RTO participation as a standardized condition to mitigate the increased generation and transmission concentration brought about by mergers; "it would be fully consistent with, and indeed required by" FPA section 205 to insist on RTO participation as a condition necessary to yield competition robust enough to produce just and reasonable market-based rates; requiring RTO participation falls within the Commission's broad discretion to fashion a remedy for undue discrimination under FPA sections 205 and 206; and the Commission could reasonably conclude that it is no longer just and reasonable for transmission service to be planned, implemented, or priced on a less-than-regional basis. Other commenters echo some or all of these points in asserting that the Commission currently has sufficient legal authority to mandate RTO participation.¹⁴⁷

Some other commenters emphasize the authority contained in particular statutory sections. One commenter states that FPA section 202(a) is an express delegation of authority to the Commission to make policy, and the stated goal of that section of assuring an abundant supply of electric energy with the greatest possible economy provides ample authority to support the conclusion that transmission facilities should be operated by an RTO. This commenter states that it is well

established administrative law that there is great deference given to an agency charged with policymaking responsibility.¹⁴⁸ Another commenter, FMPA, argues that the Commission's interconnection authority under FPA sections 202(b) and 210 provides ample basis for mandating RTO participation. According to FMPA, the Commission could find that RTO participation is necessary to "make effective" an interconnection, pursuant to FPA section 210, that has been rendered ineffective by fragmented and anticompetitive practices of transmission owners. FMPA also asserts that the Commission could use this authority through a rulemaking without following the individual procedural requirements of section 212.¹⁴⁹

In addition to those commenters finding clear authority in the FPA for an RTO mandate, a number of commenters support the suggestion, as one commenter put it, that certain benefits and rights that are within the Commission's authority and discretion to grant or deny should be withheld from utilities unwilling to participate in an RTO.¹⁵⁰ PNGC states that the Commission should use "big sticks" to obtain RTO participation, and Michigan Commission says the Commission "should use every stick, carrot, orange-colored stick and tool it can." Some commenters assert specifically that the Commission has the authority, and should use its authority, to condition mergers under section 203 and condition market-based rate authority under section 205 of the FPA on RTO participation.¹⁵¹ Some commenters also favor limiting access to non-pancaked transmission rates of RTOs to those who participate in RTOs.¹⁵²

Even some commenters that generally oppose the idea of an RTO mandate acknowledge that market-based rate authority or mergers could, on a case-by-case basis, be conditioned on RTO participation. For example, Florida Power Corp. states that the Commission could find, "given certain factual circumstances," that the granting of market-based rate authority would not be appropriate "unless the entity agreed to commit its transmission facilities to

an RTO." United Illuminating states that whatever conditioning authority the Commission may have for market-based rates or mergers could not be used as a basis for a generic rulemaking.

NECPUC cites to other sections of the FPA that the Commission might rely upon to promote RTO establishment. It supports the use of the complaint process under section 206 of the FPA in specific cases. It also suggests the use of FPA section 207 proceedings, which can be initiated by state commissions, as a vehicle for requiring RTOs where the Commission finds interstate service inadequate or insufficient. NECPUC also urges the use of joint boards and cooperative procedures between the Commission and the states under FPA section 209 as a means of resolving RTO issues.

Opposing Commission's Authority to Mandate RTO Participation. At the other end of the debate on the Commission's legal authority with respect to RTOs are those that assert that the Commission's authority to mandate RTOs is non-existent or very limited.¹⁵³ A number of commenters emphasize that FPA section 202(a) is explicitly voluntary and therefore provides no support for the Commission's authority to mandate RTOs.¹⁵⁴ FP&L states that it is questionable whether the Commission could use FPA section 202(a) as a tool to promote competition, given that section 202(a) is for the "coordination and interconnection of facilities," and coordination is arguably inconsistent with competition.

Some argue that the exercise of FPA section 206 authority to remedy discrimination on a generic basis by requiring RTOs would have to be supported by more explicit findings of discrimination than are contained in the NOPR.¹⁵⁵ For example, Florida Power Corp. and United Illuminating contend that the Commission cannot use an industry-wide solution to remedy a problem that does not exist industry-wide,¹⁵⁶ and the record does not demonstrate an industry-wide problem. EEI and others argue that the Commission may only impose a remedy that is reasonable and appropriate in light of the specific discriminatory

¹⁴⁸ Professor Koch, *citing* Chevron U.S.A., Inc. v. Natural Resources Defense Council Inc., 467 U.S. 837 (1984).

¹⁴⁹ *Citing* American Paper Institute, Inc. v. American Elec. Power Serv. Corp., 461 U.S. 402, 419-20 (1983).

¹⁵⁰ Oneok.

¹⁵¹ E.g., Oneok, TAPS, APPA, PJM/NEPOOL Customers, Illinois Commission, Industrial Consumers, East Texas Cooperatives, FMPA, TDU Systems and PNGC.

¹⁵² E.g., TDU Systems, PNGC and PJM/NEPOOL Customers.

¹⁵³ E.g., Southern Company, Puget, Avista, CP&L, Duke, STDUG, FirstEnergy, NYPP, Indianapolis P&L, FP&L, Detroit Edison, Florida Power Corp., Florida Commission, Alabama Commission.

¹⁵⁴ E.g., EEI, United Illuminating, Southern Company, Central Maine, CP&L, Duke, NYPP, Florida Power Corp., Florida Commission.

¹⁵⁵ E.g., EEI, Central Maine, Southern Company, Duke, NYPP, Dalton Utilities, Indianapolis P&L, Florida Power Corp., Entergy.

¹⁵⁶ *Citing* Associated Gas Distributors v. FERC, 824 F.2d 961 (D.C. Cir. 1987), cert. denied, 485 U.S. 1006 (1988).

¹⁴⁶ *Id.* at 33,762.

¹⁴⁷ E.g., UAMPS, PJM/NEPOOL Customers, Illinois Commission, Michigan Commission, Cinergy, Industrial Consumers, First Rochdale, East Texas Cooperatives, FMPA.

findings made and the actual practices to be corrected, and the NOPR fails to demonstrate such a nexus. Southern Company notes that the Commission has not made any finding of discrimination and that the "perception" of discrimination is an insufficient basis on which to invoke FPA sections 205 and 206. CP&L asserts that section 206 may give the Commission some authority with respect to requiring RTOs, but only in individual cases after hearings and substantial evidence of discriminatory practices. Southern Company contends that the Commission's remedial authority under section 206 must be construed in light of the voluntary nature of section 202(a) and the Commission cannot do anything indirectly under section 206 that it cannot do directly under section 202(a). Central Maine asserts that discrimination findings would not apply against a "wires only" company such as itself, and similarly, Indianapolis P&L argues that it has no ability to discriminate in favor of its own wholesale generation and therefore could not be forced to join an RTO as a remedy for discrimination.

Some commenters question the Commission's authority to condition market-based rates or mergers on RTO participation. Central Maine argues that the Commission could not conclude on a generic basis that an RTO is needed in every market-based rate case, and that the Commission could not change its existing policy on market-based rates without substantial evidence and reasoned decisionmaking. CP&L states that the Commission cannot use FPA section 205 authority to grant market-based rates merely to advance preferred policies, and cannot use FPA section 203 to condition mergers absent specific findings in a particular case. Duke contends that the Commission has no authority to issue a rule that imposes sanctions for non-participation that would make non-participation practically or economically unfeasible. Similarly, NYPP states that mergers, market-based rates, and access to non-pancaked transmission rates are economic necessities, and using them as conditions would effectively require RTO participation. Indianapolis P&L asserts that it would be inequitable and unjustifiable to withhold market-based rate authority from a utility that has a good reason not to participate in an RTO, and further, that the Commission may not pressure a utility to engage in an activity that it may not require

through direct regulation.¹⁵⁷ Similarly, Puget states that if the Commission is not mandating RTOs, which is beyond its authority, then the rule must contain no penalties for non-participation.

Several commenters point to the recent court decision in *Northern States*¹⁵⁸ as limiting the Commission's authority with respect to RTOs.¹⁵⁹ These parties assert that *Northern States* stands for the proposition that the Commission may not directly or indirectly interfere with state regulation of retail service, and that the NOPR would result in traditional utility retail responsibilities being shifted to RTOs. Specifically, for example, Puget alleges that redispatch and planned maintenance are reliability functions that affect the utility's ability to serve native load and are subject to state law. Indianapolis P&L asserts that *Northern States* makes clear that the Commission may act only under authority given by Congress.

A variety of other legal arguments are made in opposition to any Commission efforts to mandate RTO participation. Southern Company contends that since there has been no finding that Order Nos. 888 and 889 have failed, there has been no reasonable explanation as to why the Commission should change that policy. CP&L argues that the Commission's authority to enforce FPA section 205 is in the enforcement provisions of FPA sections 314, 316, and 317. CP&L also states that it would be discriminatory to have higher pancaked rates for non-participants in RTOs while participants get the advantage of non-pancaked rates. Duke and Florida Power Corp. assert that requiring involuntary wheeling and imposing common carrier status is outside the Commission's authority,¹⁶⁰ and likewise, so is mandating RTOs. Florida Power Corp. contends that requiring RTO participation would force a utility to join an ISO or divest its transmission or generation assets, and the Commission cannot compel divestiture. Florida Power Corp. and Southern Company make the point that the Public Utility Holding Company Act granted the SEC, not the FERC, the authority to restructure the electric utility industry. Florida Power Corp. further argues that requiring RTO participation would be a "taking" of utility property for which just

compensation would be owed, and that the "taking" problem is exacerbated by utilities being liable for facilities no longer under their control. Florida Commission states that the Energy Policy Act of 1992 indicated that the Commission should proceed with transmission access issues case-by-case, not generically.

Other Comments On Legal Authority. DOE submitted comments strongly supporting the Commission's efforts to establish RTOs. DOE states that while the Commission has substantial authority to accomplish much of what needs to be done, Federal legislation clarifying Commission authority, especially with respect to non-jurisdictional utilities, would greatly facilitate RTO formation.

One commenter raised the issue of what authority the Commission would rely upon to require the filings in proposed section 35.34(c). This commenter wants the Commission to clarify that the filings would be required pursuant to the information gathering authority under FPA sections 304, 307, and 311, and not under authority of section 205, which the commenter asserts provides no such authority.¹⁶¹

There were only a few comments in response to the Commission's inquiry about sections 211 and 212 or other FPA standards. Florida Power Corp. submits that the Commission cannot rely on FPA sections 211 and 212 to mandate RTOs. Florida Power Corp. notes that in Order Nos. 888 and 888-A, the Commission recognized that it does not have the authority to order wheeling pursuant to FPA sections 211 and 212 except on a case-by-case basis after an evidentiary hearing resulting in specific findings. Florida Power Corp. argues that because the Commission is fashioning an industry-wide generic solution and not acting on a case-by-case basis, the Commission cannot rely on sections 211 and 212 in this proceeding.

NARUC also notes that Congress revised FPA sections 211 and 212 to provide FERC with authority to address requests for non-discriminatory transmission service on a case-by-case basis. NARUC argues that the goal of promoting regional flexibility is more readily served by case-by-case consideration. In this way, NARUC believes that the Commission can use FPA sections 211 and 212 to take a more tailored approach rather than "one-size-fits-all" regulations that ignore market development and local conditions.

Commission Conclusion. Much of the discussion in the comments on the Commission's legal authority with

¹⁵⁷ Citing *Altamont Gas Transmission Co., v. FERC*, 92 F.3d 1239, 1246 (D.C. Cir. 1996).

¹⁵⁸ See *Northern States*, *supra* note 89.

¹⁵⁹ E.g., Southern Company, Puget, Indianapolis P&L, FP&L, Florida Commission.

¹⁶⁰ Citing *Richmond Power & Light Co. v. FERC*, 574 F.2d 610 (D.C. Cir. 1978) and *Otter Tail Power Co. v. U.S.*, 410 U.S. 366 (1973).

¹⁶¹ Consumers Energy.

respect to RTOs focuses on whether the Commission has the statutory authority to mandate that transmission owners participate in an RTO. As discussed elsewhere in this Final Rule, we have decided not to mandate generically that all public utility transmission owners must join an RTO. We conclude that the Commission possesses both general and specific authorities to advance voluntary RTO formation. We also conclude that the Commission possesses the authority to order RTO participation on a case-by-case basis, if necessary, to remedy undue discrimination or anticompetitive effects where supported by the record.¹⁶² Of course, RTO participation is not the only remedy that the Commission might employ to address these problems.

FPA sections 205 and 206. As we stated in the NOPR, the Commission is granted the authority and responsibility by FPA sections 205 and 206, 16 U.S.C. 824d and 824e, to ensure that the rates, charges, classifications, and service of public utilities (and any rule, regulation, practice, or contract affecting any of these) are just and reasonable and not unduly discriminatory, and to remedy undue discrimination in the provision of such services. In fulfilling its responsibilities under FPA sections 205 and 206, the Commission is required to address, and has the authority to remedy, undue discrimination and anticompetitive effects. The Commission has a statutory mandate under these sections to ensure that transmission in interstate commerce and rates, contracts, and practices affecting transmission services, do not reflect an undue preference or advantage (or undue prejudice or disadvantage) and are just, reasonable, and not unduly discriminatory or preferential.¹⁶³ Additionally, as discussed in Order No. 888,¹⁶⁴ there is a substantial body of case law that holds that the Commission's regulatory authority under the FPA "clearly carries with it the responsibility to consider, in appropriate circumstances, the anticompetitive effects of regulated aspects of interstate utility operations pursuant to [FPA] sections 202 and 203,

and under like directives contained in sections 205, 206, and 207."¹⁶⁵

There are two principal contexts in which the authority of FPA sections 205 and 206 has been raised. One is the use of requiring participation in RTOs as a remedy for undue discrimination by public utilities. As discussed above, many commenters believe that the evidence of undue discrimination is sufficient to justify generically mandating RTO participation as a remedy, and many others argue that the record on undue discrimination is insufficient to impose a generic, industry-wide solution. We have concluded in our discussion elsewhere in this Rule that continuing opportunities for undue discrimination exist in the electric transmission industry. However, we have also concluded that a voluntary approach to eliminating such opportunities through RTO formation (including the filing requirements and Commission supported collaboration efforts identified herein) represents a measured and appropriate response to the significant undue discrimination and other competitive impediments identified in this record.

The other context in which our authority under FPA sections 205 and 206 is raised is whether permitting a public utility to charge market-based rates for wholesale electricity sales can continue to be justified if the seller or its affiliate owns or operates transmission assets that have not been placed under the control of an RTO. The Commission has a responsibility under FPA sections 205 and 206 to ensure that rates for wholesale power sales are just and reasonable, and has found that market-based rates can be just and reasonable where the seller has no market power. The Commission has determined that to show a lack of market power, the seller and its affiliates must not have, or must have adequately mitigated, market power in the generation and transmission of electric energy, and cannot erect other barriers to entry by potential competitors.¹⁶⁶ In the past, the Commission has found that an open

access transmission tariff mitigated transmission market power.¹⁶⁷

As discussed above, some commenters believe that the Commission should insist upon RTO participation as a condition necessary to yield competition robust enough to support market-based rates, while others argue that we cannot use market-based rate authority to advance preferred policies or as a penalty. We are not adopting in this Final Rule a generic policy that participation in an RTO is a necessary condition to a public utility receiving, or retaining, market-based rate authority, nor do we propose to use the denial of market-based rate authority as a penalty for not voluntarily complying with this Rule. However, we do have an obligation to ensure that rates for wholesale power sales are just and reasonable, and we adhere to our precedent that market-based rates can be just and reasonable only where transmission market power has been mitigated and there are no other barriers to entry.

FPA section 202(a) and PURPA section 205. Section 202(a) of the FPA, the authority for which has been delegated to the Commission by the Secretary of Energy,¹⁶⁸ authorizes and directs the Commission "to divide the country into regional districts for the voluntary interconnection and coordination of facilities for the generation, transmission, and sale of electric energy." The purpose of this division into regional districts is for "assuring an abundant supply of electric energy throughout the United States with the greatest possible economy and with regard to the proper utilization and conservation of natural resources." Section 202(a) of the FPA states that it is "the duty of the Commission to promote and encourage such interconnection and coordination within each such district and between such districts."

Some commenters assert that FPA section 202(a) gives us broad authority and discretion to promote RTOs to support an abundant supply of electric energy with the greatest possible economy, while others contend that the authority is limited by the "voluntary" nature of the provision. We need not decide the precise confines of section 202(a) authority here. Clearly, this section gives the Commission the authority, after consultation with state commissions, to establish boundaries for regional districts for the voluntary interconnection and coordination of

¹⁶² We need not decide in this case the extent of the Commission's authority to mandate generically RTO participation.

¹⁶³ Once such a finding is made, the Commission is required to remedy it. See, e.g., Southern California Edison Company, 40 FERC ¶ 61,371 at 62,151-52 (1987), order on reh'g, 50 FERC ¶ 61,275 at 61,873 (1990), modified sub nom., *Cities of Anaheim v. FERC*, 941 F.2d 1234 (D.C. Cir. 1991); *Delmarva Power and Light Company*, 24 FERC ¶ 61,199 at 61,466, order on reh'g, 24 FERC ¶ 61,380 (1983).

¹⁶⁴ Order No. 888, FERC Stats. & Regs. ¶ 31,036 at 31,669.

¹⁶⁵ *Gulf States Utilities Co. v. FPC*, 411 U.S. 747, 758-59, reh'g denied, 412 U.S. 944 (1973). See *City of Huntingtonburg v. FPC*, 498 F.2d 778, 783-84 (D.C. Cir. 1974) (Commission has a duty to consider the potential anticompetitive effects of a proposed Interconnection Agreement.)

¹⁶⁶ See, e.g., *Heartland Energy Services, Inc.*, 68 FERC ¶ 61,233 at 62,060 (1994); *Louisville Gas & Electric Company*, 62 FERC ¶ 61,016 at 61,143-44 (1993) (*Heartland*). See also *Louisiana Energy and Power Authority v. FERC*, 141 F.3d 364 (D.C. Cir. 1998) (court upholds Commission's use of market-based rate authority).

¹⁶⁷ See, e.g., *Heartland*, 68 FERC at 62,061, 62,063-64.

¹⁶⁸ 63 FR 53889 (Oct. 7, 1998).

facilities in order to assure an abundant supply of electric energy with the greatest possible economy. We have decided in this Rule that we will exercise this authority, at least in the first instance, by allowing transmission owners, in consultation with other interested parties and state commissions, to propose to us what they believe to be appropriate regional districts. In this regard, we conclude that the Commission, pursuant to FPA section 202(a), clearly has the authority to direct public utilities as well as non-public utilities¹⁶⁹ to consider the regional coordination that would result from joining an RTO and to participate in Commission-sanctioned RTO discussions.

As we are not in this Final Rule mandating any particular interconnection or coordination of facilities, we need not address whether the language in FPA section 202(a) referring to "voluntary" interconnection and coordination limits our authority. It is clearly the intent and requirement of this section that the Commission encourage and promote a regional approach, which is what we are doing in this Final Rule.

Section 205 of PURPA¹⁷⁰ also supports the Commission's authority to encourage and promote regional coordination. This section, which addresses power pooling, gives the Commission the authority to exempt electric utilities from state laws or regulations which prohibit or prevent voluntary coordination, and to recommend to electric utilities to enter voluntarily into negotiations for pooling arrangements where opportunities for conservation, efficiency, and increased reliability exist. The Commission has previously interpreted section 205 of PURPA as essentially complementing the functions under section 202(a).¹⁷¹

FPA Section 203. The Commission has the authority and responsibility under section 203 of the FPA to review

mergers and other transactions involving public utilities, including dispositions of jurisdictional facilities by public utilities. There are two aspects of this authority that relate to RTO formation. First, public utilities' transfers of control of jurisdictional transmission facilities to entities such as RTOs would require section 203 approval. Under section 203 of the FPA, the Commission must approve a proposed disposition of jurisdictional facilities if it is consistent with the public interest.

Second, the Commission may grant an application under section 203 upon such terms and conditions as it finds necessary to secure the maintenance of adequate service and the coordination in the public interest of jurisdictional facilities. FPA section 203(b) explicitly gives the Commission authority to condition a public utility's proposed disposition of jurisdictional assets "upon such terms and conditions as it finds necessary or appropriate to secure the maintenance of adequate service and the coordination in the public interest of facilities subject to the jurisdiction of the Commission." Thus, for instance, the Commission has used section 203 conditioning authority to require that all mergers be conditioned on the offer of comparable open access transmission.¹⁷² In the Commission's Merger Policy Statement, it was recognized that the development of fully competitive generation markets is in the public interest and that turning over control of transmission assets to an ISO might be an appropriate remedy for anticompetitive effects of a merger.¹⁷³

Some commenters urge the Commission to make RTO participation a standardized condition to all mergers in order to mitigate increased generation and transmission concentration, while others claim that RTO imposition as a section 203 condition would require specific findings in a particular case. We do not find as a generic matter in this proceeding that no merger could be consistent with the public interest in the absence of RTO participation. However, as noted in the Merger Policy Statement with respect to ISOs, turning control of transmission assets over to an RTO might be an appropriate remedy for the anticompetitive effects of a merger. In general, our processing of merger applications can be facilitated to the extent the merging parties have resolved

potential anticompetitive issues through means such as RTO participation.

Other Legal Issues. Commenters have suggested other statutory authorities that may be relevant to our efforts to encourage RTOs. These include FPA section 207, which upon state commission complaint authorizes the Commission to remedy inadequate or insufficient interstate service; FPA sections 202(b) and 210, which address the Commission's authority to order interconnections and make effective an interconnection; FPA section 209, which authorizes the Commission to refer matters to joint boards composed of Commission and state representatives; and FPA sections 211 and 212, which address the Commission's authority to require transmission services. We agree that, under appropriate circumstances, these authorities may indeed be relevant to RTO formation. However, we do not, and need not, rely upon them for what we are requiring in this Final Rule, so we will not address here what authority they might confer.

In response to those commenters who assert that the *Northern States*¹⁷⁴ court decision somehow limits our authority with respect to RTOs, we disagree. As reflected in our recently issued order on remand¹⁷⁵ of the *Northern States* court decision, that decision addresses narrow circumstances involving transmission curtailment where the third-party transmission customer has redispatch options. We do not interpret the decision as limiting our authority to encourage or require RTO participation. Moreover, we note that formation of RTOs is likely to eliminate or significantly reduce the potential for the type of conflict encountered in *Northern States*.

With respect to the commenter seeking clarification of the authorities we are relying upon to require the filings we are mandating in this Rule, we clarify that we are relying upon the authorities contained in FPA sections 202(a), 304, 307, and 309 for the filings we are requiring under new sections 35.34(c) and (g). To the extent a public utility proposes to participate in an RTO, we will process that application pursuant to FPA sections 203, 205 or other sections as appropriate.

D. Minimum Characteristics of an RTO

In the NOPR, we proposed minimum characteristics and functions for a transmission entity to qualify as an

¹⁶⁹ The legislative history, as well as the Commission's past use of section 202(a), indicates that the provision applies to both public utilities and non-public utilities. See S. Rep. No. 621, at 49 (1935) ("public as well as private plants are included"); Reliability and Adequacy of Electric Service, Order No. 383, 41 FPC 846,47 (1969) (information on coordination requested pursuant to section 202(a) from public and non-public utilities).

¹⁷⁰ 16 U.S.C. 824a-1.

¹⁷¹ In *Public Service Company of New Mexico*, 25 FERC ¶ 51,463 at 62,038 (1983), the Commission stated that, "Our mandate under PURPA to promote voluntary coordination is similar to that exercised by our predecessor, the Federal Power Commission, for more than 40 years under Section 202(a) of the Federal Power Act." *Accord* Pacific Gas and Electric Company, 38 FERC ¶ 61,242 at 61,791 (1987) (PURPA "reaffirms the Commission's authority to promote voluntary coordination of electric utilities").

¹⁷² *El Paso Electric Company and South West Services*, 68 FERC ¶ 61,181 at 61,914-15 (1994), *dismissed*, 72 FERC ¶ 61,292 (1995).

¹⁷³ Inquiry Concerning the Commission's Merger Policy Under The Federal Power Act, 61 FR 68595 (Dec. 30, 1996), FERC Stats. & Regs. ¶ 31,044 at 30,115, 30,121, 30,137 (1996).

¹⁷⁴ See *Northern States*, *supra* note 89.

¹⁷⁵ *Northern States Power Co. (Minnesota) and Northern States Power Co. (Wisconsin)*, 89 FERC ¶ 61,178 (1999).

RTO. These characteristics and functions are designed to ensure that any RTO will be independent and able to provide reliable, non-discriminatory and efficiently priced transmission service to support competitive regional bulk power markets. In the section that follows, we discuss the four minimum characteristics for an RTO, which are:

- (1) Independence from market participants;
- (2) Appropriate scope and regional configuration;
- (3) Possession of operational authority for all transmission facilities under the RTO's control; and
- (4) Exclusive authority to maintain short-term reliability.

In our discussion below, we clarify and revise to some extent our discussion in the NOPR, but we affirm these as the minimum characteristics of an RTO.

1. Independence (Characteristic 1)

As a first required characteristic, the Commission stated that all RTOs must be independent of market participants. To achieve independence, we proposed that RTOs must satisfy three conditions. First, the RTO, its employees, and any non-stakeholder directors must not have any financial interests in any market participants.¹⁷⁶ Second, the RTO must have a decision-making process that is independent of control by any market participant or class of participants.¹⁷⁷ The NOPR defined market participant as any entity or its affiliate that buys or sells electric energy in the RTO's region or in any neighboring region that might be affected by the RTO's actions. We said that this second condition would be judged on a case-by-case basis. However, the Commission also proposed, by way of example, that an RTO could satisfy this second condition with (a) a non-stakeholder governing board and (b) a prohibition on market participants having more than a *de minimis* (one percent) ownership interest in the RTO. Third, the RTO must have exclusive and independent authority to file changes to its transmission tariff with the Commission under section 205 of the FPA.¹⁷⁸

Comments. A large number of commenters address different facets of the independence characteristic. To make the summary of comments more manageable, we grouped the comments by key sub-issues: the basic principle; who is a market participant; RTO economic interests in market participants and energy markets; voting interests of one market participant and

affiliates; voting interests of classes of market participants; passive ownership interests; RTO governing boards; role of state agencies; and section 205 filing rights.

The Basic Independence Principle. In the NOPR, the Commission reiterated its earlier statement that "the principle of independence is the bedrock upon which the ISO must be built" and that this standard should apply to all RTOs, whether they are ISOs, transcos or variants of the two.¹⁷⁹ Virtually all commenters agree with this principle. For example, EEI states that "[a] decisionmaking process independent of the control of any market participant or class of market participants should be an important aspect of the independence principle."¹⁸⁰ The TDU Systems say that "[f]ull independence is vitally important to the success of RTOs * * * and cannot be safely compromised."¹⁸¹ The Nine Commissions urge that RTOs must be "truly independent of market participants in word, deed and appearance."¹⁸² Despite the almost unanimous acceptance of the principle, there are fundamental disagreements (discussed in later sections) among commenters as to how the principle should be implemented, especially for RTOs that would operate as stand alone, for-profit transcos.

Some commenters question whether complete independence comes at too high a cost. For example, FP&L recommends that the Commission "not consider independence in a vacuum." It contends that "it would make little sense to trade off the greatest degree of independence for the highest cost structure."¹⁸³ Salomon Smith Barney makes a similar point. It contends that strict application of the independence standard could thwart the development of for-profit RTOs. Therefore, it urges the Commission "not to promulgate rules that maintain absolute purity but also throttle the * * * voluntary formation of RTOs."¹⁸⁴ Konoglie/Ford/Fleishman, three individuals from the financial community, express concern that independence will usually be interpreted to mean a separation between ownership and control as currently practiced in ISOs. They argue that, if the ISO model becomes the norm, it could lead to higher capital costs because those who own the transmission assets would not be able to

make basic investment and operating decisions. They point out that ownership usually imparts control in most U.S. industries and that transmission operating and investment efficiencies are unlikely to be achieved unless this becomes the norm in a restructured U.S. electricity industry.

PJM and WEPCO contend that a for-profit transmission company can never be independent because it will always be biased in its operating and investment decisions. Specifically, they assert that a for-profit transco will always be biased toward transmission solutions over other solutions (such as generation redispatch) and its own transmission assets over transmission assets owned by others. WEPCO, therefore, concludes that independence can be achieved only if there is an ISO operating over a for-profit transmission company.¹⁸⁵

Other commenters argue that it would be naive to believe that independence, by itself, will lead to an effective RTO. They argue that an RTO may be completely independent but it must also have sufficient operational and decisionmaking authority if it is to be effective. For example, the TDU Systems assert that independence will not be sufficient if transmission owners attempt to reserve certain decisions for themselves. It points to the transco proposals of the Entergy and the Alliance Companies as examples of a proposed RTO having insufficient decisionmaking authority. NECPUC, representing six New England commissions, argues that an RTO must have independent funding and urges the Commission to include this as an explicit requirement in the final rule. NCPA states that an RTO will not be truly independent unless it is able to make and implement independent procurement decisions.

Who Is a Market Participant? There is substantial disagreement among commenters about the proposed definition of market participant. Some commenters argue that it should be expanded; others contend that it should be narrowed. In the first group, Illinois Commission urges us to expand the definition of a stakeholder because "[a] market interest can arise through functions and activities other than just buying or selling electricity."¹⁸⁶ Enron/APX/Coral Power echo this point and contend that an RTO should "not be subject to control by, and has no interest in the success of any vendor or buyer in the competitive functions of the

¹⁷⁹ *Id.* at 33,726.

¹⁸⁰ EEI at 25.

¹⁸¹ TDU Systems at 41.

¹⁸² Nine Commissions at 8.

¹⁸³ FP&L at 32.

¹⁸⁴ Salomon Smith Barney at 5.

¹⁸⁵ WEPCO at 9.

¹⁸⁶ Illinois Commission at 29.

¹⁷⁶ FERC Stats. & Regs. ¶ 32,541 at 33,726.

¹⁷⁷ *Id.* at 33,727.

¹⁷⁸ *Id.* at 33,729.

industry."¹⁸⁷ Duke recommends expanding the definition to include "any distribution company or neighboring transmission company and/or any buyer or seller of ancillary services."¹⁸⁸ PJM urges that the definition of a market participant include any entity that owns transmission facilities or provides or buys transmission service.¹⁸⁹

TAPS, representing an informal group of transmission dependent utilities in 24 states, also urges us to adopt a broad definition of market participant to ensure RTO neutrality. It argues that millions of dollars of investments and operating costs will be affected by RTO decisions. It gives several examples of how RTO decisions can have major economic impacts. As a transmission planner, an RTO will have substantial responsibility for routing new transmission lines. Depending on its decisions, it can help or hurt one gas pipeline or another or one generator or another. As a transmission tariff administrator, it will have significant discretion in choosing how to price congestion. Any decision that it makes (e.g., zonal versus nodal pricing) could have significant impacts on the profitability of particular generators. As the supplier of last resort for ancillary services, it will have considerable discretion in defining the types and quantities of ancillary services that are needed. Depending on its decisions, some generators "will win, and others will lose."¹⁹⁰ Finally, as the "transmission-request gatekeeper," it will have substantial influence on who gets service and on what terms. To ensure both the appearance and reality of neutrality in these various decisions, TAPS urges us to adopt a broad definition of market participant.

In contrast, others contend that the proposed definition is too broad. CP&L states that a literal application of the proposed definition "would make every single residential, commercial, industrial and wholesale electric customer (and all of their affiliates) market participants."¹⁹¹ It recommends that the definition be narrowed by changing it to "those entities that are active in wholesale and non-regulated retail power markets using transmission

of the RTO."¹⁹² LPPC asks that the Commission define the term "affiliate" because it is not defined anywhere in the NOPR. It also suggests that the definition of affiliate be limited to "common control" rather than using the five-percent ownership interest standard of PUHCA.¹⁹³

A number of commenters focus specifically on the question of whether a "distribution only" entity (i.e., an entity that performs the sole function of transporting electricity at distribution voltages) should be considered a market participant. Montana Power urges us against expanding the definition to include an entity that operates "distribution-only facilities." It argues that an RTO and a distribution entity are both "delivery entities" and efficiencies can be gained by having one entity provide "total delivery service" from high to low voltages. These efficiencies of vertical integration could include the savings that would result from having maintenance performed on both transmission and distribution facilities by the same crews, the sharing of shop and warehouse space and the sharing of various administrative support functions. Sierra Pacific generally supports this view and asserts that it does not believe that a "transmission owner could so operate its facilities to materially assist affiliated transmission and distribution interests to the disadvantage of unaffiliated entities."¹⁹⁴

Salomon Smith Barney takes a more cautious view. It states that an RTO owned by distribution entities "could manipulate the grid to favor their customers over the customers of other distributors."¹⁹⁵ Trans-Elect argues that the Commission's recent attempt to impose non-discriminatory curtailment procedures on all users of the grid in the NSP service territory demonstrates that this problem already exists.¹⁹⁶ Arguing that it would be undesirable to lose distribution entities as potential investors in RTOs, Salomon Smith Barney recommends that the Commission require RTOs to follow market-based priority rules in curtailment situations to reduce the likelihood that an RTO would favor affiliated distribution entities.

Both Sierra Pacific and NEPCO *et al.* raise concerns about the interaction of the market participant definition and "state-mandated backstop power supply

obligations." NEPCO *et al.* asserts that all 23 states that have opted for retail competition to date have usually imposed a default supplier obligation (which also is referred to as a "standard offer supplier" or a "provider of last resort" obligation) on one party which is usually the incumbent provider. Sierra Pacific notes that the nature and duration of this mandated obligation varies from state-to-state "but at least some of the programs are structured so that the POLR [provider of last resort] does not compete for new customers and has no incentive to retain existing POLR customers."¹⁹⁷ Both commenters argue that providers of last resort should not automatically be considered as market participants, even though they buy and sell electricity, because this would reduce the pool of potential transco investors. Sierra Pacific states that the Commission should "leave the door open to consider the POLR issue on a case-by-case basis" and that the final regulations should explicitly say that a provider of last resort would not be deemed a market participant if its state mandated obligation gives it no incentive to make such sales.¹⁹⁸

Finally, NEPCO *et al.* raises the issue of incumbent utilities that have tried to divest themselves of their generating assets but have not yet succeeded. It points to its difficulties in divesting its minority ownership interests in nuclear plants. It requests that an entity not be automatically deemed a market participant because of these minority ownership interests especially if it has taken actions to eliminate its control over the retained ownership interest (e.g., through a long-term contract that would give marketing rights to a non-affiliated entity).

RTO Economic Interests in Market Participants and Energy Markets. Many commenters, representing a wide range of industry constituencies, agree with the NOPR's proposal that the RTO, its employees and any non-stakeholder directors must not have any financial interests in electricity market participants.¹⁹⁹ Duke recommends that, where divestment is required, the Commission should continue its past practice of allowing employees to divest personal investments in a manner that

¹⁸⁷ Enron/APX/Coral Power at 8.

¹⁸⁸ See Duke Power at 27. See also Midwest Municipals, Avista and American Forest.

¹⁸⁹ United Illuminating disagrees. It asserts that "transmission owners without power marketing interests" should not be considered as market participants. United Illuminating at 37.

¹⁹⁰ TAPS at 63.

¹⁹¹ CP&L at 23-24. American Forest believes that "the Commission did not intend such a broad exclusion, and seeks clarification on this point." American Forest at 4.

¹⁹² CP&L at 23-24.

¹⁹³ LPPC points out that the term "affiliate" is used in defining market participant but is not defined anywhere in the proposed rule.

¹⁹⁴ Sierra Pacific at 17.

¹⁹⁵ Salomon Smith Barney at 5.

¹⁹⁶ Trans-Elect at 5 citing Northern States Power Co. v. FERC, 176 F.3d 1090 (8th Cir. 1999).

¹⁹⁷ Sierra Pacific at 16.

¹⁹⁸ *Id.*

¹⁹⁹ One exception is Salomon Smith Barney. It argues that this requirement is "altogether unreasonable, in that it could require the most qualified directors and employees to dispose of mutual funds, pension plans and old investments whose tax base makes disposition unreasonable." Salomon Smith Barney at 3.

does not cause them significant financial harm.

Most commenters agree that the focus should be on current financial interests.²⁰⁰ Several commenters point out that it would be virtually impossible for an RTO to hire knowledgeable and experienced employees if the Commission were to require no past financial connections to market participants. They assert that some of the most knowledgeable candidates for RTO positions, at least in an RTO's early years of operation, are likely to be individuals who have retired from companies that are market participants and it is likely that these individuals will be receiving pensions from their former employers. In situations like this, NASUCA urges the Commission to "exclude from this prohibition * * * employee pension plans and other post-employment benefits received while a former employee of a market participant."²⁰¹ Others urge that the Commission follow the precedent that was established in the Midwest ISO decision.²⁰² Individuals would not be automatically excluded from RTO employment or directorships if their pension does not directly depend on the economic performance of their former employers (e.g., a defined benefit pension plan). TDU Systems suggests that reasonable exceptions should be made "in the case of defined benefit pension plans, general mutual funds (as opposed to utility/energy sector funds) that hold stock or bonds of market participants, or other similar financial holdings where the holder cannot direct specific investments or benefit directly from stock performance."²⁰³

In the NOPR, we asked whether there was a need to "define the financial independence requirement in more specific terms."²⁰⁴ The answer from almost all respondents was "no." For example, TDU Systems recommend that we issue a general rule with a set of guidelines and then allow for its application on a case-by-case basis. Avista agrees and states that any financial independence standard "require[s] case-by-case consideration as well as the common sense application of the rule of reason."²⁰⁵ PJM/NEPOOL Customers states that RTOs will have

the benefit of the conflict of interest standards that have been drafted for each of the functioning ISOs. They also recommend that the Commission commence a separate rulemaking on this issue.

Some commenters contend that the NOPR's treatment of financial independence is too narrowly drawn. For example, Dynegy argues that while ISOs "may ostensibly be independent of market participants—they are not independent of the market itself."²⁰⁶ As evidence of this phenomenon, it points to instances when the California ISO has tried to impose price caps on energy prices. EPSA expresses a similar view and points to the price caps proposed by ISO New England and approved by this Commission during the June 1999 heat wave, when energy prices reached \$1,600 a megawatt-hour, as another example of undesirable and inappropriate intervention by a transmission provider in energy markets. In crafting a definition of independence, EPSA urges the Commission to require that RTOs "should be indifferent to the price at which the commodity they transport clears the market."²⁰⁷

Others argue that this conflict is unavoidable as long as the Commission imposes a requirement that RTOs be the supplier of last resort for certain ancillary services.²⁰⁸ According to these commenters, this obligation will often require that the RTO be a buyer in certain ancillary service markets. If the supplier of last resort obligation is also combined with a requirement that the RTO buy efficiently, then it is inevitable that the RTO will be interested in whether the prices are high or low (i.e., it is no longer simply a disinterested market operator).

Active (Voting) Ownership Interests in the RTO. a. By Individual Market Participants and Their Affiliates. A number of commenters oppose a one-percent cap on allowed voting interests of market participants in RTOs as a necessary requirement for achieving independence.²⁰⁹ EEI states that such a cap is not "necessary, rational or supportable" for achieving the goal of independence.²¹⁰ It recommends that the Commission allow market

participants or their affiliates to own up to ten-percent voting interests in RTOs. EEI also asks for a clarification of whether an ownership restriction would "apply only to ownership in the RTO itself or does it also apply to ownership interests in the transmission facilities under the operational control of the RTO."²¹¹ PJM, which is organized as a non-profit limited liability corporation (LLC), asks the Commission to clarify whether its "members" would be considered owners.

CTA also argues for a higher cap. It states that the NOPR's emphasis on ownership is misplaced. Instead, the Commission should be concerned with the "actual control over the day-to-day affairs of the system, not some arbitrary percent ownership test."²¹² The Alliance Companies express the concern that, even though the one percent cap appears to have been proposed as a "safe harbor," it could quickly become "the only port of entry to Commission approval."²¹³

EEI observes that other government agencies allow five or ten percent ownership in voting shares before assuming that these ownership interests conveyed control.²¹⁴ For example, it notes that the SEC definition of an "affiliate" under PUHCA is limited to entities that own or control more than five percent of the voting stock of a public utility. It also observes that this Commission, in determining whether a company is an affiliate of a natural gas pipeline or an electric utility, applies a rebuttable presumption of control only when a utility owns ten percent or more of a company's voting stock. Entergy states that "there do not appear to be instances under U.S. law where one-percent ownership is considered to give rise to a risk of control."²¹⁵

Several commenters question why there should be any limits on the amount of voting shares that can be held by a market participant. For example, Allegheny asserts that "[t]he desire to maintain or obtain ownership of transmission assets by market participants should not be regarded as an evil to be avoided at all costs."²¹⁶ FP&L states that there is no need to

²⁰⁰ With respect to future financial interests, Salomon Smith Barney states that "[p]rivate enterprises do not normally, control the lives of their ex-employees." Salomon Smith Barney at 3.

²⁰¹ NASUCA at 17.

²⁰² See Midwest Independent System Operator, 85 FERC ¶ 61,250 (1998). See also Southern Company, Duke, TDU Systems and Avista.

²⁰³ TDU Systems at 39.

²⁰⁴ FERC Stats. & Regs. ¶ 32,541 at 33,727.

²⁰⁵ Avista at 11.

²⁰⁶ Dynegy at 35.

²⁰⁷ EPSA Reply Comments at 12.

²⁰⁸ See NEMA at 19. See also EPSA Reply Comments.

²⁰⁹ See, e.g., EEI, Duke, CP&L and PacifiCorp.

²¹⁰ EEI notes that the NOPR mentions the one percent cap on voting interests by market participants in the National Grid Company in England and Wales but observes that there was no obvious justification given at the time the decision was made.

²¹¹ EEI at 26.

²¹² CTA at 4.

²¹³ Alliance Companies at 18.

²¹⁴ Most investor-owned utilities agree with EEI. An exception is Cinergy which urges the Commission to incorporate the one-percent ownership standard in the final regulations "exactly as proposed" because such a prohibition "is vital to preserving a RTO's financial independence characteristic." Cinergy at 17.

²¹⁵ Entergy at 28.

²¹⁶ Allegheny Reply Comments at 10.

prohibit affiliated transcos.²¹⁷ It argues that the Commission should allow 100-percent ownership of voting equity and ensure non-discriminatory transmission access through codes of conduct and state commission oversight, in the case of a single state RTO. It observes that "in the natural gas industry there are numerous transcos (pipelines) that are affiliated with gas producers, marketers and/or distribution companies and there is no basis to conclude that this structure would be less likely to succeed in the electric power industry."²¹⁸

Other commenters disagree and urge the Commission to adopt even stricter standards on ownership than those presented in the NOPR.²¹⁹ For example, APPA recommends that the final rule prohibit any ownership interests in RTOs by market participants.²²⁰ APPA states that even a one-percent ownership would represent an unjustifiable and unnecessary exception to the independence standard. South Carolina Authority agrees with APPA and argues that the NOPR failed to present a "public policy benefit" for allowing even a *de minimis* ownership interest.²²¹ NASUCA also shares this view. In addition, it asserts that as soon as the Commission allows any ownership by market participants it will be forced to continually track the share of each market participant, including affiliates. NASUCA argues that this would be "time-consuming, difficult and expensive" and would represent the very antithesis of the independent, lightly regulated structure that the Commission wished to foster.

TDU Systems concurs and observes that any ownership by market participants will trigger the "chasing after conduct" regulation that the Commission said it hoped to avoid.²²²

In addition, TDU Systems criticizes EEI's ten percent proposal. TDU Systems asserts that EEI fails to

understand the rationale for the "safe harbor" proposal in the NOPR. TDU Systems argues that the regulatory purpose of a "safe harbor" is to ensure that "no case-by-case review of the regulatory agency is required."²²³ Therefore, TDU Systems contends that it would be inappropriate to adopt EEI's proposed ten percent because this percentage is not in the "safe harbor" but, as recognized by other regulatory agencies, raises a clear risk of control. Consumer Groups supports this view and points to one case in which a court decided that a three-percent ownership interest of a company's common stock was found to be "sufficient to assert control over the corporation because the ownership of the other common shares was widely dispersed."²²⁴

The Alliance Companies, who support a ceiling of five percent ownership in voting interests by market participants, state that they "are aware of no practical means of tracking who has an ownership interest at a threshold of less than five percent" because SEC regulations require reporting of ownership in publicly traded companies only at five-percent ownership and above. In contrast, Cinergy asserts that enforcing a lower ownership limit should not be a problem. It states that the Commission could keep track of ownership interests "through transmission owners" representations and subsequent audits if the need arises."²²⁵

APPA, which argues for absolute and total prohibition on voting ownership by market participants, asserts that even with access to SEC data it will be difficult for the Commission to keep track of who really owns voting shares since they are often registered in "street" names. Therefore, it urges the Commission to impose a total prohibition on ownership by market participants. South Carolina Authority agrees and further argues that anything less would fail to achieve the Commission's characterization of an RTO as entity in which "the control of transmission operation is *cleanly separated* from power market participants."²²⁶ It concludes that "[t]here is nothing 'clean' about permitting incumbent transmission owners to indefinitely maintain an ownership interest, voting or otherwise, in the newly created RTO."²²⁷

EPSA suggests a compromise that would allow greater flexibility with respect to initial ownership interests. It proposes that the Commission establish time limits on voting ownership. TDU Systems makes a similar recommendation with respect to passive ownership. While TDU Systems states that it would prefer an absolute prohibition on market participants owning voting shares, it suggests that the Commission might consider allowing transmission owners to "hold passive, non-voting ownership interests in excess of one percent as an extraordinary transition measure."²²⁸ However, TDU Systems recommends that such interests be reduced to one percent or below in a "relatively short period of time."

b. By Classes of Market Participants. SRP asserts that the NOPR is flawed because it is not sufficient to place a limitation on the ownership interests that can be held by a single participant and its affiliates while ignoring the possibility that other owners may have similar interests. SRP urges the Commission to recognize that "[a]n interest that may be considered *de minimis*, when viewed in isolation, could still result in effective control when aggregated for a group with common interests."²²⁹ Therefore, it recommends that limits be placed not only on the ownership interests of an individual market participant but also on the ownership interests by other market participants with similar economic interests. SRP does not recommend a specific percentage for a group cap, but Industrial Consumers urge the Commission to cap the voting interests of any group at five percent.

FP&L contends that there is no need for ownership caps for a group of market participants because they will often have conflicting economic interests. It gives the example of a group of transmission owners with ownership interests in an RTO who also own affiliated power marketers. FP&L argues these marketing affiliates will compete against each other and this rivalry will mitigate the potential for collusion among the parent companies that jointly own the RTO. Alliance Companies agree with this view. They assert that "[i]n today's competitive power markets, all market participants, including those traditionally classified within the same

²¹⁷ In contrast, APPA states that affiliated transcos should be allowed "only where such private companies operate under the direct, ongoing supervision of a strong, fully functional regional Independent System Operator." APPA at 28.

²¹⁸ FP&L at 26.

²¹⁹ See, e.g., Midwest Municipals, APPA, TDU Systems and Industrial Consumers.

²²⁰ APPA clarifies that it does not oppose market participants owning "for-profit" transcos if the transcos come under the supervision of strong fully functional ISOs. Industrial Consumers recommend that a one-percent cap should be adopted in the final rule as a general requirement rather than as a possible safe harbor. In addition, it recommends that the cap be calculated on a corporate-wide basis to avoid the situation of multiple affiliates each with a one-percent interest. See Industrial Consumers at 30.

²²¹ See South Carolina Authority at 18.

²²² TDU Systems at 41 citing FERC Stats. and Regs. ¶ 32,541 at 31,145.

²²³ TDU Systems Reply Comments at 14 (italicized in the original).

²²⁴ Consumer Groups Reply Comments at 8.

²²⁵ Cinergy at 18.

²²⁶ South Carolina Authority at 8 (quoting from FERC Stats. & Regs. ¶ 32,541 at 33,718 (emphasis added by the quoter)).

²²⁷ South Carolina Authority at 14.

²²⁸ TDU Systems at 42.

²²⁹ Salt River at 11. United Illuminating agrees and states that if the Commission "were to adopt a higher *de minimis* standard, such as five or ten percent ownership interest, it would be relatively easy for five or six market participants owning such percentages to control the operations of an RTO." United Illuminating at 39-40.

stakeholder group are likely to be competitors" and, therefore, that it is unlikely that there will be a "nexus of interest."²³⁰

EI argues that ownership caps on groups of market participants would be "impractical and extremely burdensome on Commission resources" because the Commission would have to keep track of ownership levels by every market participant and also align market participants into specific groups with "alleged common interests."²³¹ In addition, it contends that this task would be difficult to do because markets are evolving and the business objectives of individual firms will change as they buy or sell assets. Moreover, while accepting that "some market participants may have common interests at certain times" EEI believes that such "coalitions" would be "fragile, short-lived and unlikely to result in a serious threat to the independence of the RTO."²³²

A number of commenters assert that a cap on voting interests will thwart capital formation in new and existing transmission facilities. For example, UtiliCorp contends that such a cap "may potentially choke off significant sources of capital" for the formation of for-profit transcos.²³³ Various commenters from the financial community argue that such a cap would make it difficult to create RTOs that function as for-profit transcos. Salomon Smith Barney states that current owners of transmission assets need to retain a larger ownership interest, at least for a transition period, in order to avoid heavy capital gains taxes. It estimates that many current transmission owners would have to pay capital gains taxes on about 35 to 50 percent of the current book value of their transmission assets if they were to sell these assets.

Alliance Companies asserts that restrictions on ownership would reduce the potential pool of investors (*i.e.*, buyers of transmission assets) and therefore reduce the price that current owners could receive for their assets. They contend that this would be especially damaging because it would place limits on ownership by "those entities that are most likely to understand the potential value of the business model."²³⁴ Alliance Companies states that the Commission should allow five-percent individual ownership interests by industry participants because this will provide

confidence to other, non-energy industry investors that the transco will be a financial success.²³⁵ In general, the Alliance Companies and other commenters that share this view take the position that a one-percent cap for market participants will be a major impediment to the creation of for-profit transcos and that the *de facto* effect of such a cap will be to limit the industry to the ISO model.

Passive (Non-Voting) Ownership Interests in the RTO. A number of privately-owned utilities stress that the final rule must distinguish between passive and voting interests in RTOs.²³⁶ For example, while EEI is willing to accept a ten-percent cap on ownership of voting interests by individual market participants, it states that "[t]here should be no limit on the amount of passive ownership interest" because "[p]assive owners who lack voting rights have no ability to control the firm."²³⁷ Enron/APX/Coral Power also support this position. They urge the Commission to "explicitly and unambiguously allow incumbent utilities and other power industry participants to possess passive but not controlling ownership interests in an RTO."²³⁸ Southern Company states that "[p]assive ownership of transmission facilities—even up to 100 percent—should not be a concern."²³⁹ United-Illuminating, while recommending that the Commission allow passive ownership, recommends that we should not issue generic rules because passive ownership is a "complex matter that must be reviewed on a case-by-case basis."²⁴⁰

EEI contends that some of the opposition to passive ownership by market participants may simply reflect a misunderstanding of the fiduciary responsibilities that the board of a for-profit transco has to its passive owners. EEI asserts that, under Delaware law and various model statutes, the fiduciary responsibilities of a for-profit transco board, its managers and owners that hold voting rights to a passive owner are limited to maximizing the value of the transmission assets and "not the value of any other assets that

may be held by the passive owner."²⁴¹ According to EEI, a transco board has no fiduciary obligation to take actions to produce economic benefits for other assets such as generating units that happen to be owned by its passive owners. Entergy states that if there are any lingering doubts about the fiduciary obligation of the board and its voting members, a provision could be inserted in the "transco's limited liability agreement that specifically directed that managers would have no fiduciary duty to consider the private interests of members" and that such a provision would be enforceable under Delaware law.²⁴²

Consumer Groups, however, questions the legal feasibility of this approach. It cites to several law review articles which it argues raise doubts as to whether fiduciary duties assigned by a state law to the directors of a subsidiary corporation can be removed by private agreement. It also cautions the Commission not to get lost in "a lawyer's duel over conflicting citations about the treatment of passive and affiliated ownership interests" when the fundamental issue is the need to safeguard independence and "avoid any appearance of partiality."²⁴³

EEI points to our recent decision in *Entergy Services, Inc.*, as demonstrating that the Commission recognizes that passive ownership is not inconsistent with the independence principle under the ISO principles of Order No. 888.²⁴⁴ It asks that the Commission reach the same policy conclusion for any similar independence requirement in the final RTO rule. In contrast, the South Carolina Authority observes that while the Entergy decision could be read to imply that the Commission has "prejudged this issue," the Commission should now use the opportunity of this NOPR to take another look at the issue.²⁴⁵

EEI also points to actions or policies taken by other federal regulatory agencies that it argues support its contention that passive ownership does not necessarily convey control. It observes that the definitions of "holding company," "affiliate" and "subsidiary company" in PUHCA are all tied to ownership of voting rather than non-voting shares. Similarly, EEI states that the FCC "attribution rules" used to determine when broadcasters and cable companies own or control another

²³⁰ Alliance Companies at 21–22.

²³¹ EEI Reply Comments at 21.

²³² *Id.*

²³³ UtiliCorp at 7.

²³⁴ Alliance Companies at 19.

²³⁵ In contrast, APPA asserts that "if the underlying business model is sound, investors will come." APPA at 36.

²³⁶ See, e.g., EEI, Enron/APX/Coral Power and UtiliCorp.

²³⁷ EEI at 26. EEI relies on a legal memorandum that concludes that passive ownership interests are "necessarily permissible, no matter how large and no matter what other interests they are combined with." EEI Appendix H at 17.

²³⁸ Enron/APX/Coral Power at 14.

²³⁹ Southern Company at 42.

²⁴⁰ United Illuminating at 7.

²⁴¹ EEI at 26.

²⁴² Entergy at 29.

²⁴³ Consumer Groups Reply Comments at 9.

²⁴⁴ EEI at 26 citing *Entergy Services, Inc.*, 88 FERC ¶ 61,149 (1999).

²⁴⁵ South Carolina Authority at 22.

broadcaster or cable company are keyed to voting rather than passive ownership interests. According to EEI, these policies demonstrate that other federal regulatory agencies do not believe that passive ownership conveys control and that the Commission should adopt a similar policy.

EEI also contends that the Commission has already allowed a "passive economic interest" in all of the ISOs that have been approved to date. Sierra Pacific makes a similar argument. Sierra Pacific contends that "profits" made by an ISO go back to the transmission owners even though they may have relinquished operational and decisionmaking control. It argues that "this arrangement [in ISOs] is the essence of a passive ownership interest."²⁴⁶ The principal difference is that "the passive ownership interest in a Transco involves ownership in the transco itself rather than the assets operated by the Transco."²⁴⁷ However, it argues that in substance both types of interests are the same since they allow the owner to share in the profits derived from operating their transmission facilities without having any influence over that operation. Sierra Pacific concludes by urging the Commission to allow passive ownership in both types of institutions to avoid creating "an artificial incentive in favor of ISOs instead of Transcos."²⁴⁸

Enron/APX/Coral Power point to the example of National Grid Company (NGC) in England and Wales as a real world example of passive ownership of a for-profit transco by market participants. For several years after privatization in 1990, the regional electricity companies (RECs) were allowed to own NGC but were "expressly barred from participating in day-to-day management or interfering with the ability of NGC to fulfill the purpose of privatization."²⁴⁹ However, in reply comments TDU Systems contends that Enron/APX/Coral Power fails to mention that this passive ownership arrangement was terminated after several years. Citing to a recent interview with Callum McCarthy, Great Britain's Director of Gas and Electricity Supply, TDU Systems points out that the RECs were "told to divest these interests, and did so."²⁵⁰

In contrast, TDU Systems and others ask the Commission not to allow passive

ownership in the final rule.²⁵¹ TDU Systems say that "the line between passive and active ownership is often not a bright line."²⁵² As an example, it states that in the recent Alliance transco filing, the divesting transmission owners "hold supposedly passive ownership interests in the Transco, but retain the right to pass on a number of different business transactions."²⁵³ TDU Systems assert that if the Commission opens the door to ownership of RTOs by market participants, it will be forced to engage in substantial "conduct policing." Salomon Smith Barney concurs and states that passive ownership "will prove troublesome for both the utilities and FERC" because it creates a "need to constantly police supposedly passive ownership positions to make sure that they remain passive in all respects."²⁵⁴

South Carolina Authority echoes this point. It argues that by allowing passive ownership the Commission would be put in the difficult job of determining "how 'passive' a particular 'passive interest' really is."²⁵⁵ It urges the Commission not to compromise its "bedrock position on independence" because it will lead to "an endless series of extensive battles over ownership structure, corporate bylaws and rules, layered on top of continuing allegations of discrimination in the marketplace."²⁵⁶ It asks "why * * * risk compromising the independence principle?"²⁵⁷

Just as several commenters raise capital formation arguments in support of the need to allow some voting interests by market participants, many of these commenters also raise similar arguments in support of allowing passive ownership.²⁵⁸ In general, they contend that current owners are not likely to sell transmission assets voluntarily to others if selling leads to a large capital gains tax payment. They contend that passive ownership provides a creative way to allow transfer of grid operations to an independent party while reducing the tax burden on current transmission owners.

In contrast, Consumer Groups asserts that there are mechanisms other than passive ownership that would "permit 'divestiture' without tax consequences" and that an important advantage of these other mechanisms is that they

would "better assure independence."²⁵⁹ As one example, Consumer Groups asserts that a vertically integrated utility could spin off its transmission assets to its shareholders. While recognizing that the IRS Code seems to eliminate the favorable tax treatment if the spun-off corporation is sold within two years of the original distribution, Consumer Groups states that this is a rebuttable, not an absolute, prohibition and that a recent IRS proposed rule seems to suggest that favorable tax treatment could be retained if the spin-off of transmission assets is done in response to regulatory mandates. South Carolina Authority raises a different argument against regulatory policies to accommodate passive ownership. It asks why the Commission should feel obligated to minimize the federal corporate income tax responsibilities of privately owned utilities.

Several commenters recommend that we accept passive ownership at least as a necessary transition device. For example, Enron/APX/Coral Power state that "there will likely need to be some years of passive ownership by industry participants before the RTOs will have demonstrated their viability as stand-alone transmission businesses that can successfully be taken public."²⁶⁰ ISO-NE, which favors a single grid company for all of New England, observes that because of "tax and other considerations, current owners of transmission assets may wish to avoid immediate divestiture, and may wish to retain indirect ownership."²⁶¹ Salomon Smith Barney predicts that most utilities will want to dispose of passive and minority interests over time. NECPUC, representing the six New England commissions, echoes this point. It states that the Commission may have to accept "[t]ransitional periods in which the ownership interests of market participants are phased out over time." If such transitions are allowed, NECPUC urges us to ensure that they are "carefully monitored."²⁶² TDU Systems, as noted earlier, recommends that passive ownership should be used only as an "extraordinary transition measure" and should be allowed only for a short period of time.

RTO Governing Boards. Many commenters recommend that membership on RTO governing (*i.e.*, decisional) boards be limited to non-stakeholders.²⁶³ For example, the Justice

²⁵¹ See, e.g., APPA, Industrial Consumers and South Carolina Authority.

²⁵² TDU Systems at 41.

²⁵³ Entergy at 42.

²⁵⁴ Salomon Smith Barney Reply Comments at 15.

²⁵⁵ South Carolina Authority at 21.

²⁵⁶ *Id.* at 24.

²⁵⁷ *Id.*

²⁵⁸ See, e.g., Entergy and Southern Company.

²⁵⁹ Consumer Groups Reply Comments at 11.

²⁶⁰ Enron/APX/Coral Power at 14.

²⁶¹ ISO-NE at 20.

²⁶² NECPUC at 11.

²⁶³ See, e.g., Advisory Committee ISO-NE, APX, Avista, Desert STAR, Industrial Consumers, PJM.

Continued

²⁴⁶ Sierra Pacific at 11.

²⁴⁷ *Id.*

²⁴⁸ Sierra Pacific at 12.

²⁴⁹ Enron/APX/Coral Power at 14.

²⁵⁰ TDU Systems Reply Comments at 22.

Department urges the Commission to consider barring all market participants from any decision-making role. It says that this approach assures "a clean structural break."²⁶⁴ If stakeholders are allowed on the governing board, the Justice Department recommends that independents (*i.e.*, non-stakeholders) should constitute a majority of the board's voting members and that the board's voting rules not allow vetoes by any one class of stakeholders. Most commenters who support an independent board recommend that the maximum size of the board not be specified in the final rule but instead be left to the discretion of the participants. Two exceptions are the South Carolina Authority, which recommends that board size be limited to seven to nine directors, and the Midwest Municipals, which suggests that the Commission question any non-stakeholder board that has more than 10 to 15 members.

Other commenters state that a danger of non-stakeholder boards, such as those already approved by the Commission for several ISOs, is that they become isolated and sometimes unresponsive to stakeholder concerns. UtiliCorp, for example, asserts that "one of the most frequently heard criticisms of the ISOs currently in existence is their unresponsiveness and lack of accountability."²⁶⁵ Several other commenters echo this concern and recommend that an independent board be required to consult formally and informally with advisory committees of stakeholders (*i.e.*, a two-tier form of governance). For example, the Midwest Municipals recommend that RTOs with non-stakeholder boards "be required to have a senior management or advisory committee made up of market participants from each relevant market sector and subordinate, issue oriented committees" similar to those that exist in the PJM, New York and New England ISOs.²⁶⁶ STDUG recommends that if a non-stakeholder board is formed "it must be accompanied by some action forming mechanism that forces the board to listen and consider the

concerns of all members or stakeholders in the RTO."²⁶⁷

EPSA urges the Commission to pay close attention to the composition and functions of any committee structure that operates underneath a governing board because independent governance "does not stop at the ISO board."²⁶⁸ It contends that this is necessary for independence because advisory committees of stakeholders will often have *de facto* decisionmaking power. Dynegy makes specific recommendations for any stakeholder committees that operate below and report to an RTO board. It recommends that such committees be governed by "segment voting"—each industry segment would have a proportional vote; each market participant would have to choose to participate in one market segment; and the votes within a segment would be split among however many entities choose to participate in that segment. It observes that this approach has been adopted or proposed in the PJM, NEPOOL and New York ISOs.

Other commenters urge us not to prohibit stakeholder or hybrid boards consisting of stakeholders and non-stakeholders such as the one that exists in California. Cal ISO, noting that it is the only FERC-jurisdictional ISO with a stakeholder board, states that "[t]he Cal-ISO stakeholder board has worked" and urges us to confirm the acceptability of a stakeholder board in the final rule if the board is structured to ensure that no market participant or class of market participants can control the decisions of the RTO.²⁶⁹ Dairyland points out that the Commission has encouraged and approved stakeholder boards under the independence principle for ISOs in Order No. 888.²⁷⁰ Dynegy recommends a hybrid governing board with "disinterested" (*i.e.*, non-stakeholder) members comprising one-third of the board and stakeholder members comprising the remaining two-thirds.²⁷¹

²⁶⁷ STDUG at 7–8.

²⁶⁸ EPSA at 15.

²⁶⁹ Cal ISO at 15. Cal ISO points out that this has been achieved through a board of governors in which (1) no one voting class is able to block or veto an action, and (2) no two classes together are able to form a sufficient majority to make decisions, and (3) no entity (including its affiliates and subsidiaries) is able to participate in more than one voting class. See Attachment A–1 of Cal ISO.

²⁷⁰ "A governance structure that includes fair representation of all types of users would help to ensure that the ISO formulates policies, operates the system, and resolves disputes in a fair and non-discriminatory manner." Order 888, FERC Stats. and Regs. ¶ 31,036 at 31,730–731

²⁷¹ Dynegy recommends that five "segments" for the stakeholder representatives: transmission owners, transmission-dependent utilities,

However, it observes that mandated stakeholder representation would be "inappropriate" for an RTO that is a for-profit transco. California Board urges us to allow a variety of governance forms including stakeholder boards "until and unless experience shows that one form" is clearly superior to other forms of governance.²⁷² TXU Electric states that "stakeholder representation is a legitimate form of governance for a regional transmission organization" and, in fact, is the required form of governance under the recently enacted Texas electric restructuring statute.²⁷³

Role of State Agencies. Commenters express a wide range of opinions on the appropriate role of state agencies. The comments fall generally into two categories: the role of state agencies during the developmental stage and the role of state agencies after an RTO begins operating.

Many commenters believe that state commissions and other state agencies should have a major role in RTO development. NARUC argues that state commissions "should fully participate in RTO formation and development."²⁷⁴ State commissions generally take the position that their involvement is important because the size, scope and functions of an RTO will be critical for the success of their state-by-state retail choice programs.²⁷⁵ NECPUC notes that it had an important role in shaping the design of the ISO-NE before any formal filing was made at the Commission. Nine Commissions, representing state commissions from the East-Central, Midwest and Southwest regions, gives a specific example of how the Commission should defer to state commissions. They state that if a critical mass of state commissions in their region reach agreement on the appropriate boundaries for an RTO, then FERC "should provide deference to that collective state determination."²⁷⁶

Other commenters outside of the state regulatory community also address the issue of the appropriate role for state commissions. For example, Enron/APX/Coral Power say that state regulators and politicians should play a role in encouraging local transmission owners to join RTOs but "[t]he role of states * * * should extend no further."²⁷⁷

Once an RTO becomes operational, Enron/APX/Coral Power argue that state commissions should have no special

marketers, end-users and independent power producers. Dynegy at 42.

²⁷² California Board at 6.

²⁷³ TXU Electric at 9.

²⁷⁴ NARUC at 11.

²⁷⁵ See, e.g., Illinois Commission.

²⁷⁶ Nine Commissions at 6.

²⁷⁷ Enron/APX/Coral Power at A-3.

Reliant, South Carolina Authority and UtiliCorp. In general, these commenters adopt the convention used in the NOPR that a non-stakeholder is synonymous with a non-market participant. See note 187 in FERC Stats. and Regs. ¶ 32,541 at 33,726.

²⁶⁴ Justice Department at 4. The Southern Company states that if the Commission requires non-stakeholders boards RTOs that are ISOs, then it must allow transmission owners the right to establish "performance standards" for the RTO and the right to withdraw if the RTO fails to meet these standards. Southern Company at 40–41.

²⁶⁵ UtiliCorp at 11.

²⁶⁶ Midwest Municipals at 19.

role and, in fact, the RTO "should be protected from local interference." Their argument for minimizing the role of state agencies is that "no other commercial activity (with the possible exception of telecommunications) is more intrinsically in interstate commerce." Conlon, the former President of the California Public Utilities Commission, expresses a similar view ("local control, although desirable from a states' rights standpoint, should be sacrificed to get interstate control of the entire interconnection.")²⁷⁸

On the issue of voting rights for state commissions, Enron/APX/Coral Power argues that it would be inappropriate for any state commission to be a voting member of an RTO. Their rationale is that the state commission would lose its ability to monitor the relationship between the RTO and any entity that may be serving the state's domestic load if it is also a voting member of the RTO board. NECPUC expresses a similar view. While recommending that state commissions have extensive communication with the RTO and its participants, it concludes that state commissions "should not have a vote in the governance of the ISO New England."²⁷⁹ Arizona Commission says that states should have the right of ex officio membership but that "FERC should not force the states to be voting members."²⁸⁰ ISO-NE also shares this view. It contends that it would be "awkward" for a state official to serve as a voting director of an RTO for several reasons. First, it could create a conflict between the state official's duties as an RTO board member and his or her regulatory or administrative duties at the state level. ISO-NE argues that many state conflict of interest laws may expressly prohibit such service because of the conflicts it would create.²⁸¹ Second, in the case of a multistate RTO, it may be difficult for an official from one state to vote for decisions that are good for the residents of all the states served by the RTO. Third, the solution of having a board member from each state "could create gridlock or unwieldy boards."²⁸²

Florida Commission makes a distinction between for-profit and non-

profit RTOs. It says that it would be inappropriate for members of a state regulatory body or other state officials to serve on the board of a for-profit transco. However, Florida Commission believes that it may be appropriate for a state commissioner to serve on the board of a non-profit RTO if disputes involving the RTO and other parties do not come before the state commission.

Washington Commission expresses a different view. In its opinion, the role of state commissions should vary depending on the type of board. It recommends that state involvement could be limited to the selection of the non-affiliated board members for a non-stakeholder or hybrid board. In contrast, if there is a stakeholder board, Washington Commission urges that states be granted "voting member status." In the case of a for-profit transco, it urges the Commission to require a formal advisory role for the states.

Section 205 Filing Rights. Many IOUs and public systems oppose the NOPR's proposal to require that RTOs have "exclusive and independent authority to file changes to its transmission tariff with the Commission under section 205 of the Federal Power Act."²⁸³ In contrast, those who support the proposal assert that it is a necessary and logical implication of the Commission's previously stated policy that the "[a]uthority to act unilaterally * * * is a crucial element of a truly independent ISO."²⁸⁴ SRP recommends that "the need for an RTO to independently administer its own tariff must be balanced against the need for individual transmission owners to maintain control over their ability to recover their revenue requirements and meet their debt service obligations."²⁸⁵

Those who oppose the proposal focus on the case of an RTO that is an ISO. Transmission ISO Participants argues that the proposal is bad law and bad policy. Citing the Supreme Court decision in *United Gas Pipe Line Co. v. Mobile Gas Service Corp.*,²⁸⁶ it asserts that the Commission does not have the legal authority to grant section 205 filing rights to an ISO. It contends that the FPA grants this fundamental right to transmission owners that are public utilities. While a transmission owner

may "voluntarily cede" this right to an ISO, the Commission cannot compel a transmission owner, either directly or indirectly, to give up this legal right. Puget Sound argues that the proposal would have the effect of reducing the transmission-owning utility to little more than a "bystander" and could constitute an illegal "taking" under the Fifth Amendment of the U.S. Constitution.

Transmission ISO Participants also claims that the Commission's previous decisions in this area have not been consistent. It asserts that the Commission "required transmission owners to cede their section 205 rights to the ISO in our order approving the PJM ISO."²⁸⁷ But it points to the fact in a 1997 California ISO order that the Commission seemed to establish a much smaller role for the ISO ("the ISO is responsible for only collecting the revenue requirement.")²⁸⁸ Furthermore, it notes that in this same order the Commission decided to set all rate design and rate methodology issues in the dockets established for the filings made by the transmission owners, and not in a docket for the transmission tariff filing made by the ISO.²⁸⁹

Many commenters also address whether it would be practical to give RTOs FPA section 205 filing rights for transmission rate design and terms and conditions that directly affect access while transmission owners would retain section 205 rights for overall revenue requirements. A number of commenters say that this distinction is unworkable because the two are inextricably connected (*i.e.*, changes in rate design can have major impacts on revenue collections).²⁹⁰

However, other commenters argue that the Commission cannot realistically expect an RTO to be a neutral and unbiased transmission provider unless the RTO has full legal authority to propose changes in its own transmission tariff.²⁹¹ PJM states that "its ability to function would be severely hindered" unless it has the ability to unilaterally make tariff filings. It points to several recent instances of emergency filings with us as examples of why it must have its own independent filing authority without getting the prior approval of

²⁷⁸ Conlon states that these are his views and are not necessarily the views of any present or former Commissioners or staff of the California PUC.

²⁷⁹ NECPUC at 9.

²⁸⁰ Arizona Commission at 5.

²⁸¹ In contrast, Reliant recommends that "state officials should serve as board members in order to avoid conflicts in future decisions." It appears that Reliant is referring to future decisions of the state agencies. Reliant at 5.

²⁸² ISO-NE at 3.

²⁸³ See, e.g., AEP, Alliance Companies, CMUA, Duke, Florida Power Corp., LPPC, Metropolitan, Midwest Municipals, Montana-Dakota and Southern Company.

²⁸⁴ Citing NEPOOL, 79 FERC ¶ 61,974 at 62,585 (1997). See, e.g., PJM, Cal ISO, Industrial Consumers, Montana Commission, NECPUC and NASUCA.

²⁸⁵ SRP Reply Comments at 12.

²⁸⁶ 350 U.S. 332 (1956).

²⁸⁷ Transmission ISO Participants at 20.

²⁸⁸ Quoting 81 FERC ¶ 61,122 at 61,506 (1997).

²⁸⁹ However, the California ISO asserts that it has "exclusive and independent" authority "to modify the design of rates for transmission and ancillary services." See Cal ISO at 18.

²⁹⁰ See, e.g., EEI, Transmission ISO Participants and Southern Company.

²⁹¹ See, e.g., Cal ISO, PJM ISO, Industrial Consumers, Montana Commission, NECPUC and NASUCA.

transmission owners or any other group. It argues that it will not be able to satisfy its responsibility to "provide for safe and reliable operation of the transmission grid and operation of a robust, competitive, and non-discriminatory electricity market" without such authority.²⁹² However, PJM does state that transmission owners, rather than the RTO, should have the unilateral right to seek changes in the RTO's tariff to address changes in the transmission owners revenue requirements with respect to transmission facilities.²⁹³

Oneok, a power marketer, states that an RTO needs its own section 205 filing authority because it would not be able to reach a consensus and act quickly if it must get the prior approval of all stakeholders. However, Oneok suggests an alternative to what was proposed in the NOPR. It recommends a two-tier approach to transmission tariff filings. Under this proposal, "transmission-owning utilities would be free to file changes to their rates (or rate structures) at any time" to their single customer, the RTO.²⁹⁴ The RTO would then be free to "repackage" the transmission capacity and services that it purchased under these separate transmission owner tariffs in its own RTO transmission tariff filed under section 205. Oneok states that there are precedents for this approach in prior Commission practices.

Commission Conclusion. The Basic Independence Principle. In the NOPR, we repeated our earlier statement that "the principle of independence is the bedrock upon which the ISO must be built "and emphasized that this principle must apply to all RTOs, whether they are ISOs, transcos or variants of the two. We also stated that "[a]n RTO needs to be independent in both reality and perception." We reaffirm both principles in the Final Rule.

In applying these principles in the context of ISOs, we have stressed the importance of a decisionmaking process that is independent of control by any market participant or class of participants. This, in turn, required that we pay considerable attention to governance (e.g., voting shares and voting rules). Because ISOs are typically non-profit and non-share corporations, we generally did not have to consider the effect of ownership interests on the independence of the ISO. This will change with the emergence of for-profit

RTOs, such as transcos, that have ownership interests. For these types of RTOs, we will have to examine how ownership of the RTO by market participants could affect the independence of its decisionmaking process.

Who Is a Market Participant? The overall purpose of the independence standard in the Final Rule is to ensure that an RTO will provide transmission service and operate the grid in a non-discriminatory manner. Equal access requires RTOs to be independent. Implementation of this standard then requires answering the question: independence from whom? Our logic in the NOPR, which we have adopted in the Final Rule, is to define a group of entities, referred to as market participants, whose economic or commercial interests are likely to be affected by an RTO's decisions and actions.

Commenters provided many helpful comments on the definition of market participant that was proposed in the NOPR. As noted in the summary, the commenters generally fall into two broad categories: those who argue that the NOPR definition is too broad and those that argue that it is too narrow. We find that these views were not always inconsistent since the commenters were often discussing different aspects of the definition. After a careful review of the comments, we conclude that it is necessary to change the definition of a market participant that was proposed in the NOPR. The revised definition at section 35.34(b) is:

(2) *Market participant* means:

(i) Any entity that, either directly or through an affiliate, sells or brokers electric energy, or provides transmission or ancillary services to the Regional Transmission Organization, unless the Commission finds that the entity does not have economic or commercial interests that would be significantly affected by the Regional Transmission Organization's actions or decisions; and

(ii) Any other entity that the Commission finds has economic or commercial interests that would be significantly affected by the Regional Transmission Organization's actions or decisions.

(3) *Affiliate* means the definition given in section 2(a)(11) of the Public Utility Holding Company Act (15 U.S.C. 79b(a)(11)).

Before discussing how this definition is different from the NOPR definition, it is useful to consider why a definition of market participant is needed in the first place. It is the Commission's view that an RTO must be independent of any entity whose economic or commercial interests could be significantly affected by the RTO's actions or decisions. Without such independence, it will be

difficult for an RTO to act in a non-discriminatory manner. Therefore, the definition focuses on those entities whose economic and commercial interests can be significantly affected by the RTO's behavior. However, it should be emphasized that the definition of a market participant is simply a starting point for implementing the independence standard. The definition is used as a reference point for establishing limits on ownership (*i.e.*, an RTO's ownership of market participants and market participants' ownership of an RTO) and standards for independent decisionmaking or governance. As discussed below, the fact that a particular participant is defined as a market participant does not preclude it from having any active or passive ownership interest in an RTO.

We agree with many commenters that the NOPR definition was too broad in defining a market participant to be "any entity that buys or sells electric energy in the RTO's region or in any neighboring region that might also be affected by the RTO's actions." As several commenters pointed out, a literal reading of this definition would make market participants of every residential, commercial, industrial and wholesale electric customer in the RTO region and some neighboring regions. This is clearly too encompassing and was not our intent. We therefore are narrowing the definition of a market participant in the Final Rule to include those who sell or broker electric energy but not those who buy electric energy.

We recognize, however, that there may be circumstances where buyers of electric energy could buy a controlling interest in a for-profit RTO and manipulate its access and curtailment decisions to their advantage. Such an outcome would clearly be inconsistent with the independence standard. Therefore, as a backstop, we are adding paragraph (b) to the definition ("any other entity that the Commission finds has economic or commercial interests that would be significantly affected by the RTO's actions or decisions"). The addition of this paragraph allows us, on a case-by-case basis, to consider whether particular buyers of electric energy (or any other entity) could manipulate an RTO's decisions to the disadvantage of other RTO customers.

We are also dropping the phrase "in the RTO's region or in any neighboring region that might also be affected by the RTO's actions." Given the high degree of integration within the Eastern and Western Interconnections, the growth of transactions involving buyers and sellers separated by hundreds of miles and the participation of energy concerns

²⁹² PJM at 53.

²⁹³ PJM at 54. The California, New York and New England ISOs agree with PJM on this point.

²⁹⁴ Oneok at 8.

in multiple markets, we conclude that it would be virtually impossible to apply a geographically delineated standard. However, we will consider requests for waivers from entities in other Interconnections who can demonstrate that their economic or commercial interests would not be significantly affected by the RTO's actions or decisions.

We are also making one other change to the NOPR definition to expand its scope. Paragraph (a) expands the NOPR definition by including entities that provide transmission or ancillary services to an RTO. We believe that it would compromise an RTO's independence if one or more transmission owners could influence the RTO's decisions to the detriment of other market participants. Therefore, it is appropriate to include providers of transmission service as market participants.²⁹⁵ With regard to the creation of RTOs that are transcos, we have developed policies on the level of ownership that market participants may possess, as discussed below, in order to ensure that the operating decisions of the RTO are truly independent and non-discriminatory.

We believe that it is necessary to include ancillary service providers as market participants since the RTO is the supplier of last resort for ancillary services. As a consequence, the RTO is likely to have considerable discretion in defining the types and quantities of ancillary services needed and how they will be procured (e.g., market design). An RTO's decisions in any of these dimensions can have major economic effect on one or more providers of such services. Therefore, we define these entities as market participants to ensure that they are not in a position to influence the RTO's decisions to their own advantage.

Several other commenters urged us to include distribution entities as market participants. At present, most distribution entities provide a bundled service. The bundled service includes the sale of electric energy as well as the delivery of this electric energy over local distribution facilities. Since these traditional distribution entities are selling electric energy, they would be

considered market participants under the definition.

However, several commenters pointed out that a new type of distribution entity is likely to emerge with the spread of retail competition. This type of distribution entity would simply transmit electric energy over distribution facilities for others and would not sell electricity.

The issue is whether this type of pure distribution entity should be considered a market participant. Several commenters pointed to the danger of allowing one or two distribution entities to control an RTO. Their concern is that these distribution entities could use their control over the RTO to favor their distribution facilities over the facilities of non-affiliated distribution entities when the RTO has to choose among competing requests for transmission service or alternative curtailment actions. Other commenters minimize this risk and argue that distribution entities should be allowed to own RTOs because there are economies in having a single entity provide total delivery service (i.e., transmit electric energy at high and low voltages). The Commission does not wish to create impediments to the efficient integration of transmission and distribution facilities. Therefore, we will not include pure distribution entities in paragraph (a) of the market participant definition. However, if we are presented with evidence that a distribution entity is able to influence an RTO's actions or decisions to the disadvantage of other users, we may find such a distribution entity to be a market participant under paragraph (b) of the definition. Paragraph (a) of the revised definition defines all sellers of electric energy, whether retail or wholesale, as market participants. Several commenters urge us to exclude retail providers of last resort from the definition. These are entities that are required by state commissions or state law to be backup suppliers to retail customers who choose not to switch suppliers in a state-mandated retail competition program. We have decided to include such entities in the market participant definition because they are sellers of electric energy. However, the obligations and responsibilities of such entities are still being developed on a state-by-state basis. As a consequence, even though such entities may be generically referred to as "suppliers of last resort," their responsibilities and incentives may vary widely. The Commission believes that certain factors, (e.g., an entity's sole electric sales are made to satisfy a state requirement and it does not compete for

retail load) would support a finding that the entity is not a market participant.

NEPCO *et al.* point to the problem of incumbent utilities that have tried to divest themselves of generating assets but have not yet succeeded. They say that this is likely to be a particular problem for utilities that own minority interests in nuclear plants since it is currently difficult to sell such interests. NEPCO *et al.* request that they not be automatically deemed a market participant because of these ownership interests. Once again, we will entertain requests for exemption. For example, we would be willing to give an exemption if the current owner could clearly demonstrate that it has transferred to non-affiliated entities both the marketing rights and any profits resulting from the sale of electric energy associated with its ownership interest. Any compensation that the market participant receives from the non-affiliated entity should not be tied to profits on specific sales made by this entity.

RTO Economic Interests in Market Participants and Energy Markets. We reaffirm the NOPR proposal that the RTO, its employees and any non-stakeholder directors must not have any financial interests in market participants. As noted in the NOPR, our focus will be on current financial interests. Since this principle raises a number of specific issues, especially with respect to pension rights and benefits, we will continue our current policy of implementing this principle on a case-by-case basis.

Several commenters argued that the NOPR's treatment of financial independence was too narrowly drawn. For example, Dynegy, pointing to the example of ISOs, argues that while ISOs "may ostensibly be independent of market participants—they are not independent of the market itself."²⁹⁶ The participation of RTOs in the market stems from certain obligations that we require of any RTO: it is the supplier of last resort for required ancillary services and it must attempt to procure such services efficiently in competitive markets. These two requirements mean that most RTOs will be operators of bilateral and spot markets in ancillary services as well as buyers in these same markets. In addition, they will be resellers of any ancillary services that they purchase.

It is our intention that RTOs perform functions that make the transmission infrastructure operate efficiently, not that they take actions in ways that skew competitive outcomes in the market.

²⁹⁵ It is conceivable that RTO A might provide transmission service to a neighboring RTO B. In such a situation, RTO A would be considered a market participant. RTO A might also acquire ownership interests in RTO B as a first step towards consolidation of the two RTOs. We would anticipate granting a waiver to RTO A from a market participant definition and any associated ownership restrictions if we had reason to believe that the waiver could lead to a larger and more effective RTO.

²⁹⁶ Dynegy at 35.

Nevertheless we acknowledge that RTO operations may have that effect. Moreover, the two requirements may lead to an outcome that an RTO is not indifferent to whether the prices are high or low. Given this possible conflict, we will require that all RTOs must propose an objective monitoring plan to assess whether the RTOs involvement in these markets favors its own economic interests over those of its customers or members.²⁹⁷

Passive Ownership Interests in the RTO. As we have emphasized, the Commission wishes to give industry participants every reasonable opportunity to create RTOs through their own voluntary actions. However, we also recognize that mere exhortations that the industry participants should volunteer to create independent transmission entities will not ensure a truly open and reliable grid in the reasonably foreseeable future. The Commission must take actions to ensure that the stand-alone transmission business is financially attractive and viable. We must also provide a high degree of regulatory certainty and not foreclose viable options for creating and developing RTOs. To provide more certainty, the Final Rule provides guidance on our future policies for establishing revenues, incentives and performance-based regulation for proposed RTOs.²⁹⁸

We also recognize that the voluntary creation of RTOs requires that current owners of transmission assets must be willing to transfer operational control of these assets to RTOs or to divest their interests in their entirety. Therefore, it is important that we provide current transmission owners with flexibility in deciding how they will relinquish ownership or control of their transmission facilities to an RTO. Numerous commenters, ranging from IOUs to state commissions to marketers, urge the Commission not to make RTO policy in a vacuum. In particular, they stress that the Commission needs to understand that there are many existing legal and tax disincentives to the outright sale of such assets to an RTO.²⁹⁹

Among these potential impediments, commenters identify the federal capital gains tax most frequently. There was agreement among many commenters that it would be unrealistic for the Commission to expect current transmission owners to sell their

transmission facilities to an RTO if the sale becomes a taxable event that triggers a large capital gains tax. Therefore, they urge the Commission to accommodate financing and ownership arrangements that facilitate the creation of for-profit RTOs while minimizing the tax burden on current transmission owners who are willing to take actions that would promote the Commission's RTO policies. Many commenters argue that the Commission could significantly accelerate RTO development if we were to allow current transmission owners to retain a passive ownership interest in new RTOs. Several commenters contend that if the Commission fails to accommodate such arrangements, this initiative will be unproductive because our policies would be effectively biased against the creation of for-profit transmission companies that seek RTO status. They assert that such an outcome would be inconsistent with the statement in the NOPR that the Commission wishes to encourage all types of RTOs, whether they are transcos, ISOs or combinations of the two.³⁰⁰

In response to these comments, we reaffirm that it is the Commission's policy to encourage all types of RTOs. In light of our evolving experience with the workability of certain RTO models, it would be inappropriate for us to mandate a single RTO model of ownership and operation. While the dominant approach to date has been ISOs, we are receptive to alternative approaches that can provide evidence of the legitimacy of various models of ownership and operation. Because the institutions which we propose to sanction pursuant to this Final Rule will be so influential in operating the Nation's infrastructure over a period of time, the Commission resolves to implement its independence criteria with an open mind and, to the extent practicable, with flexibility. At this juncture, we therefore propose to remove unnecessary impediments to the creation of transmission companies by allowing market participants to maintain passive ownership interests in RTOs.

We reaffirm our belief that "[a]n RTO must be independent in both reality and perception."³⁰¹ This same conclusion was also reached by the DOE Reliability Task Force and the NERC Reliability Panel, two widely respected industry groups comprised of representatives from all sectors of the industry. The

DOE Reliability Task Force concluded that regional reliability entities must be "truly independent of commercial interests so that their reliability actions are—and are seen to be—unbiased and untainted." The Electric Reliability Panel concluded that "[t]o dispel suspicions that the system operator favors one participant over another * * * the operator must be independent of market participants."³⁰²

The Commission concludes that an RTO will not be successful unless all market participants believe that the RTO will operate the grid and provide transmission service to all grid users on a non-discriminatory basis. It is clear that the perception of a broad cross-section of commenters is that passive ownership may interfere with the independent operation of RTOs.³⁰³ In the view of many commenters, passive ownership is only a subtle mechanism to allow existing transmission owners to continue to control use of transmission assets and ultimately deny equal access to competitors. Therefore, we must provide assurances to all market participants that any passive ownership interest is truly passive and will in no way interfere with the independent operation and decisionmaking of the RTO. It is important to require a system of independent compliance auditing to ensure that passive ownership arrangements remain passive over time and to provide assurances to other market participants that the RTO is truly independent.³⁰⁴

Those who support the policy of allowing market participants to have passive ownership in RTOs point to the fact that the Commission has accepted many instances of passive ownership in the past. Typically, these arrangements have involved the sale and leaseback of generating units in which a jurisdictional public utility will sell a generating unit to a bank, insurance company or other financial institution. The financial institution will then lease

³⁰² See U.S. Department of Energy, *Maintaining Reliability in a Competitive U.S. Electricity Industry: Final Report of the Task Force on Electric System Reliability*, at xv (September 29, 1998); North American Reliability Council, *Electric Reliability Panel, Reliable Power: Renewing the North American Electric Reliability Oversight System* at 17 (Dec. 22, 1997).

³⁰³ See, e.g., Consumer Groups, South Carolina Authority, TDU Systems, Industrial Customers, APPA, Los Angeles, NASUCA, Arkansas Cities and Wolverine Cooperative.

³⁰⁴ The auditing requirements of this Rule represent one approach to addressing our concern that it may otherwise be difficult to assess the ongoing independence of passive ownership arrangements. We expect that parties will include in any rehearing requests their views on this approach, in general, and the particular auditing requirements that we have adopted.

²⁹⁷ This is discussed more fully under Market Monitoring. See *infra* section III.E.6.

²⁹⁸ See *infra* section 111.G.

²⁹⁹ See EEL, Southern Company, United Illuminating, Enron/APX/Coral Power, ISO-NE, NECPUC, Salomon Smith Barney and Konoglie/Ford/Fleishman.

³⁰⁰ FERC Stats. and Regs. ¶ 32,541 at 33,726.

³⁰¹ As discussed below, this overriding consideration is also relevant to active voting interests.

back the generating unit to the jurisdictional utility. Even though the financial institution is the owner of record, we have generally concluded that it is a passive owner without any real operational control and, therefore, is not a jurisdictional public utility under the FPA.³⁰⁵

There are, however, several considerations that distinguish these earlier passive arrangements from the ones that are being contemplated for RTOs. First, the passive ownership arrangements for RTOs (e.g., two-tier LLCs, synthetic leases and leveraged partnerships) may be complicated and multi-layered. Even those commenters who urge that we accept passive ownership as a necessary transition mechanism admit that such arrangements "will prove troublesome for both utilities and FERC" because they create the "need to constantly police supposedly passive ownership positions to make sure that they remain passive in all respects."³⁰⁶

Second, unlike financial institutions, the passive owners will typically own other assets (e.g., generating assets) that could reap major economic benefits if an RTO's decisions can be influenced to their advantage. Therefore, unlike financial institutions, the passive owners in RTOs may have a direct economic incentive to influence the RTO's operating and investment decisions to favor other economic interests.

In response to a request for a declaratory order from *Entergy Services, Inc.*, the Commission found that passive ownership of a transmission entity by a generating entity or other market participant could meet the Commission's ISO standards relating to governance and independence if it were properly designed. Because Entergy's proposal was incomplete, the Commission provided some limited guidance related to: board selection and removal, potential issues about the board's fiduciary duties, attraction of capital and issues about the transmission entity contracting with member companies. In this rule we provide further guidance which we believe will help RTO applicants who may be considering some form of passive ownership structure.

Based on these considerations, the Commission's policy on proposals for passive ownership of RTOs by market participants will have three key elements:

(1) Passive ownership proposals will be reviewed on a case-by-case basis. The Commission will approve a proposal only if we are satisfied that the passive owners have relinquished control over operational, investment and other decisions to ensure that the RTO will treat all users of the grid—passive owners and others—on an equal basis in all matters. The burden of proof is on the RTO to demonstrate that control of the RTO is "truly independent" and that the RTO has a decisionmaking process that is independent of control by the passive owners.

(2) The Commission requires any RTO with passive ownership interests approved by the Commission to undertake an obligation and propose processes for an independent compliance audit to ensure the independence of its decisionmaking process from the passive owners. The first independence audit will be required two years after initial approval of the RTO and every three years thereafter. The independence compliance audit must be submitted to the Commission in a public document without any requirement for approval by the RTO board.³⁰⁷

(3) The Commission will take appropriate action if it finds evidence of abuses.

We will now discuss implementation of these elements. The first element of our policy is that any RTO that wishes approval for passive ownership above the limits set for active ownership must demonstrate in its application that the passive owners will relinquish effective control over operational and investment decisions. Specifically, the RTO must demonstrate that the proposed arrangement has been designed to ensure that it can treat all users of the grid—passive owners and others—on an equal basis in the provision of non-discriminatory transmission service.

It will be difficult for the Commission to make an assessment of whether a particular passive arrangement achieves true independence in decisionmaking for the RTO board and its management unless an RTO provides complete information about the rights that passive owners have reserved for themselves both as owners of the RTO and as providers of facilities and services to the RTO. In judging any proposal, our overriding concern is that the arrangements provide a high degree of assurance that those who are not passive owners will have equal access to the services provided by the RTO.

To assure ourselves that this standard is satisfied, the Commission will need

information on the following issues: fiduciary responsibilities of the RTO board and management to passive owners; ability of the RTO to raise capital independently of its passive owners; ability of the RTO to make investment and financing decisions independently of its passive owners; the extent of control by passive owners over board selection and removal; the extent of control by passive owners over transmission rates, terms and conditions; control of passive owners over issuance of new membership interests and/or equity; services that will be provided by the passive owners or their employees to the RTO; and the extent of access of passive owners to information not available to other market participants.³⁰⁸ An RTO application seeking approval for passive ownership should provide any other relevant information that will allow the Commission to assess whether passive owners have reserved rights for themselves that are superior to those of other market participants and if such rights constitute control over the RTO.³⁰⁹

The second element requires a mechanism for assuring ourselves and market participants that any passive ownership arrangement remains passive over time. The Commission will require the RTO to notify us immediately of any changes in the underlying agreements or facts that occur after the initial filing. The Commission has relied on a similar system of self-monitoring in cases in which we have approved market-based rates. Specifically, we have required that any public utility that receives market-based pricing must notify us of any factual changes that call into question whether it should be allowed to continue to charge market-based rates.³¹⁰

We will also require a system of independent compliance auditing. The auditing must be performed by individuals or organizations that are not

³⁰⁸ For example, this could include information on the market behavior of one or more non-affiliate market participants acquired through a market monitoring program and information on the RTO's proposed investment and operational plans, except where the Commission has approved it as necessary to protect the passive owner's capital investment.

³⁰⁹ We note that many of these same concerns also apply to RTOs that allow market participants to have ownership interests in voting securities.

³¹⁰ When there is a change in the factual circumstances that were the basis for the Commission's approval of market-based pricing, we require that a public utility notify us immediately of this change or at the next update of their market power analysis. This update occurs once every three years. With respect to passive ownership, we will require that the passive owner must notify us immediately of any change in governance in ownership or governance that takes place after our initial approval.

³⁰⁵ See *Pacific Power and Light Co.*, 3 FERC ¶ 61,119 (1978); *Baltimore Refuse Energy Systems Co.*, *Wheelabrator Millbury, Inc.*, 40 FERC ¶ 61,366 (1987).

³⁰⁶ Salomon Smith Barney Reply Comments at 15.

³⁰⁷ See *supra* note 304.

affiliated with the RTO or its owners. The purpose of the auditing would be to ensure that what is passive on paper is passive in reality throughout the transition period. In particular, auditors would assess whether the passive owners have retained rights or privileges in their role as owners or providers of services that would put non-owner participants at a competitive disadvantage. The audits would cover the RTO's actions and decisions with respect to operations and investments. In order for this to be a credible auditing system, the auditors should have clear authority to obtain any information or data necessary to perform their audits and they should have the right to report any findings and recommendations to the Commission without prior approval of the RTO or any of its owners/members. An initial audit must be performed two years after our approval of the passive ownership arrangements and every three years thereafter.³¹¹ If there is evidence of abuse or we are unable to determine if the ownership interests continue to be passive, the Commission will not hesitate to order appropriate remedial action, including possible termination of passive ownership interests.

We understand that passive ownership arrangements are likely to take many forms and that the Commission has not had much experience in examining these types of arrangements in the context of RTOs. We encourage market participants to investigate the options available for passive ownership to identify those types of arrangements that will provide the greatest assurance of independence. For example, we note that the SEC's Rule 250.7(d) establishes criteria under which entities may have ownership interests that do not trigger SEC jurisdiction under PUHCA. The criteria under Rule 250.7(d) are that: (1) The entity owns the facility as a company, a trustee or holder of a beneficial interest under a trust; (2) the facility is leased under a net lease directly to a public utility company and such facility is to be employed by the lessee in its operations; (3) the company is otherwise primarily engaged in business other than that of a public utility; (4) the terms of the lease have been approved by the regulatory authority having jurisdiction over the lessee; (5) the lease extends for an initial term of not less than 15 years; and (6) the rent reserved under the lease shall not include any amount based, directly or indirectly, on revenues or income of the lessee public utility. While it is unclear whether these

exact criteria can be applied to the passive ownership arrangements that may be involved in the formation of an RTO or whether they would address the particular independence issues raised in this Rule, we believe that it would be acceptable for market participants to develop passive ownership arrangements that are purely financial. A passive ownership arrangement that is demonstrated to be purely financial could be relieved of the auditing requirement in this Rule.

Active Ownership Interests in the RTO. We now turn to a discussion of active as opposed to passive ownership. Most commenters used the term "active" ownership interests to refer to ownership of voting securities that give the owner the ability to influence or control an RTO's operating and investment decisions. We adopt this definition for purposes of our discussion and will use the terms "active" and "voting" interchangeably.

Several commenters who were strong proponents of allowing high or unlimited voting interests by market participants argue that in the NOPR the Commission was wrong to focus on any particular ownership percentage. Instead, they contend that what really matters is "actual control over the day to day affairs of the system, not some arbitrary ownership percent ownership test."³¹² We agree that the independence of an RTO ultimately depends on who makes the decisions.³¹³ But control of decisionmaking ultimately depends on who votes and how many votes each party has.

Consequently, we do not think that the Commission can ignore market participants' ownership of voting interests in the RTO.³¹⁴ To do so would require us to presume that even though a market participant has the legal right to vote for its own commercial interests, it will choose to vote for the public interest (or the general interests of all market participants). Therefore, we conclude that ownership of voting interests does matter and we cannot remain agnostic about the ownership of

voting interests in an RTO by individual market participants, their affiliates or classes of market participants.³¹⁵

a. Active Ownership by Individual Market Participants and Affiliates. A number of transmission customers argue that the cleanest solution would be an "absolute prohibition" on ownership of voting interests by any market participant.³¹⁶ We agree that this would produce a high level of certainty that an RTO is truly independent and anything less than an absolute prohibition introduces some risk. However, if our goal is to encourage the voluntary creation of RTOs, we have to accept that current owners may not relinquish ownership or control of their transmission assets unless it is in their economic interests to do so. In order to create a viable, for-profit, regional transco, at least some current transmission owners must be willing to sell their transmission assets to a new transmission company. Many commenters point out that this voluntary action is not likely to happen if the current owners anticipate large capital gains taxes as a consequence of the sale. The solution, according to many commenters, is to allow current owners to retain some voting interests, some non-voting (*i.e.*, passive) interests or both.

As with passive ownership, the Commission must balance two conflicting goals: the need to assure that any RTO will be truly independent; and of not creating disincentives for transmission owners to voluntarily relinquish ownership or control of their transmission assets. Against the backdrop of these two goals, the specific question that confronts us is how much ownership of active voting interests in RTOs should be allowed for market participants.

Several investor-owned utilities urged us to allow current transmission owners to retain as much as 100 percent voting interest in new for-profit transcos. They argue that we allow 100 percent ownership combined with codes of conduct in the natural gas industry and there is no reason why this model should not also apply to a restructured electricity industry. We disagree with

³¹² CTA at 4.

³¹³ However, independence does not automatically guarantee that an RTO will be effective in providing non-discriminatory access to the grid. Independence must also be combined with adequate operational and legal authority in order for the RTO to provide non-discriminatory access.

³¹⁴ In response to EEI's request for a clarification, we clarify that we are referring only to corporate or shareholder ownership in the RTO itself and not to ownership of transmission facilities under the RTO's operational control. The fact that such facilities are owned by market participants would not be a concern unless the owners retain legal rights and operational responsibilities that make it difficult for an RTO to provide non-discriminatory transmission service to other market participants.

³¹⁵ This is not the first time that we have emphasized the importance of voting rights. In various cases dealing with voting shares and voting rules for ISOs, we required that proposed arrangements be reformed to assure that no individual market participant or class of market participants could dominate the decisions of stakeholder committees that advised the ISO's board. See *New England Power Pool*, 88 FERC ¶ 61,079 (1999); *Central Hudson Gas and Electric Corp., et al.*, 88 FERC ¶ 61,229 (1999).

³¹⁶ See, e.g., APPA, *Consumer Groups and South Carolina Authority*.

³¹¹ See *supra* note 304.

this recommendation. The two industries, while similar in some respects, also differ significantly in the degree of vertical integration. The electricity industry is starting with a much higher level of vertical integration. As we noted in our NOPR discussion of the complaints filed since the issuance of Order No. 888, it is difficult to monitor compliance with codes of conduct when there is substantial vertical integration (*i.e.*, those who own generation and also own transmission).³¹⁷

Moreover, it is a very intrusive form of regulation and ultimately requires us to be "chasing after conduct." If such regulation is to be effective, we have to be concerned with internal corporate organization and "who spoke to whom in the company cafeteria."³¹⁸ This is not light-handed regulation. Therefore, we see little value in replicating this model in the new world of RTOs.

It would be equally unworkable to adopt the recommendations of some transmission customers that we should allow no ownership of RTOs by market participants from the outset. While this is a clean solution and greatly reduces the need to monitor for discriminatory behavior, it also reduces the likelihood that many current transmission owners will voluntarily relinquish ownership or control of their transmission facilities. As a consequence, it is likely to produce significant delays in the creation of RTOs that can support more competitive markets that would benefit consumers. Therefore, the Commission has concluded that it is in the public interest to permit some ownership of RTOs by market participants for a transition period. Within five years of RTO approval, however, active ownership by market participants must end unless the RTO seeks, and the Commission approves, an extension. Any request for extension, including a request occasioned by changed circumstances, must demonstrate that the extension is consistent with the independence standard of this rule and is otherwise in the public interest.

For the transition period, the Commission will establish a safe harbor of five percent for active ownership interests by market participants. We will allow any market participant to own up to five percent of an RTO's outstanding voting securities without the need for case-by-case review by the Commission. An active ownership interest at five percent or lower will be construed as not providing the owner with control.

The Commission will carefully evaluate, on a case-by-case basis, proposals that involve an ownership percentage higher than five percent. In deciding whether to allow active ownership interests that exceed five percent, we will look at various factors including the voting interests held by other class members (*i.e.*, other market participants with similar economic interests), the amount of passive ownership held by market participants, the degree of dispersion of voting interests among other market participants and the general public, and the rights retained by the owners as suppliers of facilities and services to the RTO. While there is no prohibition on RTO proposals that involve higher ownership percentages, it would heighten the concerns identified above and would require justification by the applicants to overcome these concerns.

We note that other Federal regulatory agencies have chosen to use a five percent value in similar situations. The SEC employs a five percent value in deciding when one entity is an affiliate of another under PUHCA.³¹⁹ The SEC also requires that any person who becomes a direct or indirect owner of more than five percent of any class of stock of a company must file a public statement with the SEC. In commenting on this latter requirement, the FCC observed that its purpose is "to ensure that investors are alerted to potential changes in control * * * which confer on their holders the potential for influence or control."³²⁰ Less than two months ago, the FCC established a five-percent "voting share benchmark" for assessing ownership interests in companies that are cable TV operators. In justifying its decision to stay with a five-percent value, the FCC noted that "[t]here is a body of more recent academic evidence that tends to confirm our earlier conclusions, demonstrating that interest holders of [five percent] can likely exert considerable influence on a company's management and operational decisions."³²¹ The FCC concluded that "ownership percentages starting at [five] percent can influence management policies."³²²

³¹⁹ See 15 U.S.C. 79b(a)(11).

³²⁰ Federal Communications Commission, In the Matter of Implementation of the Cable Television Consumer Protection and Competition Act 1999; Implementation of Cable Act Reform Provisions of the Telecommunications Act of 1996; Review of the Commission's Cable Attribution Rules, FCC LEXIS 5243, *53 (October 20, 1999) *citing* Securities and Exchange Commission v. Savoy Industries, Inc., 587 F.2d 1149 (D.C. Cir. 1978), *cert. denied*, 440 U.S. 913 (1979).

³²¹ *Id.*

³²² *Id.*

We recognize that this Commission has used higher percentages in other contexts. For example, in determining whether a company is an affiliate of a natural gas pipeline or an electric utility, we have applied a rebuttable presumption of control only when a utility or pipeline owns ten percent or more of the company's voting stock. As a general matter, since the success of RTOs will depend on both the perception and reality of independence, the Commission believes that caution requires us to allow only very limited voting interests by market participants. The Commission believes that a lower percentage is necessary in this instance because we allow other market participants with similar economic interests (*i.e.*, members of the same class) to have voting interests. Therefore, we believe that it is appropriate to impose a lower cap to reduce the risk that owners with similar outside economic interests may create a voting bloc. If, after our initial approval, we find evidence that control over the RTO is being exercised by an individual market participant or a class of market participants, we will not hesitate to take appropriate action, including ordering one or more entities to divest their ownership interests in the RTO.

The Commission recognizes that there are risks associated with allowing market participants to have any active ownership interests in an RTO. Even with a five percent active ownership interest, there is a risk that one or more market participants will be able to influence the RTO's decisionmaking process to the disadvantage of other market participants. Consequently, the RTO may fail to be an entity in which "the control of transmission operation is cleanly separated from power market participants."³²³ Accordingly, we will require that all market participants divest themselves of any active ownership interests no later than five years after our approval of the RTO. We will consider requests for extensions to this "sunsetting" requirement on a case-by-case basis. Any request for extension, including a request occasioned by changed circumstances, will be granted if the requester demonstrates that the extension is consistent with the independence standard of this Rule and is otherwise in the public interest. We will also require that any RTO that proposes active ownership by a market participant must adopt a system of independent compliance auditing to ensure that the active voting interests held by an individual market participant or classes of market

³¹⁷ FERC Stats. and Regs. ¶ 32,541 at 33,704-14.

³¹⁸ *Id.* at 33,714.

³²³ FERC Stats. & Regs. ¶ 32,541 at 33,718.

participants do not convey decisionmaking control.

b. Active Ownership by Classes of Market Participants. In the NOPR, we stated that "[a]n RTO must have a decisionmaking process that is independent of control of any market participant or class of participants."³²⁴ While we suggested a safe harbor of one percent ownership in voting securities by an individual market participant and its affiliates, we did not propose any specific cap on ownership of voting securities by a class of participants. Based on a review of the comments received, we have concluded that a policy on ownership by classes of market participants is necessary to ensure the independence of the RTO. Thus, we will review RTO proposals with respect to class ownership, considering potentially relevant factors such as voting interests held by other market participants or classes of market participants, the degree of passive ownership by market participants, the degree of dispersion of voting interests, and the rights retained by the owners as suppliers of facilities and services to the RTO. We recognize that this is a fact-specific determination that will require the Commission to evaluate, on a case-by-case basis, proposals that involve ownership by more than one market participant. We will adopt a benchmark of 15 percent class ownership. Our willingness to allow ownership by a class of participants that exceeds fifteen percent will depend on the particular circumstances of the filing (e.g., the presence of offsetting voting interests by another class of market participants with competing economic or commercial interests or proposals to sunset active ownership).³²⁵ Moreover, intervenors may also advance arguments that a 15 percent class ownership is inappropriate under certain factual circumstances.

Comments on this issue reflect widely divergent views. SRP criticizes the NOPR for failing to recognize that "[a]n interest may be considered *de minimis* when viewed in isolation, could still result in effective control when aggregated for a group with common interests." SRP contends that while the Commission explicitly recognized the importance of classes in the NOPR, we failed to do anything about it. In contrast, FP&L and others argue that there is no need for any ownership caps for a group of market participants since they will often have conflicting interests. EEI echoes this point by observing that any "coalitions" are

likely to be "fragile, short-lived and unlikely to result in a serious threat to the independence of the RTO."³²⁶ It also contends that it will be difficult to keep track of ownership interests and to categorize market participants into specific groups with "alleged common interests." Therefore, while EEI proposes a ten-percent cap on ownership interests in voting securities by individual market participants, it recommends that there be no cap on the ownership interests of any group of participants.

In several ISO orders, we rejected proposed governance arrangements because we concluded that the voting weights and rules given to classes or sectors of participants would allow transmission owners to dominate the decisionmaking process.³²⁷ We believe that the concerns that motivated these orders also hold true with respect to ownership of RTOs. It would make little sense to establish a policy on ownership by individual market participants and their affiliates while allowing five or six generators or marketers to group together to force an RTO to adopt a policy that favors their interests.

The Commission is unpersuaded by the assertions that similarly situated market participants will not have a "nexus of interests." While we recognize, for example, that individual generators may actively compete against each other for specific sales, this does not imply that there is a total absence of common economic interests among generators relative to marketers or distributors. If we were to accept this argument, it would require us to ignore the fact that the Commission routinely receives joint pleadings from non-affiliated parties with similar economic interests. Similarly, over the last two years, we have frequently observed various non-affiliated entities within ISOs voting as a bloc on issues where they have similar economic interests (e.g., existing generators voting against new generators who seek lower interconnection charges when they connect to the grid).

There is a second reason why we believe it is necessary to review class or sector ownership of voting securities in RTOs. With ISOs, we have allowed sector or class representation on the advisory and technical committees that are charged with giving advice or making recommendations to non-stakeholder governing boards. We have accepted these arrangements even

though the votes of some classes exceed 20 percent because all other classes are represented and have roughly equal voting power. Thus, independence is achieved through a diffusion of voting power among all the affected classes. While this arrangement may work for ISOs that are typically non-profit and non-share corporations, we do not think it is viable option for RTOs that have ownership shares that must be purchased. In particular, we cannot assume that all affected classes of market participants will have the financial resources to purchase ownership interests that would guarantee them a vote at the table. Therefore, we cannot presume that there will be a balance of voting power as was the case for the ISOs. In the absence of such countervailing voting blocs, we believe that it is necessary to establish lower limits on the amount of voting shares that can be owned by members of any one class of market participants.

Based on our experience to date, we do not think it is impractical to define classes of market participants with similar economic interests. This has been routinely done as part of the governance design in every one of the ISOs that we have approved. The Commission will not establish categories of classes in this Final Rule. Instead, we will allow each RTO to propose the classes that it believes are relevant to its region. However, we are inclined to define such classes broadly to avoid bypassing the class cap through narrowly defined classes.

In addition, we will require independent compliance auditing to ensure that market participants that have ownership interests will not use these ownership interests to put other non-owner market participants at a competitive disadvantage.³²⁸

The auditing should be performed by individuals or organizations that are not affiliated with the owners or RTO. The auditors would have clear authority to obtain any information or data necessary to perform their audits, and they would have the right to report any findings and recommendations to the Commission without prior approval of the RTO or any of its owners/members. An initial audit should be performed two years after our approval of the RTO. This will be the only audit required for active ownership unless the RTO or the active owners request and receive approval for an extension of active ownership interests beyond five years. If such an extension is granted, then follow-up compliance audits must be performed at three year intervals,

³²⁶ EEI Reply Comments at 21.

³²⁷ See New England Power Pool, 88 FERC ¶ 61,079 (1999); Central Hudson Gas and Electric Corp., et al., 88 FERC ¶ 61,229 (1999).

³²⁸ See supra note 304.

³²⁴ Id. at 33,727.

³²⁵ See Alliance Companies, supra note 48.

beginning with a three-year audit filed along with any request for extension.

As we discussed above with respect to passive ownership, applicants will have a continuing obligation to inform the Commission of any changed circumstances regarding active ownership. Moreover, the Commission would expect auditing for compliance with the individual and class caps established at the time of RTO approval. Where feasible, the auditors would rely on publicly available information on ownership interests (e.g., SEC data sources). Where such information is not publicly available (e.g., individual ownership interests of less than five percent), the auditors should have the authority to obtain this information from market participants and their affiliates. Any market participant that wishes to have an ownership interest in an RTO must agree to provide this information to the auditor or the Commission upon request. We would expect that market participants will comply with both the individual and class caps at all times. If the auditor finds that either cap has been violated, it must notify the Commission and the affected owners immediately and also recommend a remedy.

Since the caps do not guarantee a lack of control, the Commission expects that the auditors will also look for evidence of control over RTO decisionmaking at lower levels of ownership. These audit reports would be closely reviewed by the Commission and if there is evidence of abuse or unwillingness to cooperate with the auditors, the Commission will not hesitate to order owners to divest themselves of their active ownership interests.

RTO Governing Boards. Many commenters urge us to impose specific, detailed requirements on RTO governance. Commenters make recommendations on many different aspects of governance: the desirability of stakeholder, non-stakeholder or hybrid boards, the size of boards, the relationship between non-stakeholder boards and stakeholder advisory groups, the number of classes for stakeholder boards, the appropriate voting entitlements for individual classes on a stakeholder board; and optimal voting rules. Most of the recommendations seemed to be targeted for RTOs that are ISOs. In the Final Rule, we have decided not to impose any specific requirements on RTO governing boards other than the general requirement that they must satisfy the overall principle that their decisionmaking process should be independent of any market participant or class of participants. We have opted not to impose more detailed

governance requirements for three reasons.

First, we anticipate that RTOs will take many different forms that reflect the needs and different starting points of each region. We expect to see proposals from ISOs, transcos and hybrids. It is unlikely that a single approach to governance will work for the different types of RTOs that are likely to emerge. At this early stage, it would be counterproductive to impose a "one size fits all" approach to governance when RTOs may differ significantly in structure and patterns of ownership.

Second, our experience to date has been largely limited to reviewing governance proposals of ISOs that operate but do not own transmission facilities. A governance model that works for an ISO may not be appropriate for transcos or other types of for-profit transmission enterprises.

Third, even among the ISOs, there are different models of governance. As we noted in the NOPR, the dominant governance model (PJM, New England, New York and the Midwest) for ISOs is a two-tier form of governance. The top tier consists of a non-stakeholder board, while the lower tier consists of advisory committees of stakeholders that may recommend options to the non-stakeholder board. Generally, the top tier has the final decisionmaking authority.³²⁹ In contrast, California, employs a decisionmaking board for its ISO that consists of both stakeholders and non-stakeholders representatives. And we note that the recently passed Texas restructuring law would require a pure stakeholder governing board for the ERCOT ISO. Given the variety of governance forms that exist or are proposed for ISOs and the limited experience with these different approaches, the Commission believes that it is premature to conclude that one form of governance is clearly superior to all other forms in every situation.

Therefore, we will not mandate detailed governance requirements for RTO boards. Instead, the approach that we adopt in the Final Rule is that any RTO governance proposals, whether from an ISO, transco or a hybrid arrangement, will be judged on a case-by-case basis against the overarching standard that its decisionmaking process must be independent of

³²⁹ One exception is the New York ISO where decisionmaking is explicitly shared by a non-stakeholder Board of Directors and stakeholder Management Committee. Modification of the ISO tariffs under the FPA requires approval of the ISO Board and the Management Committee. If they fail to agree on a modification, either the Board or the Management Committee may make a filing under FPA section 206. See Central Hudson Gas & Electric Corp., *et al.*, 88 FERC ¶ 61,138 (1999).

individual market participants and classes of market participants.³³⁰

While we are not imposing any other specific requirements, the Commission believes that it is appropriate to give some general guidance based on the governance arrangements that we have reviewed to date. Where there is a governing board with classes of market participants, we would expect that no one class would be allowed to veto a decision reached by the rest of the board and that no two classes could force through a decision that is opposed by the rest of the board. Where there is a non-stakeholder board, we believe that it is important that this board not become isolated. Both formal and informal mechanisms must exist to ensure that stakeholders can convey their concerns to the non-stakeholder board. Where there are stakeholder committees that advise or share authority with a non-stakeholder board, it is important that there be balanced representation on the stakeholder committees so no one class dominates its recommendations or its decisions.

We note that this general guidance is based on our experience with governance proposals of ISOs. The Commission recognizes that these observations may not be completely relevant for an RTO that intends to operate as a for-profit transmission company. Nevertheless, we emphasize that the common element for all types of RTOs must be that they satisfy the threshold principle that their decisionmaking should be independent of market participants.

Role of State Agencies. We do not impose any specific requirements on the role of state agencies in RTOs. Such specificity would be counterproductive in light of the variation in the legal responsibilities of state commissions and RTO design across regions. However, we agree with NARUC that state commissions "should fully participate in RTO formation and development." When we undertake our collaborative efforts with the industry after issuance of the Final Rule, we encourage state commissions and other state agencies to play a key role in this effort. State involvement is important for several reasons, especially where RTOs are a critical element of the retail choice programs of many states. State commissions are in a unique position to assess whether a particular RTO design will help or hinder their efforts to promote retail competition.

³³⁰ We will require every ISO to submit an audit of the independence of its governance process two years after its approval as an RTO.

Once an RTO becomes operational, it appears that most states believe that it would be inappropriate for a state official, whether a state commission representative or some other state employee, to serve as a voting member of an RTO board. We note that NECPUC, representing the six New England state commissions, was joined by most other state commissions and commenters from other sectors of the industry in recommending that state officials should not be voting members of any RTO governing body. ISO-NE presents three reasons why it would be problematic for a state official to serve as a voting member of an RTO governing board. First, it would create a conflict between the state official's duties as an RTO board member and his or her regulatory or legal responsibilities at the state level. Second, in the case of a multi-state RTO, it would be difficult for an official of one state to represent the interests of other states if the state interests are in conflict. Third, the solution of allowing each state to have its own voting member on the RTO board could lead to large and unwieldy boards for multi-state RTOs.

While most commenters agreed that state officials should not serve as voting members of RTO boards, most of these same commenters were comfortable with allowing state officials to serve as *ex officio* members. It was thought that state officials would be better informed in making their own decisions if they could closely observe the considerations and constraints that were weighed by the RTO in making its decisions. It was thought that the ability of state officials to observe the RTO's decisionmaking process would be especially useful if the RTO had to recommend one or more expansions to the existing grid.

While we see considerable merit in the arguments that state officials should not be voting members of an RTO governing board (and note that most state commissions share this view), the Commission is not imposing such a prohibition. Since RTOs do not yet exist, it would be premature to conclude that state officials should not participate as voting members of RTO boards. There may be special circumstances in some regions that would make it in the public interest to give voting rights to one or more state government representatives. Therefore, we will be willing to entertain such proposals and perhaps revisit the issue after we gain more experience.

Section 205 Filing Rights. In the NOPR, we proposed that the RTO must have exclusive and independent authority to file changes in its transmission tariff under section 205 of

the Federal Power Act. This proposal triggered hundreds of pages of comments. Upon consideration of the comments received, as discussed below, we will modify our proposal, in part, to make clear that transmission owners who do not also operate their transmission facilities retain certain section 205 rights.

Most commenters on this issue fall into two categories. Those who oppose the proposal in the NOPR argue that it is bad law and bad policy. They contend that the Commission does not have the legal authority to grant section 205 rights over their transmission facilities to some other entity. While a transmission owner may voluntarily cede this right to an RTO, they argue that the Commission cannot compel a transmission owner, either directly or indirectly, to give up this legal right. Many transmission owners, representing IOUs, public and cooperative systems, argue that the transfer of this right to an RTO would increase their risk of recovering revenues to which they are lawfully entitled. On the other hand, those who support the proposal argue that it is a necessary and logical implication of our previously stated policy that the "[a]uthority to act unilaterally * * * is a crucial element of a truly independent transmission provider."³³¹ They contend that an RTO will not be able to function as an independent and neutral transmission provider if it has to seek the approval of transmission owners or other market participants every time it wishes to modify its tariff. They point to numerous tariff changes that the various ISOs have had to make as real world evidence of their need to move quickly and make filings at the Commission when they encounter a tariff problem that needs to be corrected.

Based on the comments received, we reaffirm our determination that RTOs, in order to ensure their independence from market participants, must have the independent and exclusive right to make section 205 filings that apply to the rates, terms and conditions of transmission services over the facilities operated by the RTO. This determination, however, is subject to several important clarifications discussed below.

We recognize that for some RTOs (in particular, ISOs), both the transmission owners and the RTO will be public utilities with respect to the same

transmission facilities,³³² *i.e.*, one or more entities will own the facilities and a different entity will operate the facilities and actually sell the transmission provided by the facilities, and that this presents a somewhat unusual situation insofar as sections 205 and 206 of the FPA are concerned. The FPA does not explicitly address who has filing authority or responsibility in this circumstance. We conclude that while the RTO must have independent and exclusive authority to propose changes in the rates, terms and conditions of transmission service provided over the facilities it operates, it also is reasonable for the transmission owners to retain certain independent section 205 filing rights with respect to the level of the revenue requirement that the transmission owners receive from the RTO and that the RTO, in turn, will collect from the transmission customers through its rates. We therefore clarify that a transmission owner must have independent authority to set the level of its portion of the revenue requirement to be collected by the RTO.³³³

Importantly, we further clarify that we expect the authorities of the transmission owners and the RTO to be exercised as follows. The transmission owners may make section 205 filings to establish the payments that the RTO will make to the transmission owners for the use of the transmission facilities that are under the control of the RTO; the RTO, in turn, will make section 205 filings to recover from transmission customers the cost of the payments it makes to transmission owners as well as its own costs, and propose any other changes in the rates, terms and conditions of service to transmission customers. Thus, the transmission owners may have on file a tariff that assures their recovery of transmission revenues from the RTO and, while they may be affecting the level of the RTO's revenue requirement, they will not be permitted to make section 205 filings for RTO services to transmission customers and will not interfere with the independence of the RTO to file proposed changes to the open access tariff.³³⁴

³³² Under FPA section 201(e), a public utility is any person who owns or operates jurisdictional facilities.

³³³ Of course, a transmission owner may voluntarily agree to relinquish this right during the RTO negotiation process or subsequently.

³³⁴ We note that some existing ISOs have adopted an approach where the transmission owners' revenue requirement is filed with the Commission in a separate transmission rate filing (*e.g.*, California ISO), while others incorporate the revenue requirement of the transmission owners, as changed from time to time, in the ISO's tariff. In either case,

³³¹ New England Power Pool, 70 FERC ¶ 61,374 at 62,585 (1997).

We believe this division of filing rights reflects a reasonable interpretation of the FPA as applied to these circumstances, and that it appropriately balances the need to ensure the independence of the RTO with the need to provide transmission owners the opportunity to recover revenues. To avoid unnecessary disputes and coordinate the interaction of these independent section 205 filings, we will require the RTO and the transmission owners to give prior notice to each other of any planned section 205 filings. Further, we strongly encourage transmission owners and RTOs to resolve rate issues prior to the filing of proposed rate changes.

We recognize that the division of filing rights described above may not be the only way to accommodate the concerns raised. Accordingly, the Commission will entertain other approaches as long as they ensure the independent authority of the RTO to seek changes in rates, terms or conditions of transmission service and the ability of transmission owners to protect the level of the revenue needed to recover the costs of their transmission facilities. The Commission will require RTOs to provide a detailed description of the process to allow us to assess its fairness and workability.

2. Scope and Regional Configuration (Characteristic 2)

The NOPR proposed as the second minimum characteristic of an RTO that the RTO must serve an appropriate region—a region of sufficient scope and configuration to permit the RTO to effectively perform its required functions and to support efficient and nondiscriminatory power markets.³³⁷ The NOPR noted that there is likely no one "right" configuration of regions and proposed to establish a set of factors that encourage appropriate regional configuration without prescribing boundaries. The NOPR suggested that a region that is large in scope would facilitate the effective performance of many of the RTO's functions, but also recognized that there may be factors that might limit how large an RTO should be.³³⁸ The NOPR also proposed a set of factors that may affect the location of regional boundaries. These factors indicate that boundaries should facilitate essential RTO functions and goals, recognize trading patterns, mitigate the exercise of market power, do not unnecessarily split existing

only the ISO is authorized to make filings that change the tariff sheets in the ISO's tariff.

³³⁵ FERC Stats. and Regs. at 33,729.

³³⁶ *Id.* at 33,730.

control areas or existing regional transmission entities, encompass contiguous geographic areas and highly interconnected portions of the grid, and take into account useful existing regional boundaries (such as NERC regions) and international boundaries. The NOPR put forth for discussion the appropriateness of existing configurations, such as the three electric interconnections within the continental United States, the ten NERC reliability councils, and the 23 NERC security coordinator areas.

The NOPR also requested comments on what portion of the transmission facilities within an appropriate region the RTO must control in order to be approved as an RTO. The Commission recognized that it might be difficult to obtain 100 percent participation of all transmission owners within a region, but that, on the other hand, it would not be appropriate to approve an RTO proposal that included only a small portion of the facilities of the region. The Commission also requested comments on how much deference the Commission should give to regions proposed to us, and to what extent state commission approval or disapproval should be taken into account.

a. How Should Initial Boundaries be Established? Comments. Most commenters agree with the Commission's proposal not to initially prescribe the boundaries for appropriate regions.³³⁷ Among the rationales asserted by these commenters is that this is a matter best left in the first instance to the stakeholders in the various regions.³³⁸ There should be deference to proposals by transmission owners and market participants.³³⁹ FERC should give deference to state commissions on scope and configuration.³⁴⁰ Boundaries should be determined naturally in a way that facilitates market transactions,³⁴¹ and size and configuration must be determined on a case-by-case basis.³⁴²

However, some commenters argue that the Commission should prescribe regional boundaries. APPA, East Texas Cooperatives, TDU Systems and the Michigan Commission urge that the

³³⁷ See, e.g., South Carolina Authority, Cleco, SRP, LG&E, Detroit Edison, Wyoming Commission, Entergy, UtiliCorp, NECPUC, MidAmerican, Enron/APX/Coral Power, Duke, NASUCA, Industrial Consumers, Connecticut, Massachusetts Division, Iowa Board.

³³⁸ See, e.g., South Carolina Authority, NASUCA, Florida Power Corp.

³³⁹ See, e.g., Entergy, MidAmerican.

³⁴⁰ See, e.g., Southern Company, NECPUC, Nine Commissions, Florida Commission.

³⁴¹ See, e.g., Duke, FirstEnergy, Allegheny, Iowa Board.

³⁴² See, e.g., NYPP.

Commission use section 202(a) authority to establish initial boundaries. APPA asserts that the Commission should establish a rebuttable presumption in favor of specific regional district boundaries based on the topology of the transmission network to enhance system security. East Texas Cooperatives argues that after the Commission established regional districts, the burden would be on those proposing different regions to show that they provide at least the benefits of the prescribed districts. Michigan Commission states that the electricity market is currently too immature to determine by itself the size of the markets, and that firm guidance is needed rather than allowing the RTO boundaries to be set by participants.

Several other commenters do not go as far in asserting that the Commission should initially set boundaries, but argue that the Commission should take a strong role in assuring proper boundaries. For example, Cenergy urges that the Commission be aggressive in establishing boundaries consistent with the proposed criteria, noting that the willingness of the Commission to exercise its authority over boundaries will determine the success of the Commission's restructuring efforts. Coalition of Alliance Users maintains that the Commission should take a direct and active role in formulating RTO boundaries. WEPCO believes that the role of the Commission should be to set criteria that encourage the establishment of sensible RTO boundaries. Project Groups assert that if the stakeholders in a region do not determine boundaries by the end of 2000, the Commission should make the determinations. LG&E states that while the Commission should show deference to voluntary RTOs, it should not hesitate to disapprove proposals with geographic shortcomings.

Commenters express a variety of views regarding whether particular regional configurations would be appropriate. Some commenters support interconnection-wide RTOs as a desirable goal,³⁴³ while others regard either an Eastern or Western interconnection RTO as unworkably large.³⁴⁴

Commenters offer specific ideas about the number and placement of RTOs. PG&E states that the long-term goal should be four or five RTOs nationwide.

³⁴³ See, e.g., South Carolina Authority, Conlon, Industrial Consumers, First Rochdale, Los Angeles, PG&E, Sonat.

³⁴⁴ See, e.g., South Carolina Authority, Desert STAR, MidAmerican, TDU Systems, CREDA, SNWA, CRC, Platte River, PSNM, SRP, Metropolitan.

Williams argues for 3 to 10 RTO nationwide, while Project Groups advocates 3 to 12 RTO nationwide. WEPCO proposes the formation of five RTOs: (1) three in the Eastern interconnection (one covering MAPP, MAIN, ECAR and portions of SPP; one covering SERC, Florida and the rest of SPP; and one covering NPCC and MAAC); (2) one for WSCC; and (3) one for ERCOT. APPA, supported by East Texas Cooperatives, suggests: (1) no more than three RTOs in the West; (2) the combination of PJM, NY ISO and ISO-NE into one RTO with the possible participation of Ontario; (3) the combination of the Alliance RTO, Midwest ISO, and MAPP into one RTO; (4) Kansas to the Carolinas under one RTO; and (5) separate RTOs for Florida, ERCOT and Hydro-Quebec.

With respect to specific regions, ISO-NE contends that it already operates a region of appropriate size and configuration. Mass Companies agrees that ISO-NE is an appropriate region. NYC argues that the formation of a northeastern RTO with a broader geographic scope than the NY ISO would help remove existing institutional impediments to the construction of new transmission lines. American Forest argues that PJM is too small, while NASUCA and Mid-Atlantic Commissions believe that PJM satisfies the size criteria. Some commenters object to a split between the area represented by the proposed Alliance RTO and the Midwest ISO.³⁴⁵ Most of the Florida commenters assert that peninsular Florida represents an appropriate region.³⁴⁶ For example, Florida Commission claims that peninsular Florida is a large and efficient marketplace that does not share parallel flows with other electrical regions; however, it states that the Florida panhandle could be in a region with all of SERC or a subregion of SERC.

Although some commenters encourage a Western interconnection-wide RTO, the majority of commenters support three or four RTOs for the Western interconnection, noting that the interests in the WSCC are too diverse and the area too large for control by a single entity.³⁴⁷ Cal ISO contends that California satisfies the minimum size criteria, but does not represent the maximum feasible area. Commenters from the Pacific Northwest generally agree that a region including Washington, Oregon, and all or portions

of Idaho and Montana is distinct enough to warrant an RTO limited to that area.³⁴⁸ CREDA and Platte River envision one RTO for the Pacific Northwest, one for California and one for the Rocky Mountain/Desert Southwest area; CRC suggests a similar alignment, with the exception of the Rocky Mountain and Southwest areas as separate RTOs.

A number of commenters make the point that, regardless of where RTO boundaries are drawn, it is important that there be integration and coordination among RTOs.³⁴⁹ NERC believes that there are two seams issues: reliability practices across seams and market practices across seams. TDU Systems suggests that there be a set of regions for reliability/operations purposes within a larger region for rates and scheduling. Industrial Consumers state that, if multiple RTOs are formed within an interconnection, RTOs should be required to coordinate their operations to collectively "simulate" an interconnection-wide RTO. Cinergy suggests that, if there were more than one RTO in a large interconnection, a "super" RTO could be established to operate and coordinate inter-RTO activities. Montana Commission states that RTO boundaries are less important than ensuring that seams do not interfere with the market, and proposes, as do others such as Ontario Power and CMUA, that the Commission require adjacent RTOs to embody consistent methods of access, pricing, and congestion management to encourage seamless trading. PacifiCorp asserts that reciprocity agreements among RTOs may be easier to achieve than having all parties in a large region agree to one RTO. Allegheny suggests that appropriate transmission pricing could provide some of the same benefits as a large RTO.

Several commenters express concern that multiple RTO proposals for the same region will be submitted. Indiana Commission contends that the NOPR leaves the door open for more than one RTO proposal for approximately the same wholesale power market region and this could limit the operational efficiency and increase the cost of transmission in the region. It suggests that the Commission consider requiring formal mediation or play an assertive role in such circumstances. Snohomish suggests favoring the RTO proposal that is negotiated pursuant to the most open process that included consumers, transmission dependent utilities and

others with a vital interest in the effective and efficient operation of the transmission grid. Midwest ISO Participants submit that the proponents of multiple RTOs meet a heavy burden and demonstrate the need for more than one RTO. In particular, it would require demonstration that the proposals: do not balkanize the market; allow for effective congestion relief; maintain reliability; facilitate construction of new transmission facilities; and allow for effective tariff administration and unbiased ATC determination throughout the region.

Commission Conclusion. We adopt the NOPR proposal on this characteristic. All RTO proposals filed with us must identify a region of appropriate scope and configuration. The scope and configuration of the regions in which RTOs are to operate will significantly affect how well they will be able to achieve the necessary regulatory, reliability, operational, and competitive benefits.

As proposed in the NOPR, we will not at this time prescribe initial boundaries for RTOs. Section 202(a) of the FPA does give us the authority, after consultation with state commissions, to fix and modify boundaries for regional districts for the voluntary interconnection and coordination of facilities. We acknowledge those commenters who believe that it may be more efficient for the Commission to establish at least a rebuttable presumption that particular boundaries are appropriate starting points. However, we conclude, as a matter of policy, that we should not attempt to draw boundaries at this time. We are convinced that the transmission owners, market participants, and regulators in a particular region have a better understanding of the dynamics of the transmission system in that region, and that they should, at least in the first instance, propose the appropriate scope and regional configuration of an RTO. There are many technical considerations involved in discerning the appropriate scope and regional configuration of an RTO, and we believe that those most familiar with such considerations in a region are in a better position to propose a workable solution.

As noted above, some commenters advocate that the NERC regions be starting points; others advocate that the Interconnections be the goal; and still others propose specific configurations that would divide the Nation as many as three to 12 RTOs. Consistent with our decision to let the parties take the initiative to propose what is appropriate for their region, we will not specifically

³⁴⁵ See, e.g., Michigan Commission, South Carolina Authority, Midwest ISO, Midwest ISO Participants, NASUCA.

³⁴⁶ See, e.g., Florida Commission, JEA, FP&L, Florida Power Corp., Tallahassee, Gainesville.

³⁴⁷ See, e.g., SRP, Metropolitan.

³⁴⁸ See, e.g., Seattle, PGE, Industrial Customers, BC Hydro, Powerex, Tacoma Power, PNGC.

³⁴⁹ See, e.g., South Carolina Authority, SPP.

endorse any particular scheme for RTO configuration.

This is not to say, however, that we will deem appropriate any regional configuration proposed. As stated in the regulatory text for this characteristic, an appropriate region is one of sufficient scope and configuration to permit the RTO to effectively perform its required functions and to support efficient and nondiscriminatory power markets. A proposed RTO could simply be too limited to satisfy several of the necessary functions. Further, we are aware that transmission owners could seek to gain strategic advantage by the way an RTO is formed. For example, an RTO could be placed to act as a toll collector on a critical corridor.³⁵⁰ An RTO could propose a configuration that interferes with the formation of a larger, more appropriately configured RTO.

As we review a proposal by a regional transmission entity for its scope and regional configuration, if we determine that the scope is inappropriate, that entity will not be deemed to be an RTO, and its participants will not be deemed to be RTO participants.³⁵¹ In response to the commenters questioning what the Commission would do if it received multiple RTO proposals for a region, we note that we hope the collaborative process we are encouraging in this Final Rule would foreclose that circumstance. However, if we are faced with multiple proposals, we would have to determine which RTO proposal best meets the objectives of this Rule.

As we stated in the NOPR, we are aware that there is likely no one "right" configuration of regions. One particular boundary may satisfy one desirable RTO objective and conflict with another. We recognize here, and elsewhere in this Final Rule,³⁵² that the industry will continue to evolve, and the appropriate regional configurations will likely change over time with technological and market developments. The Commission is also mindful of the interests of individual states regarding RTO boundaries. Given all these considerations, the Commission believes that the public interest will best be served if we provide guidance in this Final Rule, in the form of factors that affect appropriate regional configuration, without actually prescribing boundaries.

b. Scope and Configuration Factors.
Comments. A large number of

commenters agree that the factors listed in the NOPR for determining a proper scope and configuration for an RTO are generally appropriate.³⁵³ Industrial Consumers propose that the factors be codified as part of our regulations. Florida Commission, on the other hand, argues that the factors should not be mandated as part of the Commission's regulations.

Many commenters argue that the RTO region should be as large as possible, *i.e.*, bigger is better.³⁵⁴ Several commenters suggest the minimum size should be the NERC regions.³⁵⁵ Conlon suggests a minimum area should be one containing a load of 50,000 MW. PJM states that its organization demonstrates that a very large RTO is feasible, in that it manages a grid serving more than 57,000 MW of generation and containing more than 8,000 miles of high voltage transmission lines. PJM states that even larger control areas are possible as technology advances. PJM/NEPOOL Customers, claiming that all potential factors that might limit size can be overcome, argue that the Commission should not conclude that there are factors that limit size. As discussed below with respect to the congestion management function, some commenters make a particular point of emphasizing the importance of large scope to effective congestion management.³⁵⁶

Other commenters argue that bigger is not necessarily better and that there are factors that limit size.³⁵⁷ CMUA argues that the role of security coordinator and operational characteristics of a region may limit geographic scope. STDUG claims that size breeds inefficiency. Several commenters claim that requiring maximum scope upon creation may discourage RTO formation or make it more costly and take longer to achieve.³⁵⁸ NYPP expresses concern that, if an RTO is too large, it may not

be able to handle local reliability issues. Other commenters believe that the ability to plan new transmission facilities may limit scope.³⁵⁹ AEPSCO expresses concern that the voice of smaller participants could be lost in a larger RTO. Florida Power Corp. claims that there may be a security risk associated with concentrating control of too large an area into a single facility, and that large areas of non-pancaked rates may eliminate incentives for proper generator siting decisions. A number of commenters believe that either the Eastern interconnection or the Western interconnection is too large an area to be controlled by one RTO.³⁶⁰ New York Commission argues that the Commission should recognize that experience must be gained in stages before an RTO encompassing an entire interconnection can be implemented. Several commenters in the Pacific Northwest cite the failed attempt to create IndeGo as evidence that trying to create too large an RTO is unworkable, and at some point "bigger" creates more problems than it solves.³⁶¹

Some commenters offer subjective parameters for the scope of an RTO. For example, SNWA proposes that the RTO be large enough to accommodate as many market participants as possible, but not so large as to be overly burdensome to manage. SRP argues that a balance must be struck between an RTO that is too small to cover a meaningful wholesale power market and one that is too large to form and operate effectively. TDU Systems argue that RTOs should comprise the largest regions that could operate in a coordinated fashion within a short period of time with reasonable investments of funds.

A number of commenters emphasize particular factors that they consider important in determining scope and configuration. Some commenters assert that reliability and system security should be the primary determinant of scope and configuration.³⁶² Others place prime importance on trading patterns and facilitating market transactions.³⁶³ EEI states that the most efficient size and configuration of an RTO should be left to the market to determine. Other commenters propose electrical

³⁵³ See, e.g., UtiliCorp, Desert STAR, Midwest ISO Participants, Metropolitan, NECPUC, LG&E, PJM/NEPOOL Customers, Midwest Municipals, Industrial Consumers, Dairyland, TDU Systems, ISO-NE, Midwest Energy, APX, APPA, Cal ISO.

³⁵⁴ See, e.g., Cinergy, American Forest, EPSA, UtiliCorp, PG&E, NSP, Pennsylvania Commission, NJBUS, LG&E, Enron/APX/Coral Power, NASUCA, PJM/NEPOOL Customers, Cal ISO, Texas Commission, Conlon, Dynegy, Nine Commissions, Michigan Commission, Lincoln, WPSC, First Rochdale, East Texas Cooperatives, Los Angeles, Ohio Commission, EME, Ontario Power, H.Q. Energy Services, Ogelthorpe, UMPA, PG&E, Indiana Commission.

³⁵⁵ See, e.g., Cinergy, WPSC, Lincoln, Ohio Commission, PG&E.

³⁵⁶ See, e.g., LG&E, ComEd, Midwest ISO Participants, Midwest ISO.

³⁵⁷ See, e.g., AEPSCO, Tallahassee.

³⁵⁸ See, e.g., Enron/APX/Coral Power, FirstEnergy, Tri-State.

³⁵⁹ See, e.g., Dairyland, Minnesota Power.

³⁶⁰ See, e.g., South Carolina Authority, Desert STAR, MidAmerican, TDU Systems, CREDA, SNWA, CRC, Platte River, PSNM, SRP, Metropolitan.

³⁶¹ See, e.g., Industrial Customers, Powerex, Tacoma Power.

³⁶² See, e.g., CMUA, APPA, Florida Commission, Minnesota Commission.

³⁶³ See, e.g., UtiliCorp, Reliant, Duke, South Carolina Commission, NU, Florida Power Corp., Detroit Edison.

³⁵⁰ See Statement of Ohio Commission Chairman Craig Glazer, RTO Conference (St. Louis), transcript at 85-87.

³⁵¹ The proposal could be accepted, however, as something less than an RTO that represents an improvement over the status quo.

³⁵² See section F on Open Architecture.

configuration and physical power flows as important factors.³⁶⁴ CREDA and Desert STAR argue that the preservation of a Federal Power Marketing Administration project marketing area is an important consideration. Chelan argues that cost shifts need to be considered in determining scope. Platte River contends that established security coordinators should be a factor. Southern Company argues that joint ownership agreements should be a factor. Tacoma Power claims that traditional business relationships and social and political commonality are factors that affect scope.

Commenters are divided on whether points where transmission facilities are constrained should be used as an RTO boundary or internalized within an RTO. Some commenters claim that constraints should be internalized to the extent possible and not constitute boundaries between regions.³⁶⁵ NERC states that boundaries should not be placed at weak interconnections because a single entity is better able to strengthen them. On the other hand, other commenters believe that constrained facilities should constitute the boundaries, either because they may form a natural boundary between robust systems or because it makes more sense to internalize markets than to internalize constraints.³⁶⁶ APPA states that, because it is not possible to internalize all constraints, the goal should be to alleviate or mitigate the effects of interregional constraints through additional construction and RTO operating rules and pricing policies. NECPUC argues that it does not matter where constraints are if compatible methods of locational pricing are adopted by contiguous RTOs. Mid-American and Duke assert that constraints are not natural boundaries between regions because the location of points of constraint change over time as market conditions change. Several commenters, such as Dairyland and Desert STAR, take the position that the issue whether to design RTO boundaries at constrained interfaces cannot be stated generically, and must be decided on a case-by-case basis.

Commission Conclusion. The factors we believe should be used to develop appropriate regions are set out here and called regional configuration factors. These cover such considerations as how large a region should be and how boundaries should be evaluated. We do

not see a benefit to placing them in regulatory text, as suggested by one commenter, and we will not do so. The factors are intended as guidance and, as such, must necessarily be applied flexibly.

Regional Configuration Factors. As stated above, the principal consideration in evaluating the appropriate scope of an RTO is that such scope must permit the RTO to perform its functions effectively. As we stated in the NOPR, many of the characteristics and functions for an RTO proposed in this section suggest that the regional configuration of a proposed RTO should be large in scope.³⁶⁷ For example:

- Making accurate and reliable ATC determinations: An RTO of sufficient regional scope can make more accurate determinations of ATC across a larger portion of the grid using consistent assumptions and criteria.
- Resolving loop flow issues: An RTO of sufficient regional scope would internalize loop flow and address loop flow problems over a larger region.
- Managing transmission congestion: A single transmission operator over a large area can more effectively prevent and manage transmission congestion.
- Offering transmission service at non-pancaked rates: Competitive benefits result from eliminating pancaked transmission rates within the broadest possible energy trading area.
- Improving Operations: A single OASIS operator over an area of sufficient regional scope will better allocate scarcity as regional transmission demand is assessed; promote simplicity and "one-stop shopping" by reserving and scheduling transmission use over a larger area; and lower costs by reducing the number of OASIS sites.
- Planning and coordinating transmission expansion: Necessary transmission expansion would be more efficient if planned and coordinated over a larger region.

We note that the comments on this issue express a range of views. Many commenters assert that the bigger the RTO is the better, and that there really are no serious limitations to RTOs representing loads as large as several hundred thousand megawatts. Other commenters suggest a number of considerations that may militate against RTOs that are too large, including the role of security coordinator, operational

characteristics, costs of formation, local reliability issues, and the effect on smaller participants. In the NOPR, we recognized that there may be a limitation on how many facilities or transactions can be overseen reliably by a single operator, imposed either by hardware design or costs, or imposed by human limitations to process the required amount of information. We further recognized that the difficulty and cost of transferring operational control over many transmission systems to one RTO may affect regional configuration. We also noted that, as regions get larger and involve more existing owners of transmission, reaching consensus on an appropriate transmission rate design for the region may prove challenging.

We note that a number of commenters make the point that, at least for some purposes and functions, the scope of an individual RTO is less important if it is part of a group of RTOs that have adequately eliminated the negative effects of "seams" between itself and the other RTOs. NERC identifies two seams issues: reliability practices across seams and market practices across seams. We further note that other commenters suggest that large RTOs could be "simulated" through coordinated operations and consistent methods of access, pricing, and congestion management, and that there may be different acceptable scopes for reliability and operations purposes on one hand, and rates and scheduling on the other.³⁶⁸ We also detect a common theme that runs through a number of comments: large geographic size is most important for trading areas. Thus, the concept of large "seamless trading areas" for power emerges as a "scope" issue that is distinct from the scope of the region for organizing the transmission functions of an RTO.

We conclude that a large scope is important for an RTO to effectively perform its required functions and to support efficient and nondiscriminatory power markets. Adequate scope is not necessarily determined by geographic distance alone; other factors include the numbers of buyers and sellers covered by the RTO, the amount of load served, and the number of miles of transmission lines under operational control. The scope must be large enough to achieve

³⁶⁴ See, e.g., South Carolina Authority, Williams, NSP, Dynegy.

³⁶⁵ See, e.g., Industrial Consumers, First Rochdale, Minnesota Power, STDUG, NARUC.

³⁶⁶ See, e.g., Ohio Commission, EAL, Florida Power Corp.

³⁶⁷ This reiterates the conclusion we reached in the eleven ISO principles in Order No. 888, where we stated that "[t]he portion of the transmission grid operated by a single ISO should be as large as possible." Order No. 888, FERC Stats. & Regs. ¶ 31.036 at 31.731.

³⁶⁸ In a recent conference to address interregional ISO coordination in the northeast, the three northeast ISOs (ISO New England, New York ISO, and PJM ISO) and other market participants discussed current and future coordination efforts among the ISOs intended to simplify market transactions and enhance reliability in the northeast. See <http://www.dps.state.ny.us/isoconf.htm>.

the regulatory, reliability, operational and competitive objectives of this Rule.

We are receptive to flexible and innovative ways for an RTO to achieve sufficient scope. Where a proposed regional transmission entity may be of sufficient scope for some RTO purposes, but not others, an RTO may be able to achieve sufficient "effective scope" by coordination and agreements with neighboring entities, or by participating in a group of RTOs with either hierarchical control or a system of very close coordination. We do not foreclose the possibility that an RTO may satisfy some of the minimum characteristics and functions by itself, while satisfying others through a strong cooperative agreement with neighboring RTOs to create a "seamless trading area." The functions of a large RTO may be met by eliminating the effect of seams separating smaller RTOs through a contract or other coordination arrangement. One of our concerns about an RTO's scope is that the existing impediments to trade, reliability, and operational efficiency be eliminated to the greatest extent possible. However, an RTO application that proposes to rely on "effective scope" to satisfy Characteristic 2 must demonstrate that the arrangement it proposes to eliminate the effect of seams is the practical equivalent of eliminating the seams by forming a larger RTO.

Factors for Evaluating Boundaries. In addition to the factors affecting the size of a region, other factors may affect the delineation of regional boundaries. As stated in the NOPR, the Commission proposed that RTO boundaries be drawn so as to facilitate and optimize the competitive, reliability, efficiency and other benefits that RTOs are intended to achieve, as well as to avoid unnecessary disruption to existing institutions. The Commission proposed in the NOPR a list of factors it would consider in evaluating the configuration for a proposed RTO. Nearly all of the comments agree that these factors are generally appropriate.

We recognize that different factors may suggest different configurations and that assessing the appropriateness of a region's configuration will require balancing factors and a flexible approach. Given this qualification, the Commission, in evaluating an RTO's boundaries, will consider the extent to which the proposed boundaries:

Facilitate performing essential RTO functions and achieving RTO goals: The regions should be configured so that an RTO operating therein can ensure non-discrimination and enhance efficiency in the provision of transmission and ancillary services, maintain and

enhance reliability, encourage competitive energy markets, promote overall operating efficiency, and facilitate efficient expansion of the transmission grid. For example, we understand that there have been instances where transmission system reliability was jeopardized due to the lack of adequate real-time communication between separate transmission operators in times of system emergencies. To the extent possible, RTO boundaries should encompass areas for which real-time communication is critical, and unified operation is preferred.

Encompass one contiguous geographic area: The competitive, efficiency, reliability, and other benefits of RTOs can be best achieved if there is one transmission operator in a region. To be most effective, that operator should have control over all transmission facilities within a large geographic area, including the transmission facilities of non-public utility entities. This consideration could preclude a noncontiguous region, or a region with "holes." However, as we discuss below, we will not automatically deny RTO status where the RTO is not able to obtain full participation in its region.

Encompass a highly interconnected portion of the grid: To promote reliability and efficiency, portions of the transmission grid that are highly integrated and interdependent should not be divided into separate RTOs. One RTO operating the integrated facilities can better manage the grid. This is not to say, however, that every weak interconnection belongs on a regional boundary. Where a weak interface is frequently constrained and acts as a barrier to trade, it may be appropriate to place that interface within an RTO region. It may be more difficult to expand a weak interface on the boundary between two regions; this may act as a barrier to trade between the two regions.³⁶⁹

Deter the exercise of market power: While the industry should work toward a goal of virtually seamless trade between RTOs, it may be that initially a significant amount of trade may be contained within an RTO, especially if the RTO or the market establishes a power exchange that covers the same area as the RTO. Thus, to have a competitive market, it is important to

³⁶⁹ Commenters are also divided on whether weak interfaces should be encompassed within an RTO or act as a natural boundary. After consideration, we conclude that there is not a universal answer applicable to all situations. Consequently, we will address this issue as it arises in RTO proposals on a case-by-case basis.

create an RTO region that is not dominated by a few buyers or sellers of energy. Also, the RTO configuration should not be one where the RTO participants can exercise transmission market power by collecting congestion fees on a critical corridor.

Recognize trading patterns: Given that a goal of this initiative is to promote competition in electricity markets, regions should be configured so as to recognize trading patterns, and be capable of supporting trade over a large area, and not perpetuate unnecessary barriers between energy buyers and sellers. There may exist today some infrastructure or institutional barriers unnecessarily inhibiting trade between regions that could be economically reduced. RTO boundaries should not perpetuate these unnecessary and uneconomic barriers.

Take into account existing regional boundaries (e.g., NERC regions) to the extent consistent with the Commission's goals for RTOs: An RTO's configuration should, to the extent possible, not disrupt existing useful institutions. The Commission recognizes that utilities have been working together regionally in different contexts for some time, and that there is value in preserving historical institutions and relationships; but we also recognize that in the evolving market, efficiencies may call for new configurations.

Encompass existing regional transmission entities: Because existing ISOs, and any other regional transmission entities we may hereafter approve, already integrate transmission systems, it may not be efficient to divide them into different regions. This is not to say, however, that RTO boundaries must coincide with existing regional transmission entities. An appropriate region may well be larger, and there may be circumstances that support combining or reconfiguring existing entities.

Encompass existing control areas: Many existing control areas are relatively small. It may be advisable not to divide them further. However, parties would not be precluded from proposing to divide a control area if they show this to be beneficial.

Take into account international boundaries: The Commission recognizes that natural transmission boundaries do not necessarily coincide with international boundaries. Indeed, a large part of Canada's transmission system, and a small part of Mexico's transmission grid, is interconnected on a synchronous basis with that of the U.S. Accordingly, an appropriate region need not stop at the international boundary. However, this Commission

does not have, and is not intending by this rule to seek, jurisdiction over the facilities in a foreign country. We will ask our international neighbors to participate in discussion of these issues. Perhaps what may be thought of as a "dotted line" boundary at the international border could be used to indicate that a natural transmission region does not necessarily stop at the border, while this Commission's jurisdiction does.

Although most commenters generally support these factors, other considerations are proposed as factors. For example, some commenters claim that we should make reliability and system security the dominant factor, while other commenters propose that we make trading patterns and market transactions the dominant factor. After consideration, we do not think it appropriate to identify one factor as the most important. Although it is essential that reliability not be jeopardized by RTO formation, and it is important to promote competition, we do not believe that one goal needs to be sacrificed to achieve the other.

Other commenters suggest additional factors that they deemed important to RTO boundaries, including, for example, established security coordinators, joint ownership arrangements, and Federal power marketing administration project marketing areas. We do not intend the factors we have listed to be exclusive: other factors may have merit for a particular region. We encourage parties to identify additional factors they believe relevant as we consider specific RTO proposals.

c. Control of Facilities Within a Region. We proposed in the NOPR to accept as RTOs only those proposals for which a region of appropriate scope and configuration is identified and the proponents represent a large majority of the transmission facilities within the identified region. We solicited comments on how best to balance our goal of having RTOs in place that operate all transmission facilities within an appropriately sized and configured region against the reality that there may be difficulties in obtaining 100-percent participation in all regions in the near term. We asked if we should deny RTO status for any proposal that does not include all transmission facilities within an appropriate region, or if we should require that the RTO at least negotiate certain agreements with any non-participants within its region to ensure maximum coordination.

Comments. Almost all commenters argue that RTO status should not be withheld if the RTO participants are

unable to obtain participation by all transmission owners in the region.³⁷⁰ Several commenters, such as Desert STAR and Minnesota Power, note that, if the Commission does not mandate 100 percent participation, it does not make sense to make it a condition of RTO approval. Other commenters propose standards to consider in determining when a proposed RTO represents sufficient facilities in the region. For example, Desert STAR suggests that the RTO have more than a majority of transmission owners and has not restricted membership. Southern Company proposes a standard that sufficient facilities include most of the major transmission facilities and the RTO can show benefits. MidAmerican proposes that the RTO be able to demonstrate that it would improve the wholesale market of any subregion of the country without hindering the wholesale market of any other region of the country. Enron/APX/Coral Power argues that an RTO should be approved if it provides an improvement even with "gaps." Midwest Municipals believe that an RTO should be accepted if the Commission can make the judgment that the proposal with "gaps" is likely to encourage others to join through the strength of its operations and the facilities support the development of a competitive generation market. CRC suggests a standard that the proponents make a showing that they have diligently tried to accommodate the concerns and needs of the nonparticipating transmission owners.

Some commenters, such as NJBUS and Cal ISO, believe that an RTO should include the participation of all jurisdictional transmission owners in the region. Duke, however, opposes any attempt by the Commission to determine the appropriate level of participation, stating that the market should determine the participation level. Some commenters, such as Metropolitan, support having the RTO develop coordinated operations agreements with non-participants, while other commenters, such as Avista and Duke, caution that requiring such agreements would be contrary to market principles and would give the non-participating party too much bargaining power.

Seattle contends that the Commission should guard against utilities that would add to the RTO some facilities that are not necessary for RTO operations merely to obtain incentives. It argues

³⁷⁰ See, e.g., Desert STAR, Southern Company, Metropolitan, MidAmerican, Nevada Commission, Avista, Enron/APX/Coral Power, Duke, PJM/NEPOOL Customers, Cal ISO, Midwest Municipals, CRC, NPRB, Minnesota Power, Tri-State, TVA.

that small municipal control areas should have some latitude to determine which of their facilities are regional for RTO purposes. Seattle also questions what "participation" entails for a utility that has limited transmission facilities.

Commission Conclusion. To satisfy the scope and configuration characteristic of this Final Rule, all or most of the transmission facilities in a region must be included in the RTO. Any RTO proposal filed with us should intend to operate all transmission facilities within its proposed region.

We recognize, however, that the proponents of an RTO may not be able to obtain agreement by all transmission owners in a region of appropriate scope and configuration to transfer operating control of their facilities to the RTO. This may occur, for example, because certain facilities may be owned by governmental entities that have restrictions on transfer of control that may require time to resolve. We do not believe that it would be desirable to deny RTO status or delay RTO start-up where the transmission owners representing a large majority of the facilities within a region are ready to move forward, while a few others are not. On the other hand, we do not believe it would be desirable to approve an RTO proposal for a region if the proponents represent only a small portion of the facilities in an otherwise satisfactory region.

Not knowing the full extent of difficulties that may be involved to achieve participation by all transmission facilities, we will not decide generically to automatically deny RTO status for lack of full participation. If an RTO proposal does not cover all the transmission facilities within its proposed region, it should identify the reasons for this, any continuing efforts to include all facilities, and any interim arrangements with the non-represented facility owners to coordinate transmission functions within the region. The Commission may at a future time determine whether the use of its authorities under FPA sections 202(a) and 206 is appropriate to rationalize proposed regions in order to accomplish the objectives of those sections, as discussed elsewhere in this Final Rule.

3. Operational Authority (Characteristic 3)

In the NOPR, the Commission proposed that the RTO have operational authority for all transmission facilities under its control.³⁷¹ We stated that this

³⁷¹ FERC Stats. & Regs. ¶ 32,541 at 33,734 and proposed § 35.34(i)(3). In the NOPR, we used the terms "operational authority" and "operational

requirement raised two questions: Which functions must an RTO perform? How should an RTO perform the functions that it has reserved for itself? With respect to the question of which functions an RTO should perform, the Commission proposed that, at a minimum, the RTO must have operational authority over all transmission facilities transferred to the RTO and must be the security coordinator for its region.³⁷² As security coordinator, the RTO would be responsible for real-time monitoring of system conditions (including voltage, frequency, transmission and generation availability, and power flows) in order to anticipate potential reliability problems, and for directing and coordinating relief procedures to respond to transmission loading problems (such as assisting the control area in alleviating the loading, halting additional interchange transactions, reallocating the use of the transmission system, selecting the transmission loading relief procedure, and implementing emergency procedures, including directing that the control area immediately redispatch generation, reconfigure transmission or reduce load). Those proposing an RTO may also decide to have their RTO perform other traditional control area functions (such as maintaining the energy balance, interchange schedules and system frequency). The Commission proposed, however, that an RTO would not be required to be a single control area because of concerns over potentially high costs and technical limitations. Instead those proposing an RTO would be given flexibility in determining the best division of functions between the RTO and any providers of other control area functions if there are no other grid operators in its region. However, the Commission insisted that an RTO must be ultimately responsible for providing reliable and non-discriminatory transmission service.³⁷³

With respect to the second question of how an RTO will perform its functions, the Commission proposed that an RTO be given considerable flexibility in determining whether it will control facilities directly, delegate functions, or use a combination of these methods.³⁷⁴ For example, we stated that an RTO proposal could have the RTO operate a

responsibility" interchangeably. For purposes of clarity and consistency, we will use only the term "operational authority" to describe this function and have revised the proposed regulatory text accordingly.

³⁷² FERC Stats. & Regs. ¶ 32.541 at 33,734 and proposed § 35.34(i)(3)(ii).

³⁷³ *Id.*

³⁷⁴ *Id.* and proposed § 35.34(i)(3)(i).

single control area, or establish a master-satellite hierarchical control structure with one central and multiple distributed control centers (in either case it could propose to lease equipment and convert employees from existing control centers).³⁷⁵ The Commission also proposed that the RTO must submit a public report assessing its operational arrangements no later than two years after it begins operations.³⁷⁶

Comments. Comments on the Functions an RTO Must Perform. Most commenters agree that the RTO must have operational authority³⁷⁷ for the transmission facilities under its control.³⁷⁸ Some commenters claim that this authority is necessary to prevent anticompetitive behavior by transmission owners.³⁷⁹ Some commenters further contend that this authority must extend to all facilities involved in wholesale transactions so that the transmission owner does not retain control of "access ramps" that happen to be at low (34kV or 69kV) voltage levels.³⁸⁰ In contrast, some utilities express concern that RTO authority over low voltage facilities will unnecessarily complicate operations.³⁸¹

Several commenters oppose operational authority over the transmission system by the RTO. Some commenters claim that the Commission does not have the legal authority to require transmission owners to transfer control to any other entity.³⁸² Midwest Energy and SPP believe a transfer of authority would be too costly to implement. Other commenters maintain that the owner and operator of the

transmission system must be the same entity in order to avoid liability disputes.³⁸³ Mass Companies suggests that transmission owners retain authority to ensure the safe and prudent management of their facilities. ComEd suggests that transmission owners retain operational authority with the RTO having oversight responsibility.

Commenters are divided whether the RTO should be required to be a control area operator. The existing ISOs in California, New England and PJM, which are all control area operators, report that this structure is working in their regions. Some commenters express concern over potential harm to competitive markets if control area authority is not transferred to an independent entity.³⁸⁴ ICUA recommends that the RTO be the sole control area operator. Many other commenters support a single control area as the ultimate goal, but suggest that the RTO be allowed to evolve to this structure and not be required to consolidate control areas immediately.³⁸⁵ Other commenters express concern about potential costs associated with control area consolidation, but agree that such action would be acceptable if and when the RTO decides it is necessary for reliability or other reasons.³⁸⁶

Commenters that oppose requiring control area consolidation provide a variety of reasons.³⁸⁷ Enron/APX/Coral Power state that only an RTO that is a transco should perform control area functions. The Florida Commission is concerned that control area consolidation may result in a security risk. Tri-State and WEPCO believe that there are higher priorities in RTO development (such as eliminating pancaking, and promoting regional system planning) and that emphasizing control area consolidation may inhibit RTO formation.

With respect to specific control area functions, numerous commenters discuss the need for an RTO to have some control of generation in order to ensure system reliability, especially

³⁸³ See, e.g., Florida Power Corp., Georgia Transmission, JEA, MidAmerican, Southern Company, Enron/APX/Coral Power.

³⁸⁴ See, e.g., APPA, APS, Arkansas Consumers, NASUGA, NJBUS, TDU Systems.

³⁸⁵ See, e.g., Conlon, Illinois Commission, Los Angeles, First Energy, Minnesota Power, SRP, TDU Systems.

³⁸⁶ See, e.g., CP&L, ECAR, EEI, Entergy, EPSA, Southern Company.

³⁸⁷ It appears that the Florida Commission and JEA believe that such a transfer would involve RTO control of retail dispatch. It also appears that Dynergy believes that the basic control area function of frequency control is identical to dynamic scheduling, which they believe should not be centralized or consolidated.

³⁷⁵ *Id.*

³⁷⁶ *Id.* at 33,735.

³⁷⁷ Operational authority refers to the authority to control transmission facilities, either directly or through contractual agreements with the entities that do have direct control. In contrast, security coordination refers to real-time monitoring of system conditions in order to anticipate potential reliability problems, and directing and coordinating relief procedures to respond to transmission loading problems.

³⁷⁸ See, e.g., APPA, Cal ISO, Duke, East Texas Cooperatives, Entergy, EPSA, First Rochdale, Georgia Transmission, Illinois Commission, IMEA, ISO-NE, Michigan Commission, Minnesota Power, Montana-Dakota, NASUCA, NECPUC, Nevada Commission, Mid-Atlantic Commissions, PacifiCorp, PJM, PJM/NEPOOL Customers, SNWA, Southern Company, SRP, SPRA, Tri-State, UtiliCorp, WPSC.

³⁷⁹ See, e.g., Illinois Commission, IMEA, NASUGA, PJM/NEPOOL Customers.

³⁸⁰ See, e.g., First Rochdale, IMEA, UMPA.

³⁸¹ See, e.g., Montana-Dakota, Tacoma Power.

³⁸² See, e.g., Florida Commission, Puget. It appears that the Florida Commission interprets a transfer of operational control as a transfer of retail dispatch authority. Although other commenters such as WPSC believe that the RTO having operational authority, they believe that the Commission may need legislative action to obtain the authority to require such a transfer.

during emergency situations.³⁸⁸ Minnesota Power suggests that the Commission include "control generation as required to ensure reliability" as an additional minimum function in the final rule. It also recommends that responsibility for area control error (ACE) and automatic generation control (AGC) be transferred to the RTO as control area functions because separating these functions from transmission operations can lead to reliability problems. Other commenters request that the balancing function be transferred to the RTO to prevent discriminatory behavior by transmission owners.³⁸⁹

There is widespread agreement among commenters that the RTO must be the security coordinator. Marketers, utilities, existing ISOs and customers all agree that coordination and reliability will be enhanced if a regional organization is responsible for maintaining grid security.³⁹⁰ Some commenters state that the authority of a security coordinator to receive commercially sensitive information to order the curtailment of transactions and the shedding of firm load also grants it the ability to favor its own merchant functions. Confidence in comparable and non-discriminatory transmission service, therefore, will be improved if these functions are performed by an entity that is independent of all market participants.³⁹¹ Though essentially in support of our proposal, NERC and MidAmerican assert that it is not necessary to link each RTO to a single security center, but rather it is possible to allow a single security coordinator to assume responsibility for more than one RTO. NERC points out that if an RTO performs all the characteristics and functions specified in the NOPR, it will necessarily be a security coordinator.

A number of parties state that the RTO must have access to real-time system information in order to perform

its functions as security coordinator.³⁹² Montana-Dakota explains further that security centers, by definition, will be equipped with the hardware and software required to assume basic operational control of the system, which are beyond that required strictly for security functions.

Only two commenters express concern over the need for the RTO to be the security coordinator. ComEd, though supporting some security functions for the RTO, asserts that the RTO's role can be limited simply to one of oversight. ComEd does not believe that the RTO needs access to real-time data, and instead would allow the individual control areas to perform the bulk of the security functions. The only commenter that argues against making the RTO a security coordinator is Avista, which states that the security coordinator in the Pacific Northwest is already an independent body and has the authority necessary for ensuring reliability; therefore, no changes are required.

Comments on How an RTO Should Perform Its Functions. Overall, commenters strongly agree with the Commission's proposal to permit those proposing an RTO the authority to decide the type of control they require: direct, functional or a combination. Some commenters believe direct control is the best approach to prevent abuse of sensitive information and better ensure reliability.³⁹³ However, Manitoba Board and Canada DNR express concern that continued coordination between U.S. and Canadian utilities might be undermined if highly centralized systems are developed and controlled by U.S. entities. A few commenters contend that it is best for the RTO to delegate control authority.³⁹⁴ The majority of commenters support some form of hierarchical control structure, where the RTO would establish a master control center and direct the operations in the existing geographically distributed control centers, which would become satellite centers.³⁹⁵ PJM and ISO-NE indicate that they both currently operate with a hierarchical

control structure, where the ISO control center is the master control room that directs the actions of the satellite control centers.

A number of supporters of the hierarchical structure specifically request that the Commission ensure that the RTO has the authority to direct all actions at the satellite control centers and that the satellite centers will be independent in order to prevent discriminatory transmission service and the transfer of commercially valuable information to market participants.³⁹⁶ Montana-Dakota and Otter Tail believe a major benefit of the hierarchical structure is improved emergency response and system security in a large region if the RTO is coordinating and directing the actions of all operators in the region. Finally, Enron/APX/Coral Power believe the standardization of balancing practices for a large region is an important benefit of a hierarchical system.

Commission Conclusion. Which Functions Must an RTO Perform? We reaffirm the determination proposed in the NOPR that an RTO must have operational authority for all transmission facilities under its control and also must be the security coordinator for its region. We recognize that it is difficult to draw a precise line between transmission control and generation control,³⁹⁷ and we also recognize that given the changing nature of the industry, terminology such as "control area operator" is undergoing definitional changes.³⁹⁸ Accordingly, it is difficult to state precisely what functions an RTO must have in order to have full operational authority for transmission facilities. Moreover, our desire to allow RTOs flexibility dissuades us from trying to be too precise. However, certain concepts are basic and generally understood in the industry.

³⁹⁶ See, e.g., EAL, East Texas Cooperatives, ISO-NE, Industrial Consumers, LG&E, NASUCA, PJM, PJM/NEPOOL Customers, Powerex, Project Groups, Tri-State.

³⁹⁷ See NERC Operating Manual Policy 2 which can be found at www.nerc.com. As we have stated before, the dividing line "between transmission control and generation control is not always clear because both sets of functions are ultimately required for reliable operation of the overall system." *Midwest ISO*, 84 FERC at 62,151. The idea that the entity that controls the transmission system must have some degree of control over some generation seems to be generally recognized. See Docket No. ER98-1438-000 Applicants' Response at 3.

³⁹⁸ We note that the definition of a control area, and consequently the functions that must be performed by a control area, is currently being reexamined by the NERC Control Area Criteria Task Force in an open forum. See NERC web page at www.nerc.com.

³⁸⁸ See, e.g., NASUCA, First Energy, Otter Tail, PJM, PJM/NEPOOL Customers, Professor Hogan, Project Groups, SPRA, UtiliCorp, Williams, WPPI. We also discuss below in more detail the issue of congestion management as an RTO minimum function.

³⁸⁹ See, e.g., East Texas Cooperatives, WPPI, Project Groups.

³⁹⁰ See, e.g., Allegheny, APPA, APX, Cal ISO, ComEd, Dynegy, East Texas Cooperatives, Enron/APX/Coral Power, Entergy, EPSA, LG&E, Mass Companies, MidAmerican, Midwest Energy, Montana-Dakota, NASUCA, NECPUC, NERC, NJBUS, PJM/NEPOOL Customers, PPC, Professor Hogan, Seattle, South Carolina Authority, SPP, SRP, Tri-State, UtiliCorp, Williams.

³⁹¹ See, e.g., LG&E, PJM/NEPOOL Customers, SPP, UtiliCorp. See also *supra* section III.D.1 for a more detailed discussion of independence as an RTO minimum characteristic.

³⁹² See, e.g., Montana-Dakota, PJM/NEPOOL Customers, South Carolina Authority, Williams.

³⁹³ See, e.g., East Texas Cooperatives, First Rochdale, Illinois Commission, PJM/NEPOOL Customers.

³⁹⁴ See, e.g., MidAmerican, Seattle, South Carolina Authority.

³⁹⁵ See, e.g., ECAR, Enron/APX/Coral Power, EPSA, East Texas Cooperatives, First Rochdale, Industrial Consumers, ISO-NE, LG&E, Los Angeles, Lincoln, MidAmerican, Montana-Dakota, NECPUC, NASUCA, Otter Tail, PJM, PJM/NEPOOL Customers, Project Groups, Seattle, South Carolina Authority, Tri-State. Many of these commenters support eventual consolidation when any cost and technical barriers are overcome and if the RTO decides it is necessary.

One necessary aspect of operational authority as used here refers to the authority to control transmission facilities. This includes, but is not limited to, switching transmission elements into and out of operation in the transmission system (e.g., transmission lines and transformers), monitoring and controlling real and reactive power flows, monitoring and controlling voltage levels, and scheduling and operating reactive resources. Functions such as these must be included within the operational authority of an RTO.

We conclude, as proposed in the NOPR, that the RTO is also required to be the NERC security coordinator for its region. The role of a security coordinator is to ensure reliability in real-time operations of the power system. As security coordinator, the RTO will assume responsibility for: (1) performing load-flow and stability studies to anticipate, identify and address security problems; (2) exchanging security information with local and regional entities; (3) monitoring real-time operating characteristics such as the availability of reserves, actual power flows, interchange schedules, system frequency and generation adequacy; and (4) directing actions to maintain reliability, including firm load shedding.

We believe that the RTO must be security coordinator for several reasons. The functions of the security coordinator are enhanced when they are performed over large regions. In addition, the independence of the security coordinator is important for ensuring non-discriminatory transmission service, and the RTO will have that independence. As we stated in *Midwest ISO*:

This role [the role of a security coordinator] is central to maintaining grid reliability and non-discriminatory access. Under proposed NERC policies, security coordinators would be required to anticipate problems that could jeopardize the reliability of the interconnected grid. In the course of performing these reliability functions, the Security Coordinator would receive considerable information which is commercially sensitive. Therefore, it is important that the proposed Midwest ISO Security Coordinator be performed by an entity that is independent of market participants.³⁹⁹

However, we will allow flexibility in how the RTO performs its security coordinator functions. For example, an RTO may contract these responsibilities out to an independent security coordinator if this is justified. Also, this

³⁹⁹ 84 FERC at 62,158.

requirement does not prevent more than one RTO from sharing a single security coordinator as suggested by NERC.

As proposed in the NOPR, we will not at this time require the RTO to operate what traditionally has been thought of as a single control area for its region. However, the RTO must perform the control functions required to satisfy the minimum characteristics and functions in this Final Rule, including the transmission control and security coordinator functions discussed above,⁴⁰⁰ in a non-discriminatory manner for all market participants.⁴⁰¹ We will permit those developing an RTO proposal flexibility in deciding on the particular division of operational responsibilities with existing control areas.

We recognize that the feasibility of consolidating existing control areas into a single such area may be limited by cost and technical considerations. However, we note that physical consolidation may be unnecessary when a hierarchical control structure is used to define a single control area by making existing control areas subject to RTO direction (and so avoiding the high costs and technical uncertainty associated with centralization of physical control for a very large RTO region). Hierarchical control is a form of power system control that relies on a master-satellite control structure, which establishes a single controlling authority without requiring the construction of a single, consolidated control room. Existing control centers are not replaced, but continue to operate, independent from market participants, as satellite control centers reporting to the RTO master control center. The RTO security center assumes the dual role of the master control center and security center, with clear authority to direct all actions at the satellite centers.⁴⁰²

We conclude that each region should be free to decide if and when the region will transition to a hierarchical control structure, consolidate the control areas in its region, or adopt a different control structure that best meets the region's needs.

⁴⁰⁰ For example, several commenters state that an RTO must have some authority over generation to ensure system reliability. The RTO is required to have some authority as a minimum characteristic, as discussed with respect to short-term reliability.

⁴⁰¹ In our order approving the Midwest ISO, we stated that our approval of the ISO was based on the applicants' commitment that the ISO would be able to "take all actions necessary to provide nondiscriminatory transmission service, promote and maintain reliability." *Midwest ISO*, 84 FERC at 62,159.

⁴⁰² See, e.g., Marija Ilic and Shell Liu, *Hierarchical Power System Control: Its Value in a Changing Industry*. Springer-Verlag, 1996.

How Should the RTO Perform Its Functions? We conclude that those designing the RTO should have flexibility to decide how it would exercise its operational control authority. The RTO operate the transmission system through direct physical operation by RTO employees, contractual agreements with other entities (e.g., transmission owners and control area operators) or implement a hierarchical control structure involving a combination of direct and functional control. Under these arrangements, the personnel of existing control centers might become employees of the RTO or remain as employees of the control center owner, while being supervised by RTO personnel. We will leave it to the discretion of the region to decide on the combination of direct and functional control that works best for its circumstances.⁴⁰³

However, regardless of the method of control chosen, the RTO must have clear authority to direct all actions that affect the facilities under its control, including the decisions and actions taken at any satellite control centers. The system of operational control chosen must ensure reliable operation of the grid and non-discriminatory access to the grid by all market participants. In addition, to ensure that the RTO does not become locked into an operational system that is unsatisfactory, the Commission will require the RTO to prepare a public report that assesses the efficacy of its operational arrangements no later than two years after it begins operations.

4. Short-Term Reliability (Characteristic 4)

The fourth proposed characteristic of an RTO is that it must have exclusive authority for maintaining the short-term reliability of the transmission grid under its control. In the NOPR we identified four basic short-term reliability responsibilities of an RTO: (1) the RTO must have exclusive authority for receiving, confirming and implementing all interchange schedules; (2) the RTO must have the right to order redispatch of any generator connected to transmission facilities it operates if necessary for the reliable operation of these facilities; (3) when the RTO operates transmission facilities owned by other entities, the RTO must have authority to approve and disapprove all requests for scheduled outages of transmission facilities to ensure that the outages can be accommodated within established reliability standards; and (4)

⁴⁰³ This issue is also addressed in greater detail in our discussion of the RTO's role as a provider of ancillary services as an RTO minimum function.

if the RTO operates under reliability standards established by another entity (e.g., a regional reliability council), the RTO must report to the Commission if these standards hinder its ability to provide reliable, non-discriminatory and efficiently priced transmission service.⁴⁰⁴

Comments. General Comments. Commenters address both general concerns about reliability as well as the four basic proposed short-term reliability responsibilities of an RTO. Most commenters generally agree that the RTO should have the responsibility for short term-reliability.⁴⁰⁵ Several commenters raise questions regarding definition and scope of "short-term" reliability. TEP requests that the Commission further define the time period involved. It suggests that designating a specific time period (whether one month, six months or a year) would be beneficial to evaluating this characteristic. Enron/APX/Coral Power requests that the Commission make clear that "short-term" is intended to mean "real-time."

While agreeing that the RTO should be given ultimate control over facilities necessary to preserve reliability, SMUD expresses concern that the RTO should not be encumbered with responsibility for facilities that do not serve a regional transmission function. TANC requests that the RTO's responsibility over reliability not infringe on the management responsibilities of local regulatory authorities or interfere with the management and operation of the local system facilities of a utility distribution company.

PG&E requests that the Commission require that the RTO rely primarily on market mechanisms to maintain reliability. However, PJM/NEPOOL Customers urge the Commission to ensure that the RTO's actions in maintaining the short-term reliability of the grid do not unreasonably impinge on the freedom of business decisions inherent in a competitive supply market. Several commenters, such as San Francisco and Minnesota Commission, state that because the primary function of a RTO is ensuring short-term reliability, it should be more clearly defined and should not be compromised by any other RTO market functions.

PJM suggests that the Commission grant additional authorities to the RTO to ensure reliability, including the authority to (1) collect information, (2) direct operations in the control area, (3) assure that those it directs will respond in a predictable manner (which the RTO can achieve through training and drills) and (4) declare an emergency, direct emergency operations, and determine when emergency conditions have ended.

Southern Company notes that the industry has little, if any, experience in granting a new entity control over the operations of a transmission system that encompasses a broad, multi-state region.⁴⁰⁶ It claims that transmission owners and State commissions must be assured that the RTO is capable of operating a regional transmission system reliably before an RTO is formed. New York Commission indicates that the authority of States to require the maintenance of electric system reliability should be recognized in establishing responsibilities. Iowa Board believes that there is a need for greater regional development of reliability standards to reflect regional needs and conditions. It requests that State commissions be involved in the decisionmaking process of an RTO to ensure that electric facilities are properly sized and located and that additions are not detrimental to the reliability of the grid.

Comments on Interchange Scheduling. The Commission proposed that, in the context of the RTO's role as the recipient and evaluator of all requests for transmission service under its own FERC-approved tariff, an RTO that is a control area operator must also receive, confirm, and implement all interchange schedules between adjacent control areas.⁴⁰⁷ The Commission expressed concern that non-RTO control area operators would receive commercially sensitive information involving its competitors in implementing interchange schedules and questioned whether there is any Commission action, other than its current code of conduct standards, and short of requiring consolidation of all control areas within a region, which could address this concern.

Several commenters agree that the RTO should have authority over

receiving, confirming and implementing all interchange schedules.⁴⁰⁸ PJM believes that an independent ISO is in the best position to exercise the scheduling authority of an RTO. It suggests that an RTO that is independent of commercial interests in the market does not face the commercial information problem because it does not compete with market participants and consequently would make scheduling decisions in an unbiased and fair manner.

PJM/NEPOOL Customers claims that interchange scheduling oversight must be performed by an independent entity because it would be neither possible nor desirable for a non-RTO control area operator to perform this function without access to commercially sensitive information. It suggests that the RTO maintain direct control over interchange scheduling either by using RTO employees or a master satellite arrangement where ultimate responsibility remains in the RTO master control area operating room. APX suggests that requiring a contractor (acceptable to the RTO and the control area operator) to operate the control area operator facility could help address this concern.

Enron/APX/Coral Power believes that the risk is eliminated if transmission operations, including control-area operations, are operationally separated from the load and generation of vertically-integrated utilities. Barring such complete separation, this risk could nevertheless be substantially obviated if the RTO provided control area operators with information only about scheduled net interchanges between control areas without disclosing the individual transactions making up the new schedules.⁴⁰⁹

However, other commenters contend that control area operators will continue to need information on individual transactions in order to implement interchange schedules and to ensure real-time reliability.⁴¹⁰ Desert STAR believes that work should be done in this area to determine what information is required by control area operators and when they must receive it in order to carry out their reliability responsibilities.

Florida Commission states that this issue has already been resolved within the Florida Reliability Coordinating Council (FRCC) by requiring all entities who operate control areas within the

⁴⁰⁴ FERC Stats. and Regs. ¶ 32,541 at 33,735.

⁴⁰⁵ See, e.g., American Forest, Cal ISO, California Board, Cinergy, CMUA, CSU, EAL, Enron/APX/Coral Power, Entergy, EPSA, Industrial Customers, NASUCA, NECPUC, PJM, PNGC, SMUD, UtiliCorp, H.Q. Energy Services, Mass Companies, Mid-Atlantic Commissions, MidWest Energy, Minnesota Commission, NY ISO, PacifiCorp, PG&E, Williams, WPSC.

⁴⁰⁶ Southern Company notes that the California and ERCOT ISOs operate within the boundaries of a single state. In PJM, New York and New England, the control of the grid remains remarkably unchanged because the ISOs in those regions were already operating the system on behalf of the transmission owners and adopted the institutions and infrastructures of an ISO.

⁴⁰⁷ FERC Stats. & Regs. ¶ 32,541 at 33,735-36.

⁴⁰⁸ See, e.g., Cal ISO, CMUA, Entergy, Mass Companies, NECPUC, Nevada Commission, PJM/NEPOOL Customers, PJM, SMUD, Southern Company, WPSC, PG&E.

⁴⁰⁹ See also Southern Company.

⁴¹⁰ See, e.g., Duke, Florida Power Corp.

region that require access to commercially sensitive information to sign agreements that separate reliability personnel and the relevant information from their wholesale merchant personnel.

Several commenters, such as Duke and Florida Power Corp., state that no additional Commission action is necessary. These commenters believe that the existing code of conduct standards are working and the reciprocity provisions of Order No. 888 provide for compliance with the code of conduct standards by all non-public utility control area operators. Florida Power Corp. also notes that within the FRCC, all entities operating control areas are required to sign agreements verifying functional separation.

Comments on Generation Redispatch. In the NOPR, the Commission proposed that the RTO's reliability authority include the ability to order redispatch of any generator connected to the transmission grid when necessary for the reliability of the grid. However, the RTO would have no authority over initial unit commitment and normal dispatch decisions.⁴¹¹

Several commenters agree that the RTO have some authority to order redispatch when necessary to maintain the reliability of the grid.⁴¹² Sithe, however, believes that, in the evolving competitive marketplace, redispatch authority alone is insufficient. It argues that the RTO should also provide appropriate incentives to the owners of assets that are needed for reliability to maintain those assets and make them available for operation in constrained areas. Sithe urges the Commission to consider adopting a final rule that provides RTOs with sufficient commercial authority, "including the necessary financial resources" to enter into market-rate business arrangements, that assure availability of assets needed for reliability. Sithe states that without this authority, the RTO may not have sufficient tools to fully ensure reliability, because must-run generators would have little incentive to continue to operate in constrained areas.

CMUA maintains that it is insufficient to vest authority in the RTO to maintain short-term reliability without also vesting enforcement powers to ensure compliance with RTO dispatch instructions. Allegheny and other commenters agree that RTOs should be

able to direct redispatch, particularly if the redispatch is accomplished under a market-based compensation scheme as a part of transmission service pricing methodology that uses the redispatch costs to set marginal system use costs. However, they argue that in no case should the RTO be able to direct generation redispatch unless the generator is compensated at market value (unless market power issues are involved).⁴¹³

Avista expresses serious concern with the breadth of a redispatch requirement. It believes that the right to order redispatch of generation should be negotiated among the parties in the region without a presumption that the RTO must have broad redispatch authority, except in emergency circumstances. Avista and others note that a negotiated approach is particularly important to operators of hydroelectric resources which are subject to numerous environmental and operating restrictions that limit their ability to redispatch.⁴¹⁴ Avista and SMUD request that the Commission clarify that the RTO's authority to redispatch is limited to emergency circumstances affecting reliability.

Chelan believes that RTOs should be required to enter into arm's-length agreements with those generators that are willing to service redispatch requests, and compensate those generators for supplying this service. RTOs should not be allowed to unilaterally redispatch a generating unit without the generator's consent, and without compensation.

Commenters, such as Cal ISO and Nevada Commission, suggest that the Commission require reliability-related services (i.e. redispatch) be provided to RTOs under a set of uniform rates, terms and conditions. Such a requirement would reduce the Commission's administrative burden of contracts governed by different sets of terms and conditions.

EME believes that the RTO's control over dispatch of generation should be carefully circumscribed. It recommends that reliability functions be internalized into explicit procedures for congestion pricing. It states that in most cases proper pricing signals can provide sufficient incentives for generators to schedule operation of their facilities to ensure system reliability.

Industrial Consumers states that the RTO's redispatch decisions regarding "any generator" must be qualified to excuse on-site generators that serve an

industrial load, especially those that serve a critical steam host. For environmental, safety and economic reasons, these units should not be forced to redispatch except as a last resort option.

Metropolitan supports an RTO having authority to order redispatch of any generating unit when necessary for the reliability of the grid. However, "reliability" must be carefully defined to avoid RTO interference with normal market operations by redispatching generation for its own convenience, or to alleviate adverse market conditions.⁴¹⁵

Several commenters oppose the proposal to allow the RTO to redispatch generation.⁴¹⁶ PG&E believes that the proposal would give too much latitude to RTOs and create an incentive to impose centrally determined fixes on market operations, rather than allowing market mechanisms to self-correct. Therefore, PG&E argues that RTOs should be allowed to redispatch generation facilities only when there is a true reliability emergency as specified in the RTO tariff. Moreover, RTOs should be able to redispatch only those units that have actually participated in the market.

PJM/NEPOOL Customers believes that the authority as proposed in the NOPR is too broad and must be further defined. It requests that the Commission ensure that this authority is exercised only during only the most serious circumstances when grid reliability is truly in danger. It suggests that the Commission promulgate or pre-approve reliability standards for determining when the RTO can order redispatch of generators, the amount of generation assets that the RTO will have authority over and standards for the redispatch order. Southern Company recommends that the Commission provide only general guidance concerning redispatch and allow the regions to develop more specific procedures.

When considering allowing an RTO to redispatch a Federal hydroelectric generator, SPRA emphasizes that the Commission must recognize that individual Federal hydroelectric generators are under the control of either the Corps, the Bureau of

⁴¹¹ Metropolitan believes the Cal ISO's definition of system emergency appropriately describes the circumstances in which redispatch may be appropriate. A "system emergency" is described as "any abnormal system condition which requires immediate manual or automatic action to prevent loss of load, equipment damage or tripping of system elements which might result in cascading outages or to restore system operation to meet the minimum operating reliability criteria."

⁴¹² See, e.g., PG&E, Southern Company, Reliant, SMUD.

⁴¹³ FERC Stats. and Regs. ¶ 32,541 at 33,736.

⁴¹⁴ See, e.g., Cal ISO, Cinergy, CMUA, NECPUC, PJM, UtiliCorp, Entergy, Allegheny, LG&E, Lincoln, Metropolitan, Minnesota Power, Nevada Commission, Otter Tail, Southern Company, TDU Systems, NASUCA, Reliant, Mass Companies, TAPS.

⁴¹⁵ See, e.g., Cinergy, Chelan, Southern Company, LG&E, Reliant.

⁴¹⁶ See, e.g., CMUA.

Reclamation or the International Boundary Waters Commission, not the PMA. While a PMA may belong to an RTO, it is unlikely that other Federal agencies will. The Commission must give careful consideration to determine that RTO redispach authority does not prohibit or limit a PMA's ability to fulfill its statutory obligations.

Comments on Transmission Maintenance Scheduling. In the NOPR, the Commission proposed that an RTO which operates transmission facilities owned by other entities be authorized to approve or disapprove all requests for scheduled outages of transmission facilities in order to ensure that maintenance outage schedules meet applicable reliability standards.⁴¹⁷

The Commission requested comments on a number of issues related to this proposed requirement: Does it cede too much or too little authority to the RTO? If the RTO requires a transmission owner to reschedule its planned maintenance, should the transmission owner be compensated for any costs created by the required rescheduling? Would it be feasible to create a market mechanism to induce transmission owners to plan their maintenance so as to minimize reliability effects? Should an RTO that is an ISO have any authority to require rescheduling of maintenance if it anticipates that the planned maintenance schedule will adversely affect power markets? If the RTO is a transco, can it manipulate its transmission maintenance schedules in a manner that harms competition?

The Commission stated that the RTO's regional perspective will allow it to coordinate individual maintenance schedules with each other as well as with expected seasonal system demand variations. Because the RTO will have access to extensive information, it will see the "big picture" and be able to make more accurate assessments of the reliability effect of proposed maintenance schedules than individual, sub-regional transmission owners.

Commenters address essentially three issues related to transmission maintenance scheduling: the RTO's authority; appropriate compensation; and use of market mechanisms.

RTO Authority to Schedule Transmission Maintenance. Many commenters support giving an RTO authority over transmission maintenance scheduling.⁴¹⁸ Duke,

however, believes that an enforcement mechanism may also be needed. First Rochdale recommends that transmission owners be given the right to protest an RTO's actions to the Commission. Reliant, however, opposes RTO authority over maintenance scheduling, arguing that transmission maintenance decisions must reside with transmission facility owners.

Seattle and NYPP suggest that the Commission define an RTO role only for scheduling facility outages that are clearly associated with the regional transmission network because internal subtransmission and radial transmission facilities do not have regional significance. Turlock supports restricting the RTO's authority to the grid it manages to prevent its outage scheduling authority extending beyond the grid for which it is responsible. On the other hand, TDU Systems claims that an RTO should also coordinate maintenance of interconnected distribution facilities that are not under its control, if maintenance on those facilities would adversely affect RTO operations.

Duke suggests that with the creation of an RTO that is not a transco, a set of governing principles for outage coordination should be established. The parties should agree on the timing of requests for planned maintenance and the timing of responses to those requests. If for any reason, other than the gross negligence of the transmission owner, a scheduled maintenance outage was determined to be a problem after an agreement is reached, rescheduling the outage would require the mutual consent of the transmission owner and the RTO.

EAL recommends that appropriate contracts with existing transmission facility owners that ensure the continued reliable operation of the grid are required. Principal elements of such contracts would include standards of service, provisions for information sharing and reporting, maintenance scheduling, transmission facility ratings, testing and performance expectations. Maintenance scheduling should include provisions for maintenance deferral under instructions from the RTO if required for system security reasons only.

NYPP states that arrangements for outages should be made well in advance of the outage start date because RTO approval of proposed schedules could become the critical path. If approval is delayed, or subsequently revoked, the transmission owner will incur

significant expenses that should be reimbursed.

Montana-Dakota suggests that the effects of rescheduling can be decreased by having the RTO review and approve all transmission maintenance schedules on a weekly, monthly and quarterly basis. After reviewing the transfer capability and market effects of the proposed outage, the RTO should communicate the need to reschedule to the transmission owner far enough in advance of the planned outage to allow the owner to reschedule, possibly to avoid any cost impact. Montana-Dakota notes, however, that the closer the date of the outage, the higher the probability of an economic impact.

Southern Company requests that the Commission clarify that once an RTO approves a scheduled outage, it should be allowed to change that schedule only if implementing the plan would compromise system integrity or reliability.

Seattle believes that the NOPR fails to provide adequate assurances to transmission owners that a timely maintenance schedule will be adopted by the RTO. The RTO must establish timely dates certain for maintenance outage requests from operating entities. To do this the RTO must adequately balance safety considerations, and the cost of deferring maintenance with commercial impact. For these reasons, an RTO should not be permitted to arbitrarily postpone required maintenance.

Compensation. Nearly all of the commenters believe that transmission owners should be compensated in some form if they are required by an RTO to reschedule maintenance.⁴¹⁹ Avista argues that the transmission owners' shareholders should not bear the burden of decisions made by an independent body that result in reduced revenues or increased costs for the transmission owner.

Metropolitan states that if an RTO requests a transmission owner to reschedule planned maintenance for reliability concerns, a transmission owner should be compensated only for its direct costs necessarily and reasonably incurred in complying with the RTO's request. Direct costs may include, for example, increased labor or equipment expenses arising from the rescheduled maintenance. However, Metropolitan does not believe a transmission owner should recover lost

⁴¹⁷ FERC Stats. and Regs. ¶ 32,541 at 33,736-37.

⁴¹⁸ See, e.g., Cal ISO, NECPUC, PJM, Desert STAR, Entergy, PGE, Allegheny, Avista, LG&E, Lincoln, Tri-State, WPSC, CRC, Duke, EAL, First Rochdale, Industrial Consumers, ISO-NE, Metropolitan, Montana-Dakota, NASUCA, New Smyrna Beach, NYPP, Oneok, PG&E, Southern

Company, SRP, Turlock, WPPI, Florida Power Corp., Nevada Commission.

⁴¹⁹ See, e.g., PJM, TANC, WPSC, Avista, Lincoln, CRC, Duke, Metropolitan, Minnesota Power, Montana-Dakota, NASUCA, NPRB, NYPP, PJM/NEPOOL Customers, Reliant, TDU Systems, Turlock, Florida Power Corp., Reliant, Desert STAR, Southern Company.

opportunity costs arising from the rescheduled maintenance because opportunity costs are uncertain and speculative.

Southern Company argues that, if an RTO requires a transmission owner to reschedule a previously approved outage, the RTO should compensate the transmission owner for any additional costs caused by the rescheduling.

NASUCA believes that the RTO should compensate transmission or generation owners only to the extent that incremental costs are incurred due to the rescheduling of outages. NASUCA argues that it is unlikely that owners would incur significant incremental costs, especially for transmission outages.

Some commenters such as PGE and Minnesota Power state that if an RTO requires a transmission owner to reschedule its planned maintenance for reliability reasons in an emergency situation, the RTO should not be required to compensate the transmission owner. However, if an RTO requires a transmission owner to reschedule its planned maintenance for economic reasons, the RTO should be required to compensate the transmission owner for liquidated damages.

Other commenters such as Tri-State and Cal ISO oppose transmission owners being compensated for the rescheduling of maintenance work. Cal ISO states that, where an RTO properly exercises such authority by requiring a transmission owner to reschedule a maintenance outage, that transmission owner is not entitled to compensation for the costs associated with rescheduling. Tri-State recommends factoring any additional expense into the revenue requirement that the transmission owner receives from the RTO.

Market Mechanisms. PJM/NEPOOL Customers suggests that the RTO enact a compensation mechanism in transmission outage rescheduling situations or propose to use a market mechanism to encourage transmission owners to plan maintenance so as to minimize reliability effects. Minnesota Power, however, argues that maintenance rescheduling to benefit power markets is analogous to generation redispatch and should be paid for by the benefitting market participants.

Montana-Dakota believes that an RTO should have the authority to reschedule maintenance for market effects if there is an incremental cost reimbursement mechanism in place that would provide an incentive to the transmission owner to change maintenance schedules to benefit the market.

Metropolitan argues that an RTO with authority to unilaterally reschedule transmission maintenance for market considerations could have a destabilizing effect on the power market. Emerging markets require predictability to thrive, and therefore RTOs should interfere in market operations only when necessary to address reliability concerns.

Florida Power Corp. suggests that, while it may be feasible to develop a market mechanism to induce transmission owners to plan their maintenance to minimize reliability effects, it would be far simpler to retain the existing structure in which a single entity both owns and operates the transmission system. When ownership and operation are combined, a single entity is responsible for both reliability and maintenance, and thus has a natural incentive to seek an optimal balance between these activities. Thus, Florida Power Corp. opposes RTOs having authority to reschedule maintenance to manage the performance of the market.

Turlock also does not believe an RTO should have authority to make transmission outage decisions based on market considerations. Turlock, as well as Desert STAR and CRC, believe instead that consideration should be given to motivating transmission owners to appropriately schedule their maintenance outages, to minimize impacts on competitive markets.

Comments Generation Maintenance Scheduling. The short-term reliability characteristic, as proposed in the NOPR, would not give an RTO authority over proposed generation maintenance outage schedules. However, the Commission noted that some generation control is necessary for reliable operation of a transmission system. The Commission asked whether an RTO should have some authority over generation maintenance schedules and, if so, how much.⁴²⁰

The majority of commenters support an RTO having at least some authority over generation maintenance schedules.⁴²¹ However, most commenters suggest limiting the RTO's authority. Some commenters suggest that an RTO have authority only for generating units that are "must-run" or that the RTO has under contract due to the requirement to maintain system

reliability.⁴²² Desert STAR believes that an RTO should not attempt to manipulate the commercial power market when reliability is not affected.

Cinergy supports an RTO having the ability to request changes to a schedule to serve reliability needs, coordinate transmission outages, and maximize grid efficiency to increase ATC for transmission customers' use, so long as generators receive compensation at market-based prices for missed market opportunities. Other commenters agree that an RTO should compensate the generation owner if a schedule change is necessary.⁴²³

A few commenters claim that the RTO should not have any authority over generation maintenance schedules.⁴²⁴ SPRA states that requiring such authority would discourage or prevent participation by PMAs because other Federal agencies own the hydroelectric plants that generate the power marketed by the PMAs.

Tri-State does not believe that an RTO should have approval authority over generation maintenance outages because these outages are driven by the cost considerations associated with generation plant equipment replacement or rehabilitation. However, Tri-State agrees that an RTO must have advance knowledge of the scheduled generation outages in order to assure transmission system reliability and adequacy of reserves. Other commenters concur with a notification requirement.⁴²⁵ Cinergy notes, however, that while it believes a generator may be required to submit its maintenance schedule to an RTO, the RTO should be prohibited from sharing that information with any other market participants, or affiliates of market participants.

Comments on Performance Standards. In the NOPR, the Commission discussed the establishment of performance standards by an RTO for transmission facilities under its direct or contractual control.⁴²⁶ For example, an RTO could establish a standard that identifies specific performance targets for planned and unplanned outages of facilities. The Commission requested comments on whether a non-profit ISO could establish incentive schemes for the transmission owners whose facilities it operates.

PJM believes that an RTO will be capable of developing performance

⁴²⁰ FERC Stats. and Regs. ¶ 32,541 at 33,737.

⁴²¹ See, e.g., Cinergy, NECPUC, PJM, Desert STAR, WPSC, Cal ISO, EAL, Industrial Consumers, ISO-NE, Turlock, Florida Power Corp., Metropolitan, Minnesota Power, Montana-Dakota, NASUCA, Nevada Commission, NYPP, PSNM, TDU Systems.

⁴²² See, e.g., Desert STAR, Metropolitan, Turlock, Florida Power Corp., PSNM, NYPP.

⁴²³ See, e.g., WPSC, LG&E, Montana-Dakota.

⁴²⁴ See, e.g., Duke, PJM/NEPOOL Customers, SPRA, Tri-State, Empire District.

⁴²⁵ See, e.g., Enron/APX/Coral Power, FirstEnergy, Mass Companies, Metropolitan.

⁴²⁶ FERC Stats. and Regs. ¶ 32,541 at 33,737.

standards and incentives to encourage transmission owners and generators to operate and maintain reliable facilities. It states that market participants cooperatively can create market-oriented incentives to maintain their transmission and generation facilities effectively.⁴²⁷

Duke also believes that incentive schemes can be developed. It suggests that the revenues collected from users by the RTO could be returned to transmission owners according to a prearranged formula that incorporates quality standards for reliability. Thus, the revenue allocation would reflect transmission owner performance in providing a reliable system.

PSE&G believes that RTOs will, and should, be able to offer incentives to participants to ensure that reliability standards are not only met but exceeded. It states that a mechanism of linking payment with performance, measured against accepted benchmarks, has worked well for many years in PJM.

EAL states that appropriate contracts with existing transmission facility owners that ensure the continued reliable operation of the grid are required. It suggests that these contracts include standards of service, provisions for information sharing and reporting, maintenance scheduling, transmission facility ratings, testing and performance expectations.

Industrial Consumers believes that an RTO could establish performance standards for transmission facilities that takes into account the "reliability" of each facility. It argues that a facility that has frequent unplanned outages should not receive the same compensation as a facility whose availability is more reliable. It suggests that a transmission owner be precluded from recovering fixed costs during periods of unplanned outages that exceed some minimum threshold based on superior performance.

Cal ISO indicates that its tariff provides for the implementation of maintenance standards, and penalties under those standards, to ensure both adequate maintenance and system reliability. These provisions act in concert with the California ISO's authority to coordinate and approve maintenance outages.

Southern Company believes that the establishment of performance standards for transmission facilities controlled by an RTO is misplaced. Transmission owners plan and operate their transmission systems according to NERC and regional reliability standards, as well as State legal and regulatory

requirements. Thus, while Southern Company doesn't claim that performance-based incentives are inappropriate, it points out that there already are existing standards to ensure reliable system operations.

Comments on Facility Ratings and Operating Ranges. Reliable operation of the transmission system in the short-term requires both continuous monitoring of equipment availability and loading, and actions to maintain loading levels within the established operating ranges and equipment ratings. The NOPR suggested that RTOs are best situated to establish ratings and operating ranges for two reasons. First, they will have the most complete information about expected and real-time operating conditions. Second, RTOs will be trusted because they will not have any economic interests in electricity market outcomes and they will not be owned or controlled by any market participants. The Commission proposed to let RTO established equipment ratings prevail in a dispute with a transmission owner pending the outcome of a dispute resolution process.⁴²⁸

Nearly all commenters that address this issue oppose the NOPR proposal. South Carolina Authority urges the Commission to proceed with caution to prevent avoidable damage to persons or property. SRP argues that ratings and operating ranges influence the useful life and maintenance cost of equipment, as well as the level of service to the end-use customer, and notes that each transmission owner has a legitimate interest in the ratings. SRP believes that the ideal situation would be to establish ratings by mutual consent of the transmission owner and RTO. If they cannot agree, the issue should go to dispute resolution.

NYPP and Mass Companies oppose this proposal because transmission owners have the fiduciary responsibility to protect their assets. Furthermore, they state that the rating of equipment necessarily requires a particularized knowledge of the equipment and related facilities that is unlikely to be possessed by the RTO.

Metropolitan believes that a well-established reliability organization is best suited for establishing maximum transmission line ratings that can be sustained over most of the hours in a year because it will include the cooperation of technical groups representing all systems, not just those under RTO control. It sees no benefit from moving this responsibility to RTOs when the reliability councils have

historically performed this function with a minimum of controversy. EAL suggests that since the owner of the transmission facility assumes the equipment, personnel and public risks for the operation of its equipment, the RTO could fulfill an audit role to ensure that facility ratings by the owners follow industry norms.

Seattle suggests that the Commission instruct RTOs to work cooperatively with facility owners, since ratings on most power transmission equipment are a function of age and past usage, and a new entity will not have such historical information.

Southern Company states that transmission owners have responsibilities to their shareholders and State commissions to operate their equipment safely and reliably. SPRA believes that this proposal has the potential to create significant liability risks for the United States.

Entergy believes that a transco has an advantage at performing this function because it will have the natural incentive to maintain the highest and safest ratings for the transmission facilities since it will be solely and directly responsible for the risks and rewards of equipment ratings.

Comments on Liability for Actions. Given that an RTO has responsibility for system reliability, the NOPR requested comments on the appropriate extent of an RTO's liability for its actions, and whether RTO facility ownership changes this determination.⁴²⁹

Most commenters believe that liability must be linked to the entity operating and controlling the transmission assets. Several commenters recommend that all RTO governing documents and operating agreements clearly establish the RTO's liability for any facilities that it operates but does not own.⁴³⁰ SRP recommends that the Commission not set a hard and fast rule, but rather give deference to assignments of liability worked out between the RTO and the transmission owner in the course of negotiating an operating agreement.

Salomon Smith Barney believes that an RTO should be paid to run the network, and should suffer the consequences if it is not run well. Given this reasoning, it believes that an RTO requires sufficient capital to bear the risk, and that it operates under a regulatory scheme that acknowledges that higher risk taking requires a higher return.

Other commenters focus on how to apportion liability. Several commenters

⁴²⁹ FERC Stats. and Regs. ¶ 32,541 at 33,738.

⁴³⁰ See, e.g., Seattle, PGE, Desert STAR, PSNM, South Carolina Authority.

⁴²⁷ See also LG&E.

⁴²⁸ FERC Stats. and Regs. ¶ 32,541 at 33,737-38.

suggest that the governing standard for liability for a particular activity should be the same standard that the Commission has approved for comparable ISO conduct. Thus, for example, the RTO would be subject to liability only on account of its reliability activities when damage caused by its actions is found to be the result of gross negligence or intentional misconduct.⁴³¹

Other commenters believe that, if the RTO assumes authority to ensure proper maintenance and reliability of the system, it should assume that role fully (*i.e.*, assume liability for its decisions) and it should hold transmission owners harmless for any increased cost responsibility.⁴³²

Tri-State believes that an RTO should not be held liable for the inevitable errors and omissions that will occur during transmission system operations except in the instance of gross negligence. It believes that without some form of indemnification, the RTO could be the target of numerous lawsuits alleging financial harm as a result of RTO actions.

TANC believes that the RTO should be held liable for the consequential damages resulting from the RTO's instructions, if damage is caused to the transmission owners facilities as a result of the RTO requiring a transmission owner to operate its facilities in a manner that is inconsistent with prudent utility practice.

Comments on Reliability Standards. In the NOPR, the Commission expressed a potential concern regarding an RTO's implementation of reliability standards that are established by another entity. The Commission identified two specific concerns: (1) regional or sub-regional reliability groups may not be as independent from market participants as RTOs; and (2) almost every reliability standard will have a commercial consequence. The NOPR proposed to require an RTO to notify the Commission immediately if implementation of externally established reliability standards will prevent it from meeting its obligation to provide reliable, non-discriminatory transmission service.⁴³³

Most commenters generally support the proposal in the NOPR, although a few commenters believe that the NOPR proposal does not go far enough. On the other hand, some commenters seek clarification or oppose the NOPR proposal; most commenters that oppose

the NOPR proposal believe that RTOs must be subordinate to national or regional reliability groups.

PJM/NEPOOL Customers and other commenters agree that the RTO is an appropriate institution to evaluate whether other rules and requirements are impacting its ability to perform its function and to inform the Commission of this fact.⁴³⁴

PSE&G requests that the Commission clarify in its Final Rule that RTOs, not reliability trade associations, will have primary responsibility for resolving reliability issues in the future. It suggests that reliability trade associations can continue to play a role in developing reliability standards to be incorporated into RTO tariffs; these standards would then be implemented by the RTOs and ultimately enforced by the FERC. The standards, however, must be developed through a fair and open consensus process, such as the American National Standards Institute (ANSI) process.

EPSCA believes that reliability standards should be uniform throughout the United States. Reliability standards should be established at the national level through an industrywide representative organization, subject to review and approval by the Commission. Reliability rules should deviate regionally only if necessary to reflect specific operating conditions that are unique to a particular region. EPSCA requests that existing reliability rules be considered carefully by the RTO, and reviewed by the Commission, as to their function and importance. EPSCA and other commenters suggest that RTOs replace existing regional reliability councils as the entity responsible for maintaining compliance with nationally established reliability standards.⁴³⁵

Conlon claims that the RTO must have the ability to establish various reliability standards that every participant. He suggests that the RTO, or the Commission with delegated authority to the RTO, set mandatory standards and impose sanctions or fines for violations.

Cal ISO believes that RTOs are the appropriate entities to establish reliability standards. Regional organizations (not a single national standard-setter) should have the flexibility to develop standards that reflect regional priorities as well as individual issues related to particular areas or configurations in the transmission grid. It recommends that RTOs have the authority and

responsibility to develop regional reliability standards, subject to general oversight by an appropriate independent national reliability organization such as NAERO.

Similarly, Entergy believes that the RTO should have the primary role, authority and responsibility to adopt, implement and enforce regional reliability standards. Entergy further argues that this authority must be subject to regional oversight, especially as to reliability issues between and among interconnected RTOs.

Some commenters argue that the Commission should provide additional authority to RTOs. For example, PJM believes that an RTO should have exclusive authority for administering the regional reliability of the bulk power system. It argues that no entity external to an RTO's region should have authority to dictate reliability rules that adversely affect the reliability in a region served by an RTO. Thus, PJM believes the Commission should extend this proposal beyond the proposed reporting requirement. In its opinion, RTOs that are responsible for a particular area of the bulk power market system best can develop tools that are designed to meet the needs of their individual areas. PJM requests that the Commission insist in its rule that RTOs play a significant role in setting any national reliability standards. Sithe suggests that RTOs should also have independent authority to modify existing rules, and/or to place new rules before the Commission for its review and approval in order to promote rules that intrude less into the markets and that promote efficiency goals, as well as system reliability.

Illinois Commission argues that the proposal is not adequate and that the Commission must more directly address the concern over lack of independence between reliability standards development, enforcement organizations and commercial market interests. Illinois Commission suggests some possibilities: (1) require NERC/regional reliability council reform so that the process of establishing and enforcing reliability guidelines, standards, and policies is independent of discriminatory generation/transmission owner influence; (2) require that all NERC/regional reliability council guidelines, standards, and policies be approved by FERC prior to their adoption; or (3) reform NERC so that it is independent of generation/transmission owners, then eliminate MAIN and ECAR and require the Midwest ISO to act as the regional standards setting entity and as the

⁴³¹ See, e.g., NY ISO, Cal ISO, Nevada Commission, New York Commission.

⁴³² See, e.g., Avista, Minnesota Power, SPRA, MidAmerican, Florida Power Corp.

⁴³³ FERC Stats. and Regs. ¶ 32,541 at 33,738-39.

⁴³⁴ See, e.g., Entergy, NECPUC, NASUCA.

⁴³⁵ See, e.g., Cal ISO, Duquesne, Nevada Commission, Statoil.

reliability enforcement entity for the Midwest Region.

A few commenters seek clarification.⁴³⁶ British Columbia Ministry requests that the Commission clarify how the RTO roles and responsibilities overlap with duties outlined for the Self Regulating Reliability Organization in the North American Electric Reliability Council's draft legislation. New York Commission and Iowa Board request that the Commission recognize the authority of the states to require the maintenance of electric system reliability.

NERC and several other commenters generally oppose the proposal. NERC urges the Commission to include an obligation that the RTO adhere to the reliability rules adopted by NERC and the relevant regional reliability council as a condition of becoming an RTO. NERC states that RTOs must be designed, implemented and operated consistent with NERC operating and planning policies. NERC notes it will revise its operating and planning policies to recognize and accommodate these emerging institutions, as necessary.

Several commenters such as Duke and SERC supports the work of NERC to establish consistently applied reliability standards and supports NERC's authority to enforce these standards. Duke also supports NERC and the regional reliability councils continuing to play a vital role in setting reliability standards. NERC oversight of reliability should prevent different RTOs from applying different standards and will ensure that inter-RTO reliability matters will be dealt with effectively. CEA suggests that the reliability responsibilities authorized for RTO's be respectful of the carefully balanced design of the evolving NERC/NAERO.

SRP requests that each RTO be required to join NERC, or NAERO when formed. In addition, other commenters such as SRP and Los Angeles propose that RTOs be required to use planning and design criteria that comply with the criteria established by the appropriate NERC (or NAERO when established) regional reliability council.

NYPP believes that properly constituted local and regional reliability councils authorized by FERC should have the authority to establish criteria necessary to maintain the reliability of the transmission system including the reliability of discrete locations (e.g., the

supply of reactive power to support voltage in load pockets).⁴³⁷

FirstEnergy requests that the role of the regional reliability councils be clarified with respect to regional RTOs. Also it would have us identify the need boundaries so that each RTO reports only to one regional reliability council. In addition, the regional reliability councils may need to undergo a transformation similar to NERC/NAERO to expand the role of the various industry segments.

Commission Conclusion. The Commission adopts the proposal in the NOPR that the RTO must have exclusive authority for maintaining the short-term reliability of the grid that it operates. Although many commenters support this requirement, some pose additional questions regarding how this function will be performed by the RTO. Some commenters request that the Commission define better the time period associated with "short-term" reliability. We clarify that the term "short-term" is intended to cover transmission reliability responsibilities short of grid capacity enhancement. It includes all time periods, including but not limited to "real-time," necessary for the RTO to satisfy its reliability responsibilities, up to the planning horizon. There is no time gap between what is included within short-term reliability and the RTO's planning responsibilities.

Commenters also request more specificity in describing the RTO's functions. The facilities that will be under RTO control, the specific functions that the RTO must perform, and how the RTO will execute its responsibilities and direct operations, are all defined above in the section on operational authority. PJM's additional request that the RTO have authority to collect information is discussed in both the operational authority and the market monitoring sections.

PG&E requests that the RTO rely on market mechanisms to maintain short-term reliability. PJM/NEPOOL Customers requests that reliability and commercial activities be kept separate. We will not require the RTO to rely on market mechanisms in every instance to maintain short-term reliability. The Commission believes that some reliability functions may not be conducive to supply through competitive market mechanisms since a reliable power system provided to one customer cannot be withheld from other

customers, viz., many reliability functions are, in economic terms, "public goods." In Order No. 888, we identified some functions necessary to maintain grid reliability as ancillary services and required them to be provided as separate products. These services and their potential inclusion in emerging markets is discussed in the section on ancillary services below. We cannot conclude at this time that it is appropriate to rely solely on market mechanisms to supply the reliability functions that the transmission system operator must perform, but we expect that over time most of the generation services that perform these functions will be competitively procured.

Interchange Scheduling. We conclude that the RTO must have exclusive authority for receiving, confirming and implementing all interchange schedules, which are often coincident with schedules for unbundled transmission service. This function will automatically be assumed by RTOs that operate a single control area. If the RTO structure includes control area operators who are market participants or affiliated with market participants, the RTO will have the authority to direct the implementation of all interchange schedules. As stated in the NOPR, a remaining concern is that non-RTO control area operators, who are also competitors in energy markets, have unequal access to commercially sensitive information and could use this knowledge of their competitors' schedules and transactions to gain an unfair competitive advantage in the energy markets. In the event that the RTO filing includes a structure in which non-RTO control area operators receive sensitive information, we will require the RTO to monitor for any unfair competitive advantage, and report to the Commission immediately if problems are detected. In addition, to address concerns about protecting commercially sensitive information, we will require the RTO or any entities who operate control areas within the RTO's region that require access to commercially sensitive information to sign agreements that separate reliability personnel and the relevant information they receive from their wholesale merchant personnel.

Redispatch Authority. We conclude that the RTO must have the right to order the redispatch of any generator connected to the transmission facilities it operates, if necessary for the reliable operation of the transmission system.⁴³⁸

⁴³⁶ See, e.g., Canada DNR, Manitoba Board, Cal DWR, Entergy, Minnesota Commission, PSE&G.

⁴³⁷ The Commission has authorized the establishment of the New York State Reliability Council and has accepted the relationship between it and the NY ISO.

⁴³⁸ Redispatch for congestion management is addressed under different rules, as discussed in the section on congestion management.

We also require each RTO to develop procedures for generators to offer their services and to compensate generators that are redispatched for reliability. In order to maintain the reliability of the transmission system, the entity that controls transmission must also have some control over some generation. In general, we believe this control should be through a market where the generators offer their services and the RTO chooses the least cost options. This authority does not extend to initial unit commitment and dispatch decisions for generators. However, for reliability purposes, the RTO should have full authority to order the redispatch of any generator, subject to existing environmental and operating restrictions that may limit a generator's ability to change its dispatch.

Some commenters request that we define what is meant by redispatch for reliability. We clarify that we intend the authority for generator redispatch to be used by the RTO to prevent or manage emergency situations, such as abnormal system conditions that require automatic or immediate manual action to prevent or limit equipment damage or the loss of facilities or supply that could adversely affect the reliability of the electric system, or to restore the system to a normal operating state.⁴³⁹

Transmission Maintenance Approval. We conclude that, when the RTO operates transmission facilities owned by other entities, the RTO must have authority to approve and disapprove all requests for scheduled outages of transmission facilities to ensure that the outages can be accommodated within established reliability standards. Control over transmission maintenance is a necessary RTO function because outages of transmission facilities affect the overall transfer capability of the grid. If a facility is removed from service for any reason, the power flows on all regional facilities are affected. These shifting power flows may cause other facilities to become overloaded and, consequently, adversely affect system reliability.

The RTO is expected to base its approval on a determination of whether the proposed maintenance of transmission facilities can be accommodated within established state, regional and national reliability

standards. The RTO's regional perspective will allow it to coordinate individual maintenance schedules with other RTOs as well as with expected seasonal system demand variations. Since the RTO will have access to extensive information, it will be able to make more accurate assessments of the reliability effect of proposed maintenance schedules than individual, sub-regional transmission owners.

If the RTO is a transmission company that owns and operates transmission facilities, these assessments will be an internal company matter. However, if there are several transmission owners in the RTO region, the RTO will need to review transmission requests made by the various transmission owners.⁴⁴⁰ In this latter case, we expect the RTO to: receive requests for authorization of preferred maintenance outage schedules; review and test these schedules against reliability criteria; approve specific requests for scheduled outages; require changes to maintenance schedules when they fail to meet reliability standards; and update and publish maintenance schedules as needed.

We conclude that, if the RTO requires a transmission owner to reschedule planned maintenance, the transmission owners should be compensated for any costs created by the required rescheduling only if the previously scheduled outage had already been approved by the RTO.

We encourage the RTO to establish performance standards for transmission facilities under its direct or contractual control. Such standards could take the form of targets for planned and unplanned outages. The rationale for this requirement is that two transmission owners should not receive equal compensation if one owner operates a reliable transmission facility while the other operates an unreliable facility. For RTOs that are transcos, we will require that such quality standards be made explicit in any rate proposal.

Generation Maintenance Approval. We conclude that the RTO is not required to have authority over proposed generation maintenance schedules. However, we acknowledge that there are reliability advantages to the RTO having this authority, and we would accept RTO proposals where the participants choose to grant the RTO such authority. In our order approving

the Midwest ISO, we observed that "the dividing line between transmission control and generation control is not always clear because both sets of functions are ultimately required for reliable operation of the overall system."⁴⁴¹ Because of this close connection between generation and maintenance of system reliability, it is essential for generator owners and operators to provide the RTO with advance knowledge of planned generation outage schedules so that the RTO can incorporate this information into its reliability studies and operations plan. However, although a generator may be required to submit its maintenance schedule to an RTO, the RTO should be prohibited from sharing that information with any other market participants, or affiliates of market participants.

Facility Ratings. After consideration of the comments, we conclude that it is inappropriate here to require RTOs to establish transmission facility ratings. We encourage, however, such ratings to be determined, to the extent practical, by mutual consent of the transmission owner and the RTO, taking into account local codes, age and past usage of the facilities.

The Commission acknowledges the concern that changes in existing equipment ratings may lead to problems of equipment safety and possible damage. We further recognize that the RTO may initially need to rely upon existing values for equipment ratings and operating ranges so as not to disrupt reliable system operation. However, as an RTO gains experience operating or directing the operation of the transmission facilities in its region, we expect this responsibility to migrate to the RTO, as facility ratings have at least an indirect effect on the ability of the RTO to perform other RTO minimum functions (e.g., planning and expansion, ATC and TTC). If there is a dispute over equipment ratings, the parties should pursue resolution through an ADR process approved by the Commission.

Liability. After consideration, we will determine the extent of RTO liability relating to its reliability activities on a case-by-case basis.

Reliability Standards. We conclude that the RTO must perform its functions consistent with established NERC (or its successor) reliability standards, and notify the Commission immediately if implementation of these or any other externally established reliability standards will prevent it from meeting its obligation to provide reliable, non-discriminatory transmission service.

⁴³⁹ In general, a power system can be in one of three states: normal, emergency and restorative. When all constraints and loads are satisfied, the system is in its normal state; when one or more physical limits are violated, the system is in an emergency state; and when part of the system is operating in a normal state yet one or more of the loads is not met (partial or total blackout), the system is in a restorative state.

⁴⁴⁰ Since some of these transmission owners may also own generation, they may have an incentive to schedule transmission maintenance at times that would increase the prices received from their power sales. A transmission company, not affiliated with any generators, would not have these same incentives.

⁴⁴¹ Midwest ISO, 84 FERC at 62,180.

E. Minimum Functions of an RTO

In the NOPR, we proposed seven minimum functions that an RTO must perform. In general, we proposed that an RTO must:

- (1) administer its own tariff and employ a transmission pricing system that will promote efficient use and expansion of transmission and generation facilities;
- (2) create market mechanisms to manage transmission congestion;
- (3) develop and implement procedures to address parallel path flow issues;
- (4) serve as a supplier of last resort for all ancillary services required in Order No. 888 and subsequent orders;
- (5) operate a single OASIS site for all transmission facilities under its control with responsibility for independently calculating TTC and ATC;
- (6) monitor markets to identify design flaws and market power; and
- (7) plan and coordinate necessary transmission additions and upgrades.

We basically affirm these seven functions with the clarifications and revisions as noted below. In addition, we have added interregional coordination as an eighth minimum function, as discussed below.

1. Tariff Administration and Design (Function 1) Sole Administrator of Tariff

In order to ensure non-discriminatory service within the region, the NOPR proposed that the RTO be the sole administrator of its own transmission tariff.⁴⁴² The RTO would thus be the sole authority making decisions on the provision of transmission service including decisions relating to new interconnections. The NOPR requested comments on several aspects of this standard, including how the authority over interconnections would work for ISOs that do not own transmission and would not be performing the construction. The NOPR also sought comment on whether authority over interconnection should apply to all new interconnections, including those for reliability and connections to other regions.

Comments. The vast majority of commenters addressing these issues agree with the proposal that the RTO be the sole administrator of its own tariff.⁴⁴³ Commenters noted many of the

benefits of an RTO being the sole tariff administrator: it will eliminate confusion; reduce transactions costs; assure that access decisions are independent;⁴⁴⁴ reduce reliability concerns;⁴⁴⁵ and ensure consistent ratemaking across the RTO.⁴⁴⁶ Some commenters suggest that their respective organizations already meet this requirement, including ISO-NE and NY ISO, which ask whether sharing authority with transmission owners for non-discriminatory access meets the standard.

But some of the commenters that support the proposal had specific concerns and suggestions: the Commission should adopt specific pricing regulations and expressly permit expedited declaratory orders on pricing;⁴⁴⁷ the Commission should take a more active approach in developing innovative rates;⁴⁴⁸ there may be a problem for an RTO located in both the United States and Canada if there is disagreement over the tariff by the respective authorities;⁴⁴⁹ and quicker decisions are likely if a stakeholder board is not involved.⁴⁵⁰

A number of commenters also supported the proposal with respect to the RTO's authority over interconnections.⁴⁵¹ Some of these commenters expressed concerns and recommendations about the Commission's proposal, *e.g.*, transmission owners should be a part of the decision process;⁴⁵² transcos will be better able to integrate interconnection decisions into a unified strategy covering investment, operations, maintenance and facility design;⁴⁵³ RTOs should not have the authority to deny a generator that is not optimally located on the grid;⁴⁵⁴ interconnection policy should rely more heavily on market mechanisms;⁴⁵⁵ the transmission owner should develop the actual interconnection agreement to insure adequate protections for its equipment;⁴⁵⁶ national fees and technical standards should be established for interconnections;⁴⁵⁷

authority over interconnections should involve coordinated planning and construction, not "autonomous, unilateral authority";⁴⁵⁸ RTOs need to develop procedures and guidelines so that there are no adverse impacts of interconnection on existing facilities;⁴⁵⁹ RTOs should have authority to assess the impact of a new interconnection on regional facilities but should only have authority over interconnections involving RTO facilities, not all regional facilities;⁴⁶⁰ and an RTO must be required to show harm to deny an interconnection request.⁴⁶¹

A few commenters opposed the Commission's proposal or suggested making significant modifications. With respect to tariff administration, Seattle opposes the Commission giving RTOs with small control areas blanket authority to approve new interconnections and also argues that the RTO should not be given authority over the interconnection of customer based backup and load shaving generators, QFs, or subtransmission and radial transmission facilities (used to reinforce municipal grids). TXU Electric argues that the Commission should be more flexible and allow RTOs to choose whether to administer the tariff of other entities. TXU Electric notes that in ERCOT, each owner has its own tariff with its own revenue requirement but with uniform terms and conditions of access and that this approach can protect the owner better than an RTO tariff. Florida Commission recommends that the question of tariff administration be determined on a regional basis with endorsement by state regulators.

With respect to RTO authority over interconnections, Mass Companies argues that the RTO should not have the authority over interconnections because such authority is unlawful, impairs reliability, and because the transmission owner is in a better position to perform this function. SRP suggests that an RTO's exclusive right to administer its own tariff and the right to control interconnections may establish a property right that would jeopardize a public power's tax free status by being declared a private business use. This would be a potential problem if the RTO were not a governmental entity or a 501(c)(3) non-profit organization. To prevent this, SRP says that the RTO would have to be structured carefully with these concerns in mind. DOE indicates that the authority over interconnection is a concern for PMAs

⁴⁴⁴ PJM.

⁴⁴⁵ PJM/NEPOOL Customers.

⁴⁴⁶ UAMPS.

⁴⁴⁷ Entergy.

⁴⁴⁸ Illinois Commission.

⁴⁴⁹ Canada DNR.

⁴⁵⁰ New Smyrna Beach.

⁴⁵¹ See, *e.g.*, Entergy, PJM, South Carolina Authority, Southern Company, Tri-State, Desert STAR, East Texas Cooperatives, Enron/APX/Coral Power, Sitch and PG&E.

⁴⁵² Cal ISO.

⁴⁵³ Duke.

⁴⁵⁴ Minnesota Power.

⁴⁵⁵ PG&E.

⁴⁵⁶ Southern Company.

⁴⁵⁷ Distributed Power and EAL.

⁴⁵⁸ SPRA.

⁴⁵⁹ TANC.

⁴⁶⁰ Metropolitan.

⁴⁶¹ Williams.

⁴⁴² FERC Stats. and Regs. ¶ 32,541 at 33,739-740. The authority to file changes in the RTO tariff is discussed above under the Independence Characteristic.

⁴⁴³ See, *e.g.*, Allegheny, APX, SMUD, NASUCA, NY ISO, East Kentucky, Utilicorp, JEA, LG&E, Enron/APX/Coral Power, EPSA, South Carolina Authority, First Energy, Cal DWR, California Board, PacifiCorp and NSP.

because of the NEPA requirements which must be accommodated. Industrial Consumers would amend the proposed Regulatory Text on tariff administration to add "throughout the interconnection within which the Regional Transmission Organization resides" to the requirement to promote efficient use and expansion. Industrial Consumers also propose that the Regulatory Text on interconnection be amended to add the responsibility to coordinate transmission needs across the interconnection. Finally, Industrial Consumers would amend the provision that RTOs review and approve requests for new interconnections to add "by new loads that take service at transmission voltages and by any new generation resource regardless of the nominal voltage at the generator's point of interconnection. Any proposal to increase the nameplate-rated capacity at an existing generating site shall be treated as a new request for interconnection" to clarify that the RTO is to authorize such interconnections and minimize entry barriers to new sources of generation.

Commission Conclusion. We note the strong support for this standard in the comments and we adopt the NOPR's requirement that the RTO be the sole provider of transmission service and sole administrator of its own open access tariff. Included in this is the requirement that the RTO have the sole authority for the evaluation and approval of all requests for transmission service including requests for new interconnections.⁴⁶²

With the RTO the sole provider of transmission service, transmission customers have a nondiscriminatory and uniform access to regional transmission facilities. This type of access cannot be assured if customers are required to deal with several transmission owners with differing tariff terms and conditions. As noted in the NOPR, the RTO must be the provider of transmission service in the strong sense of the term. Mere monitoring and dispute resolution are insufficient to meet the requirements of this standard.

The requirement that the RTO administer its own tariff and not the tariff or tariffs of other entities received little objection in the comments, even from ISOs where this requirement is not currently being met.⁴⁶³ One commenter, SCE&G proposes that the RTO's tariff only cover its own costs and wheeling. The transmission owners would

maintain standard open access tariffs which would be administered by the RTO. We reject this proposal. To provide truly independent and nondiscriminatory transmission service, the RTO must administer its own tariff and have the independent authority to file tariff changes.

Mass Companies argues that the RTO is not in as good a position as transmission owners to judge requests for new interconnections. SPRA and Metropolitan suggest that an RTO's authority over new interconnections should be limited. Because the ability for customers to obtain nondiscriminatory access to the regional transmission system, whether over existing facilities or over new facilities, is integral to a competitive market for generation, we reject these proposals to modify our original position on new interconnections.

Other commenters, as noted above, support this standard but have specific concerns they would like to see the Commission address. The concerns listed do not cause us to change our original proposal. These concerns, to the extent they apply, should be voiced at the time RTO proposals are filed and they will be considered on a case-by-case basis.

Multiple Access Charges. The NOPR proposed that the RTO's tariff must not result in transmission customers paying multiple access charges. We affirm that proposal in this Final Rule. Because the issue of multiple access charges is a rate issue, we discuss in detail the comments we received on this issue, the reasons for our conclusion, and the concepts of pancaked rates, license plate rates, and uniform access charges in Section III.G of this Final Rule addressing transmission ratemaking policy for RTOs.

2. Congestion Management (Function 2)

In the NOPR, we proposed to include congestion management as a minimum function that an RTO must perform.⁴⁶⁴ Specifically, we proposed to require the RTO to ensure the development and operation of market mechanisms to manage transmission congestion. We proposed that the RTO must either operate such markets itself or ensure that the task is performed by another entity that is not affiliated with any market participant. In carrying out this function, we stated that the RTO must satisfy certain standards or demonstrate that an alternative proposal is consistent with or superior to satisfying the standard. We further proposed that the market mechanisms must accommodate

broad participation by all market participants, and must provide all transmission customers with efficient price signals regarding the consequences of their transmission usage decisions. We proposed to allow RTOs considerable flexibility in experimenting with different market approaches to managing congestion through pricing. However, we stated that proposals should ensure that (1) the generators that are dispatched in the presence of transmission constraints are those that can serve system loads at least cost, and (2) limited transmission capacity is used by market participants that value that use most highly. We asked for comments as to what specific requirements, if any, may best suit these goals.⁴⁶⁵

We stated in the NOPR that traditional approaches to congestion management such as those that rely exclusively on the use of administrative curtailment procedures may no longer be acceptable in a competitive, vertically de-integrated industry. We thus concluded that efficient congestion management requires a greater reliance on market mechanisms, and stated our belief that a large regional organization like an RTO will be able to create a workable and effective congestion management market. We stated that while it is our intent to give RTOs considerable flexibility in experimenting with different market approaches to managing congestion, we believe that a workable market approach should establish clear and tradeable rights for transmission usage, promote efficient regional dispatch, support the emergence of secondary markets for transmission rights, and provide market participants with the opportunity to hedge locational differences in energy prices.

The Commission invited comments on the requirement that RTOs must be responsible for managing congestion with a market mechanism, and posed the following questions. Can decentralized markets for congestion management be made to work effectively and quickly? Can the RTO's role be limited to that of a facilitator that simply brings together market participants for the purpose of engaging in bilateral transactions to relieve congestion? If not, will these markets require centralized operation by the RTO or some other independent entity? How can an RTO ensure that enough generators will participate in the congestion management market to make possible a least-cost dispatch? Are there any special considerations in evaluating

⁴⁶² Of course, eligible applicants always have the right to seek interconnections from the Commission pursuant to sections 202(b) and 210 of the FPA.

⁴⁶³ See, e.g., ISO-NE at 9.

⁴⁶⁴ FERC Stats. & Regs. ¶ 32,541 at 33,741-43.

⁴⁶⁵ *Id.* at 33,754-55.

market power in a congestion market operated or facilitated by an RTO? In addition, we proposed to allow up to one year after start-up for this function to be implemented. We noted that market approaches to congestion management may take additional time to work out, and asked for comments on whether this additional implementation time period is warranted, and whether one year is an appropriate additional time period.

Comments. Using Market Mechanisms to Manage Congestion. Although opinions vary as to the proper role of the RTO in managing congestion, many commenters believe that efficient congestion management requires greater reliance on market mechanisms.⁴⁶⁶ CSU believes that congestion management is uniquely amenable to a market solution. CSU states that there will be a continuing need for some type of market mechanism to address constraints and this mechanism is best established at the regional level and best placed with an entity independent of wholesale power market participants.

Some commenters emphasize that it is better to use market mechanisms to manage congestion than to rely on the physical interruption of power flows.⁴⁶⁷ NERC contends that if the industry had in place more market-oriented mechanisms that dealt effectively with constraints, then the frequency of transmission loading relief (TLR) procedures would decrease. Professor Hogan claims that with efficient pricing, users have the incentive to respond to the requirements of reliable operation. He asserts that, absent such price incentives, market choices would need to be curtailed in order to give the system operator enough control to counteract the perverse incentives that would be created by prices that did not reflect the marginal costs of dispatch. PJM/NEPOOL Customers argues that, when faced with a transmission congestion circumstance, the RTO should redispatch generators to the extent possible.

Also, Statoil claims that the use of TLR procedures is inherently discriminatory. Statoil claims that most transmission owners serving retail load do not engage in interchange transactions or use the pro forma tariff at the same level as new competitive market entrants attempting to enter historically captive markets. Statoil thus argues that, even if TLR is applied in a

comparable manner, it will still disproportionately and adversely affect new competitive market entrants.

Role of the RTO in Congestion Management. Commenters offer a variety of views concerning the proper role of the RTO in congestion management. Some advocate an active role for the RTO in operating an energy market that is highly centralized.⁴⁶⁸ Others envision the RTO's role as being much smaller, perhaps limited to that of a facilitator that brings together market participants for the purpose of engaging in voluntary transactions to relieve congestion.⁴⁶⁹ Still others, such as Southern Company and EEI, believe that RTOs are not necessary to make congestion management work. EEI argues that while congestion management does require a coordinated regional or interconnection-wide solution, it does not require the extensive infrastructure and responsibilities associated with what the Commission has proposed to define as RTOs. EEI notes that NERC's Congestion Management Working Group is exploring available options for congestion management, independently of whether RTOs exist.

PJM/NEPOOL Customers believes that an independent entity must operate any congestion management market. It believes also that that entity must have sufficient power and centralization to address congestion problems effectively and quickly. Consequently, it urges the Commission not to consider proposals that include a decentralized market for congestion management or that limit the RTO role to that of a facilitator of bilateral transactions to relieve congestion. In addition, it contends that the RTO must retain sufficient authority over generators that choose to make themselves available to ensure that those generators will participate in the congestion management market. Duke states that, eventually, decentralized markets may organize in a manner to accomplish effective congestion management, but at this time, the congestion management function should be centrally managed.

PJM claims that RTOs can facilitate efficient, broad-scale congestion management. PJM states that by combining multiple transmission systems over a large geographic region, an RTO can have an effective pricing system to price efficiently actual transmission flows in a region. PJM

argues that not only should the Commission require that RTOs be responsible for managing congestion with market mechanisms, the Commission also should prohibit any other entity from acting in a manner that detracts from the RTO's ability to employ its market mechanisms.

Cleveland believes that an effective way to manage congestion may be to combine a market-based mechanism with a power exchange. It states that the RTO's redispatch function and the bidding process available through a power exchange should jointly operate to minimize the congestion.

H.Q. Energy Services contends that control over the management of congestion goes hand-in-hand with control over reliability. It believes that, ideally, an RTO should establish a congestion pricing system that manages congestion with minimal operator intervention. However, H.Q. Energy Services argues that, without control over reliability, an RTO will not be in the position to accurately and fairly allocate available transmission capacity because it cannot send the correct congestion pricing signals.

Sithe contends that the Commission should not allow overly decentralized systems whereby individual utilities in a region continue to manage congestion relief, especially if those utilities continue to own generation. Arkansas Consumers believe that the RTO's congestion management function helps provide a remedy for any anti-competitive activity on the part of generators or transmission owners. First Rochdale contends that only fully independent operation of an RTO is likely to lead to open markets in which all entities can compete freely. Duke asserts that there are no special considerations in evaluating market power in a congestion market operated or facilitated by an RTO.

Other commenters stress that the RTO's role in managing congestion using market mechanisms should be strictly limited. Indeed, the South Carolina Authority opposes a centralized arrangement for managing congestion as being unduly restrictive and perhaps anti-competitive. WPSC argues that the role of the RTO should be limited to acting as a clearinghouse so that market participants are aware of the range of alternatives available for dealing with congestion. WPSC contends that the market will then dictate which mechanisms are used in any particular instance. SPP suggests that the RTO can be a facilitator of congestion relief and that there is no need for the Commission to require that the RTO adopt a centralized approach,

⁴⁶⁶ See, e.g., United Illuminating, CSU, Duke, NASUCA, Los Angeles, NYPP, DOE, SMUD, Otter Tail, PG&E, FirstEnergy, Mass Companies, Enron/APX/Coral Power, Nevada Commission.

⁴⁶⁷ See, e.g., NERC, Sithe, NASUCA, Cineroy, Professor Hogan, PJM, Dr. Ilic.

⁴⁶⁸ See, e.g., PJM, Professor Hogan, CSU, Sithe, NERA, Duke, PJM/NEPOOL Customers, H.Q. Energy Services, Minnesota Power, FTC.

⁴⁶⁹ See, e.g., APX, SPP, South Carolina Authority, Alliant Energy, WPSC, NSP, TANC, Williams.

such as locational marginal pricing, for managing congestion. SPP states that it is a facilitator of congestion relief and intends to continue in that role under its new proposal. SPP states that it will identify which generators can relieve a constraint and the relative impact of redispatching those generators. It will then be the customer's responsibility to contract with the owner of these generators for redispatch services. SPP notes that this method relies on the market and bilateral contracts for the redispatch solutions. SPP claims that the market can also provide for price assurance and for long-term redispatch obligations. PG&E claims that with the proper information, bilateral market-based redispatch could be used within an hour of the occurrence of congestion on any part of the controlled system.

APX argues that the RTO should not conduct the trading process because it will impede the adaptation of trading to market conditions, which is essential for market development. APX claims that all competitive industries use decentralized trading through forward contracts, and no competitive industry uses a central bidding agent to create its market. Consequently, APX believes that the Commission should limit the RTO's role in congestion management to that of a provider of last resort. PG&E argues that although the RTO may administer certain market mechanisms such as congestion management, it is important that the RTO not view itself as responsible for energy pricing and other aspects of supply and demand interactions, all of which, PG&E contends, can be most effectively managed by the market unless material and lasting market flaws are present.

Similarly, Cinergy argues that the mechanism for price transparency in the commodity market should be developed and implemented by the market, not the RTO. Cinergy recognizes, however, that an economic congestion management system depends on a power market mechanism that provides price transparency for determining economic dispatch of generation. Consequently, Cinergy notes, RTOs will be confronted with issues of applying an economic dispatch valuation mechanism. Cinergy argues that such mechanism should evolve from the marketplace, not directly from the RTO. Cinergy proposes that the RTO would administer the congestion management system, but would not be involved in the commodity market infrastructure unless its involvement was mutually agreeable among all stakeholders.

Williams claims that decentralized markets for congestion management, operating under the auspices of RTOs,

can work effectively and quickly in an environment in which market participants have the correct incentives. Williams states that depending upon the geographic size of RTOs and the extent of congestion within each, zones for congestion management may have to be developed. Williams provides a detailed description of how a zonal approach to congestion management can be implemented.

Both CP&L and Enron/APX/Coral Power believe that the role of the RTO in congestion management should depend on the time frame in which the decisions are being made. These commenters prescribe different roles for the RTO in each of three different time frames.

The Direct Dispatch Authority of the RTO. While supporting the use of pricing and other market mechanisms to manage congestion, a number of commenters state that an RTO must have authority to direct redispatch if necessary to ensure grid reliability.⁴⁷⁰ For example, Otter Tail contends that the RTO should have direct authority to order redispatch of generation for purposes of relieving congestion and during system emergencies. Otter Tail states that this dispatch should be directed for the generating units that can most economically reduce the congestion. Otter Tail states that because there is a need for immediate, real-time response to system contingencies and to relieve transmission congestion, the RTO should have control of generating units. East Kentucky contends that to effectively manage congestion, the RTO must have absolute authority to order redispatch of all generators on the RTO transmission system. However, for this to work, East Kentucky states that the RTO will have to compensate the generator with firm transmission service for the additional out-of-pocket costs incurred due to the redispatch, plus an amount for lost margins on lost revenue. It suggests that generators with non-firm transmission service would have to redispatch as directed by the RTO but would have to bear their own costs.

NERC notes that market mechanisms may offer better ways of dealing with congestion management than does physical interruption of power flows, but asserts that it will always be necessary to have a non-market mechanism such as transmission loading relief in place to ensure that the stability of the grid is always

⁴⁷⁰ See, e.g., Otter Tail, NERC, Allegheny, EME, NASUCA, East Kentucky, Williams, Minnesota Power, CSU. See also *supra* section III.D.3, which addresses the appropriate scope of the RTO's operational authority.

maintained. However, EME believes that the extent of RTO control over dispatch of generation should be carefully circumscribed to ensure maximum development of competitive markets in wholesale power and ancillary services. Seattle contends that where transparent power supply markets exist, price differences are widely known to the market and congestion can be resolved bilaterally with no intervention by an RTO. PJM notes that since implementing LMP, it rarely has needed to take emergency actions to alleviate transmission congestion.

Minnesota Power believes that RTOs must have the authority to require that all generators, existing and new, agree to redispatch as a condition of grid connection. Minnesota Power also believes that the RTO must have the authority to penalize generators who subsequently refuse a redispatch order, or claim a false unplanned outage. CSU asserts that generation redispatch is essential in Front Range Colorado, which can be expected to have an increasing population of gas-fired generation within the boundaries of the constraints. It contends that the inability to redispatch these units for any reason other than reliability would severely hinder the ability of an RTO to address capacity constraints.

MidAmerican states that, although congestion must be managed using pricing signals from the market, circumstances may occur where immediate actions are required and time does not permit normal bidding to allow the marketplace to respond. It contends that during such events, the RTO must be required to follow previously established procedures.

However, Seattle argues that the RTO should not have authority to redispatch generation to accomplish congestion management without unanimous consent of the stakeholders. Seattle notes that many Northwest generating plant operators are subject to fishery-related hydroelectric dispatch constraints. Seattle states that because these constraints are particular to the owners of the generating facilities, these resources are not well suited to third party dispatch.

Managing Congestion by Eliminating It. Some commenters contend that the ultimate goal of RTOs should be the elimination of congestion within their respective areas of control.⁴⁷¹ Powerex believes that it is better to eliminate congestion at its source through facilities upgrades, if economically and environmentally feasible, rather than

⁴⁷¹ See, e.g., Williams, Powerex, Manitoba Board, Salomon Smith Barney.

attempting to manage congestion on a long-term basis through congestion pricing schemes. Salomon Smith Barney believes that the Commission has overemphasized congestion pricing as a vehicle to price the existing network rather than as a vehicle to induce investment when such investment is an economical alternative.

TDU Systems state that they do not want management of significant transmission congestion to become a long-term function of RTOs. They claim that minor congestion (*i.e.*, congestion that is economically dealt with through redispatch of generators) will always be a feature of wholesale transmission markets, and an RTO should properly manage it. However, they argue that an RTO should deal with significant persistent transmission congestion by constructing (or having constructed) the appropriate transmission or generation facilities.

Desirable Attributes of Market Mechanisms. Many commenters offer their views on the desirable attributes of any market mechanisms that are used to manage congestion.⁴⁷² For example, PJM/NEPOOL Customers urges the Commission to employ three general criteria to evaluate any proposal: simplicity, visibility and predictability. They state that the proposed approach to relieve the congestion should be simple to administer, both for customers and for the RTO. They believe that market participants should be able to examine the operation of the congestion management mechanism on a real-time basis and verify that transmission access is being appropriately accorded to entities that most desire transmission service. They state that such visibility will engender confidence by market participants in the congestion management mechanism. In addition, they believe that the congestion management mechanism must be predictable to all transmission users to determine the anticipated price that will be necessary to ensure the continuation of transmission service if congestion occurs.

Cinergy states that an economically efficient congestion management system must begin with properly defining information posting requirements. Accordingly, Cinergy argues that the Final Rule should ensure that requisite information on congestion is posted on the OASIS. Similarly, Williams and Industrial Consumers believe that RTO access to region-wide information on network conditions and power

transactions, coupled with efficient congestion management and well specified transmission rights, could help RTOs in taking preemptive actions against potential curtailment incidents. Statoil and EPSA believe that, ideally, economic rationing schemes should be uniform across RTOs and should be implemented as an ancillary service under a regional transmission tariff. Montana Commission asserts that congestion management must be efficient. CMUA believes that congestion management mechanisms must do their job, but not unreasonably interfere with choices by market participants.

Some commenters believe that efficient congestion management requires a transparent commodity market. Cinergy states that market mechanisms that include locational pricing and financial rights for firm transmission have been successfully implemented where they are supported by a power exchange or pool pricing mechanism that provides market-clearing prices and price transparency. CalPX emphasizes the value of a separate power exchange and argues that the bifurcation of the exchange and transmission operator functions does not add to the market cost of congestion management, as some have suggested. Also, Otter Tail believes that the development of an hour-ahead power exchange within the RTO would improve grid reliability.

Many commenters support the NOPR's requirement that market mechanisms be used to manage congestion and note the particular value of using price as a tool to manage congestion.⁴⁷³ Some commenters specifically endorsed the proposed requirement that congestion pricing proposals must meet the two efficiency objectives set forth in the NOPR.⁴⁷⁴ PJM/NEPOOL Customers state that these two objectives are fundamental to the operation of a market and to the ultimate goals of electricity supply competition.⁴⁷⁵ SMUD believes that a well-designed congestion management policy, that provides proper locational price signals without creating opportunities for gaming or cost shifting, will attract market participation. SMUD agrees that market participants must be given efficient

price signals concerning their use of the transmission system, but claims that this is difficult because the existing transmission grid was not designed with the capability to operate as a common carrier or to serve customers in an open access manner. Also, a few commenters expressed doubts about the overall value of using pricing mechanisms to manage congestion,⁴⁷⁶ and others cited reasons to move cautiously.⁴⁷⁷ Tri-State is skeptical that market mechanisms for managing congestion will lead to a least-cost dispatch. Tri-State states that entities with firm transmission rights on the congested path may be reluctant to participate voluntarily in generation redispatch that will jeopardize the economics of long-term power supply contracts or firm resources, even if the result would lower costs.

Several commenters suggest principles to guide the design of congestion pricing mechanisms.⁴⁷⁸ NASUCA states that any mechanism for using congestion prices for managing transmission system flows should be easy to implement; designed to minimize cost shifts; designed to support an economically efficient dispatch; and coordinated with the underlying transmission rate design. PacifiCorp states that key components of a good market-based congestion clearing methodology are: (1) Tradable transmission capacity reservations; (2) a system in which all parties who can clear congestion can bid to do so; (3) the establishment of congestion costs far enough in advance to facilitate reasoned decision-making; and (4) the avoidance of any RTO rules that substantially reduce liquidity in power markets. UtiliCorp believes that a congestion management system should establish tradeable rights for transmission usage, promote efficient regional dispatch, support the emergence of secondary market for transmission rights, and give market participants the opportunity to hedge locational differences in energy prices. However, Enron/APX/Coral Power disagrees on the latter feature. It contends that the monopoly wires business should not be allowed to encroach on what they see as the highly competitive and innovative business of providing hedges against locational price differences of energy or capacity or against price volatility of these or any other competitive products.

Cal DWR and Metropolitan urge the Commission to adopt RTO ratemaking principles that include off-peak rates.

⁴⁷² See, e.g., PJM/NEPOOL Customers, United Illuminating, Allegheny, EPSA, SMUD, Los Angeles, NASUCA, Duke, NERC, Professor Hogan, EME, PJM, DOE, CSU.

⁴⁷⁴ See, e.g., PJM/NEPOOL Customers.

⁴⁷⁵ However, Montana Commission asks the Commission to specify more precisely the nature of the pricing and congestion management methods that will satisfy the NOPR's efficiency objectives.

⁴⁷⁶ See, e.g., LIPA, Transmission ISO Participants.

⁴⁷⁷ See, e.g., EPSA, Tri-State.

⁴⁷⁸ See, e.g., NASUCA, NJBUS, PJM/NEPOOL Customers, EPSA, Enron/APX/Coral Power.

⁴⁷² See, e.g., NASUCA, CMUA, NSP, PG&E, Statoil, SMUD, UtiliCorp, PacificCorp, PJM/NEPOOL Customers, Metropolitan, Cal DWR.

Cal DWR believes that customers should face accurate transmission price signals and, therefore, transmission prices should be lower in periods of off-peak demand for transmission. Cal DWR believes that off-peak pricing provides an accurate price signal over the longer term, promoting investment necessary to shift transmission usage to off-peak periods. In addition, Metropolitan believes that off-peak pricing can help to resolve problems of cost-shifting.

A number of commenters emphasize certain benefits of a well designed congestion pricing policy, claiming that price signals can assist RTOs and market participants in determining the efficient size and location of both new generation and new grid expansions.⁴⁷⁹ Los Angeles argues that ensuring accurate market signals through the creation of a congestion pricing mechanism will be the keystone to future system planning. Los Angeles states that these signals should alert generators to the advantages of siting in congested areas, motivate marketers and distribution companies to develop demand-side management options, and generally foster marketplace innovation. Los Angeles also believes that congestion price signals should help in determining the proper size of transmission upgrades that the RTO might build to relieve congestion. Otter Tail believes there exists a great need for new transmission capacity and, indeed, argues that the overall focus of the NOPR and FERC transmission policy should be on providing the appropriate financial incentives to assure investment in and expansion of the system.⁴⁸⁰ To ensure that price signals translate into appropriate expansion of the grid, SMUD believes that the RTO must be sufficiently independent and strong to require the expansion of the grid. NASUCA notes that, while congestion cost pricing may help to signal where new generation and transmission lines are needed, it may not be necessary for the efficient daily operation of the transmission grid.

Other commenters believe that it may be difficult to design market mechanisms to provide incentives for the efficient expansion of the grid.⁴⁸¹ H.Q. Energy Services states that currently, the rules for congestion management do not act as a sufficient incentive to transmission owners to

upgrade facilities. NWCC states that it is unclear whether congestion charges can act as a means of driving transmission expansion, since adding transmission is, by nature, capacity-based. NWCC also states that it is unclear whether congestion costs will be an adequate incentive for market participants to finance transmission expansion on their own, given the extensive permitting and regulatory requirements that are involved. LIPA states that, while new location-based pricing mechanisms have not been in place long enough to determine if they will provide empirical evidence that is helpful in identifying efficient transmission expansions, it believes that the mechanisms do not provide sufficient incentives for development of transmission. Also, LIPA claims that they do not provide a useful signal when reliability, as opposed to economic efficiency, drives the need for transmission enhancements.

SoCal Edison criticizes the congestion management policies implemented by the Cal ISO, stating that procedures intended to encourage the voluntary mitigation of congestion through investment in new transmission may not provide a sufficient incentive. SoCal Edison contends that, while correct congestion price signals will assist in the identification of transmission investment needs, they will not eliminate fundamental disputes among affected market participants over the responsibility for the costs of new transmission or eliminate the risks associated with attempting to construct new transmission projects. It asserts that the Commission cannot simply assume that the market will respond to congestion signals if, at the same time, it is creating a regulatory climate that discourages investment in new transmission. SoCal Edison believes that impediments to grid expansion can be overcome only if the Commission adopts transmission pricing policies that more accurately reflect the value that new transmission investments bring to electric consumers. Similarly, FirstEnergy argues that if the Commission desires an efficient generation market that optimizes the public good, then a mechanism that allows transmission owners to capitalize on increases in the transmission capacity at fair market value must be found. FirstEnergy contends that the interaction of these free market forces will drive the proper allocation of resources between transmission and generation over the long term.

Locational Marginal Pricing. A number of commenters advocate the use of locational marginal pricing (LMP) for

congestion management.⁴⁸² Professor Hogan states that, with LMP, the security-constrained economic dispatch process would produce prices for energy at each location, incorporating the combined effect of generation, losses and congestion. He states that the corresponding transmission price between the location where power is supplied and where it is used would be determined as the difference between the energy prices at the two locations. Professor Hogan therefore contends that this same framework is easily extended to include bilateral transactions. Professor Hogan states that, with LMP, the system operator coordinates the dispatch and provides the information for settlement payments, with regulatory oversight to guarantee comparable service through open access to the pool run by the system operator through a bid-based economic dispatch. He claims that PJM implemented LMP after experimenting with an alternative market model and pricing approach that proved to be fundamentally inconsistent with a competitive market and user flexibility. He states that the earlier pricing system allowed market participants the flexibility to choose between bilateral transactions and spot purchases, but did not simultaneously present market participants with the costs of their choices. He states that this created perverse incentives. Professor Hogan argues that LMP is the only workable system that can support a non-discriminatory competitive market that allows for participant choice and flexibility.

PJM states that the Commission correctly concludes that LMP will "encourage efficient use of the transmission system, and facilitate the development of competitive electricity markets." PJM notes that, under LMP, transmission customers are assessed congestion charges consistent with their actual use of the system and the actual redispatch that their transactions cause. It claims that this provides an economic choice to non-firm transmission customers to self-curtail their use of the transmission system or pay congestion charges determined by the market. PJM believes that by basing congestion charges on the true redispatch cost, parties behave in a rational and efficient manner. It states that the market determines the clearing price for transmission congestion and which customers ultimately utilize the transmission system. PJM states that the use of fixed transmission rights (FTRs)

⁴⁷⁹ See, e.g., Allegheny, EME, United Illuminating, EPSA, SMUD, Los Angeles, NASUCA, CSU.

⁴⁸⁰ Other commenters emphasize the need for significant investments to expand transmission capacity. See, e.g., EPRI, Salomon Smith Barney.

⁴⁸¹ See, e.g., Transmission ISO Participants, SoCal Edison, H.Q. Energy Services, LIPA, NWCC.

⁴⁸² See, e.g., Professor Hogan, PJM, NERA, Sithe, Allegheny, Mid-Atlantic Commissions, DOE, Duke, United Illuminating, EME.

enables market participants to pay known, fixed transmission rates and to hedge against congestion charges.

The FTC believes that accurate LMP signals for investment to reduce congestion may become even more important as distributed generation presents opportunities for small-scale, fine-tuned (with respect to both size and location) generation investments to relieve transmission congestion, in place of large-scale transmission or generation investments. EME endorses the LMP pricing approach adopted by PJM and the New York ISO, and states that the Midwest ISO and the Alliance RTO should be encouraged to adopt similar approaches. The CalPX notes that the separation of the CalPX and the ISO in California does not prevent the use of a locational pricing model that incorporates the individual buses and transmission lines in the network.

Allegheny believes that "[c]onsistent locational marginal price dislocations readily identify system expansion, or other congestion relief, requirements as well as serve as an indicator of the most economic fix to congestion patterns over time." It claims that there would be no incentives for the RTO or transmission owners to maintain congestion, since there is no financial impact on them from LMP because any excess payments received by the RTO during congestion are returned to holders of FTRs. Allegheny recommends that the Commission remain flexible in considering other pricing innovations for congestion management, but believes that a simplified locational marginal pricing methodology should be established as a default market mechanism against which other pricing innovations are evaluated.

Some commenters, however, criticize the locational marginal pricing approach to congestion management.⁴⁸³ APX argues that, because LMP requires the RTO to implement a centrally optimized dispatch, it will discourage, if not eliminate, the commitment of forward contracts in the energy market and replace the price discovery of forward markets with ex post pricing. APX contends that because LMP price calculations occur only periodically and in a single iteration, price visibility is restricted compared to a continuous forward market. APX claims that this diminished visibility can make the result less efficient and more vulnerable to an exercise of market power. APX contends that, for most industries, a process of continuous trading creates efficiency in a competitive market,

while the LMP optimization process has no role for trading. APX asserts that no competitive industry uses optimization to simulate and substitute for market outcomes. APX contends that under LMP, the system operator, not the market, will specify the structure of the optimization problem. APX claims that markets process information much more flexibly and comprehensively through the self-interested trading behavior of buyers and sellers. APX asserts that this is the strength of markets and the critical shortcoming of LMP.

Dynergy claims that markets for FTRs have yet to fulfill their promise to provide market participants with critically important price certainty for their transmission transactions. For example, Dynergy states that allocation problems still exist, in that only a small portion of available FTRs is being auctioned off in certain markets while a large number are being withheld for incumbents' use. Dynergy argues that in order for FTRs to provide a truly effective hedge against transmission price increases resulting from LMP in the hourly market, hourly FTRs would have to be available in a liquid market at a moment's notice, but nothing close to such a market exists. Dynergy suggests that, because the LMP model has yet to be implemented successfully due to the lack of a liquid FTR market, the time is ripe to look at other models, such as a physical rights model.

LIPA claims that neither the opportunity to obtain fixed transmission rights nor the prospect of locational price reductions are sufficient to encourage efficient generation and transmission expansions. For example, LIPA notes that awarding a transmission expander transmission rights that entitle it to collect congestion rents on the expanded capacity creates an incentive that runs counter to the purpose of the expansion; *i.e.*, the more successful the expansion is in eliminating congestion, the less value the incentive has for the expander. Also, LIPA believes that locational pricing systems are biased toward using generation to solve congestion problems on the transmission grid and, as a result, could lead to market power abuse by an operator that sites a new generator in a load pocket and then takes advantage of transmission limitations to manipulate the operation of other generators that it owns.

The Virginia Commission claims that pricing mechanisms incorporating locational marginal prices tend to produce intense signals over short time frames, particularly when constraints are seasonal and driven by extraordinary events such as extreme

weather. The Virginia Commission therefore believes that, at least initially, locational marginal prices may provide incentives for short-term actions for congestion relief, rather than longer term solutions such as the construction of additional transmission or generating facilities in a particular location.⁴⁸⁴ The Virginia Commission also states that the use of locational marginal pricing is heavily dependent on the existence of transparent short-term competitive power markets. It urges the Commission to evaluate carefully proposals that place greater reliance on market mechanisms through the use of price signals, and to condition the use of such mechanisms on the existence of such things as fully functioning power exchanges, the establishment of fixed transmission rights and the existence of secondary markets for such rights.

CP&L argues that while the proposed congestion management rule appears to permit only PJM-redispach types of arrangements, CP&L does not believe that the PJM model is the only workable congestion management process. Rather, CP&L believes that congestion is best managed through the coordinated reservation and scheduling of transactions on the grid rather than post-congestion fixes. Also, TDU Systems states that it may be difficult to transplant the PJM model to regions that do not have a centrally dispatched, tight power pool to use as an RTO platform.

Some commenters claim that LMP is more complex than necessary,⁴⁸⁵ although Allegheny believes that today's technology mitigates these concerns. The FTC states that, despite the apparent virtues of LMP, it may be reasonable to back away from a full application of an LMP approach if doing so provides benefits to consumers from increased competition in generation markets. For example, the FTC states that, in light of its alleged complexity and the difficulty that financial markets may have in anticipating congestion charges, LMP may inhibit the formation of efficiency-enhancing futures markets in electricity generation and trading because congestion prices are more uncertain under LMP than under other pricing approaches (such as zonal transmission congestion pricing). The FTC thus suggests that the Commission may want to continue to entertain alternatives to LMP if a reasonable case is made that benefits to consumers are

⁴⁸³ See, e.g., APX, LIPA, TDU Systems, CP&L, Virginia Commission, Tri-State, Dynergy.

⁴⁸⁴ The Brattle Group believes that, in addition to locational congestion pricing, some form of regulatory incentives may be needed to bring about efficient investment in the transmission grid.

⁴⁸⁵ See, e.g., PG&E, PJM/NEPOOL Customers, FTC, Tri-State, Dynergy.

greater under the alternatives than under LMP.

Managing Congestion with Tradable Transmission Rights. Several commenters emphasize the importance of including explicit transmission rights in any congestion management plan that relies on market mechanisms.⁴⁸⁶ EPSA believes that when transmission rights are clearly defined and allocated, ATC calculations can be made more accurately and congestion management simplified. DOE notes that financial transmission rights will provide a hedge against long-term fluctuations in spot prices, will encourage the development of competitive markets and will likely contribute to efficient generation and transmission resource planning. SMUD emphasizes that, without the pricing hedge provided by such rights, it cannot guarantee its customer-owners low cost or reliable transmission service.

A number of commenters emphasize that transmission rights must be tradeable in a secondary market.⁴⁸⁷ Indeed, some commenters believe that the use of firm (physical) transmission rights along with a robust secondary market in these rights is the most workable solution for efficient congestion management.⁴⁸⁸ Seattle notes that with an effective market for transmission rights, market participants may be afforded transmission-based options for resolving congestion. It states that market participants that invest in transmission facilities that increase capacity can receive the right to use or sell that capacity. Enron/APX/Coral Power believes that the RTO should be charged with developing a workable market approach to congestion and parallel-path management based on clear and tradeable rights for transmission usage that promote efficient regional dispatch, and support the emergence of secondary markets for transmission rights. Enron/APX/Coral Power contends that this will require that RTO systems be operated as they are in the Western Interconnection based on physical rights. It suggests that, in order to ensure a firm right to schedule service over an interface when it is constrained, a customer would have to demonstrate ownership of sufficient property rights in the interface. Enron/APX/Coral Power suggests three options for obtaining rights: (1) From the RTO in the primary auction or other primary form of allocation; (2) from holders of rights in the secondary market; and (3)

from the RTO in the form of short-term released rights not scheduled by their holders. Enron/APX/Coral Power states that by defining and enhancing physical property rights, the market for those rights will provide *ex ante* transmission prices that include the cost of purchasing rights in constrained interfaces. It claims that this will permit dispatch decisions to be made on the basis of delivered energy prices. Enron/APX/Coral Power states that to ensure that no market participant can exercise market power by hoarding property rights, the rights should be designed as use-or-lose so that if a right is not scheduled it can be used by others on a non-firm basis.

Similarly, Dynegey proposes a physical rights model in which a limited amount of firm physical rights would be sold and only those holding physical rights would be allowed to schedule when capacity is constrained. Under Dynegey's proposal, only those with preassigned FTRs would be allowed to schedule on a firm basis at a set price. Dynegey states that others could submit non-firm schedules, subject to curtailment, or, if the party is willing, redispatch. Dynegey adds that the proponents of rights that are financial only argue that it is impossible to define physical rights as "100 percent firm" from a given source to a given sink. Dynegey states that, while such arguments are convincing, the capacity between a source and sink may actually be available for a significant percentage of the time to a reasonable degree of certainty and, accordingly, could be sold as firm.

APX states that the definition of transmission property rights requires the calculation of stable power distribution factors that show the proportion of a power transaction that flows over each path on the grid connecting the source-sink pair. It states that after defining the property rights, the RTO can conduct an auction to allocate them. APX states that, following the auction, holders of transmission rights can retain them or trade them in a secondary forward market. APX believes that FTR trading will provide a more direct and comprehensive valuation of rights than LMP. Desert STAR states that it plans to rely on firm transmission rights markets as the primary vehicle for managing commercially significant congestion, and the use of incremental/decremental generation bids to manage other congestion.

Other commenters, however, doubt that a system of physical transmission rights can be used effectively to manage

congestion.⁴⁸⁹ NERA states that most commodity markets operate according to a process based on physical contracts or rights traded in decentralized markets separated from physical operations. NERA adds, however, that most commodities do not flow on an integrated grid where network externalities are so strong and complex that a monopoly system operator is needed. NERA argues that network externalities on any complex electricity grid make it virtually impossible to define physical transmission rights that will use the system fully and yet can be traded in decentralized markets. Also, Professor Joskow believes that on complex electric power networks with loop flow, a financial rights system can be designed more easily and can work more smoothly and efficiently than can a physical rights system.⁴⁹⁰

Some commenters offer additional notes of caution regarding the use of transmission rights. For example, APPA states that one must guard against market participants using transmission rights to act strategically. APPA argues that if a generator can adversely affect transfer capability, it may seek to purchase and resell transmission rights in the secondary market after manipulating its internal operations to create congestion on the grid. RECA considers proposals that allow customers to purchase long-term rights to mitigate the risk of congestion pricing to be unacceptable because such proposals result in long-term firm customers having to pay a premium for price stability. Also, CSU contends that no party should hold any entitlement over a constrained path due to transmission ownership which predates the formation of the RTO. CSU argues that, because all parties dedicating bulk transmission assets to the RTO will be fully compensated for their embedded costs, there should exist no reserved rights of use other than those purchased from the RTO. In addition, Great River is concerned that the NOPR's proposal regarding the establishment of clear and tradeable transmission rights is not consistent with the flexibility that transmission customers currently have under network service. Great River urges the Commission to carefully consider congestion management proposals that preserve network-like

⁴⁸⁹ See, e.g., NERA, Professor Joskow, Allegheny.

⁴⁹⁰ Professor Joskow notes that Enron/APX/Coral Power claims that two unpublished papers he has co-authored with Jean Tirole conclude that physical rights designed on a use-it-or-lose-it basis (so that they cannot be hoarded) more effectively prevent the exercise of market power than financial rights, which can always be hoarded. He states that this is not what the papers conclude.

⁴⁸⁶ See, e.g., PJM, SMUD, DOE, Enron/APX/Coral Power, EPSA, NSP, Seattle, Professor Hogan, EME.

⁴⁸⁷ See, e.g., DOE, NSP, Enron/APX/Coral Power, Seattle, Nevada Commission.

⁴⁸⁸ See, e.g., APX, Enron/APX/Coral Power, Tri-State, Desert STAR.

service, even if such proposals do not result in the identification of asset-based transmission rights.

Other Mechanisms for Managing Congestion. Some commenters support yet other market mechanisms for managing congestion.⁴⁹¹ EPSA notes that other pricing approaches that deserve consideration include the RTO's use of supply-side bids to relieve congestion in load pockets, as well as the use of bilateral arrangements to solve congestion problems. Also, NSP recommends that the RTO offer a "firming" service, at posted rates, that would provide customers with the assurance that their transaction will occur under most curtailment conditions. In addition, NSP proposes that the RTO offer a real-time redispatch service that will allow transmission customers to buy through congestion at real-time prices. Cal ISO notes that the Commission has accepted its zonal approach to congestion management, which relies on market mechanisms to manage inter-zonal congestion. PG&E claims, however, that while providing a more understandable picture of congestion, such a system must still solve the problem of intra-zonal congestion. Also, the Montana Commission recommends that the congestion management regime that was developed as a part of the IndeGO proposal serve as a model for how to manage congestion on the transmission system. However, Avista claims that the IndeGo proposal proved to be too complicated to solve a problem that exists only on a few select transmission paths in the Pacific Northwest.

Costs and Revenues in Congestion Management. A number of commenters urge the Commission to pay close attention to issues related to the distribution of the costs and revenues of congestion management among market participants.⁴⁹² In particular, several commenters caution that congestion pricing mechanisms should ensure that congestion costs are fairly allocated and should not result in excessive revenues or monopoly profits for transmission owners.⁴⁹³ APPA states that only after we have a nationwide framework of truly independent RTOs should the Commission consider a new approach to transmission pricing that would allow the RTO to price transmission capacity rights and usage on congested paths above embedded costs while discounting uncongested paths below

embedded costs, subject to a balancing account to ensure that the total transmission revenue requirement is not over-recovered.

Similarly, TDU Systems believe that while the formation of RTOs is a unique opportunity to experiment with new forms of transmission pricing, the Commission should be mindful that an RTO will be a large regional transmission monopoly. TDU Systems question the wisdom of designing congestion pricing mechanisms to ensure that limited transmission capacity is used by market participants who value that use most highly. It states that such an auction-to-the-highest-bidder approach could reap monopoly rents for transmission providers, at the expense of consumers. TDU Systems thus argues that over-reliance on economic self-interest and market mechanisms in transmission pricing may become a recipe for new forms of undue discrimination. It suggests that an incentive to avoid expanding the system in order to collect monopoly rents can be removed by placing any excess revenues from congestion pricing in a fund earmarked for transmission system expansion.

TDU Systems also recommends that the Commission encourage congestion management plans that distinguish between congestion caused by the RTO's obligation to provide service to firm transmission customers, and congestion caused for economic reasons. It argues that, in the case of the former, the costs of relieving the congestion should be averaged over the firm RTO transmission customers that are using its system. However, it claims that economic congestion occurs because market participants wish to take advantage of short-term production cost economies to minimize their power costs. In this case, TDU Systems argues that the specific loads purchasing the generation should pay the associated congestion costs. Also, RECA states that long-term firm transmission customers are the ones that use and pay to support the system throughout the year, but the auction approach allows a short term trader to outbid these customers at the very times they need it most. Enron/APX/Coral Power notes that, if the RTO's regulated rates for transmission service, including congestion management, are properly designed to reward the RTO for cutting operating costs and maximizing throughput, then it would not have to assign the grid expansion costs to new generators that interconnect. Instead, the RTO would charge the new generator only the cost of local interconnection with the grid.

Dynegy claims that, with respect to each transmission provider's system, there is a predictable level of constraints and, similarly, some representative level of costs associated with relieving those constraints. Dynegy believes that such costs should be rolled into firm transmission rates that can be quoted up front and with certainty. Dynegy argues that transmission providers would have an economic incentive to operate their transmission systems efficiently if they are given an uplift cost target, and are rewarded for beating the target and penalized for exceeding the target. EPSA states that some congestion pricing mechanisms can impose potentially huge costs on individual transactions, which can be detrimental to the goal of fostering wholesale competition. EPSA thus urges the Commission to consider whether these pricing mechanisms provide greater benefits than a system that internalizes more of the congestion costs. Indeed, EPSA argues that it is still appropriate to spread many of those costs to all system users because redispatch generally benefits all users of the transmission system.

NCPA asserts that, in order to prevent large increases in the cost of generation for customers in congested areas, some non-discriminatory way must be found to return the extra revenues collected to those customers. NCPA believes that this will require restructuring of tariffs, but failure to address the problem is likely to keep utilities with customers in congested areas out of the California ISO. Similarly, the South Carolina Authority is concerned that certain centralized market mechanisms would cause cost shifts for those participating in an RTO, and if so, potential participants opt out. Also, the Wyoming Commission is concerned that, by offering rewards for transmission investment such as a higher return on equity, the Commission would effectively be discouraging a more market-oriented review of alternatives to building transmission to solve congestion problems.

Some commenters emphasize the importance of ensuring full cost recovery for generators that are redispatched by an RTO to alleviate transmission constraints or to provide other support services.⁴⁹⁴ NERC contends there must not be disincentives, in the form of unrecovered costs, to having generators perform these vital functions. MidAmerican asserts that optimal dispatch will occur during congestion management as long as all power suppliers are fully compensated at

⁴⁹¹ See, e.g., Cal ISO, Montana Commission.

⁴⁹² See, e.g., TDU Systems, NCPA, Los Angeles, Wyoming Commission, SMUD, South Carolina Authority.

⁴⁹³ See, e.g., APPA, RECA, TDU Systems, Los Angeles, EPSA.

⁴⁹⁴ See, e.g., Allegheny, Platte River, NERC.

market prices. Cinergy claims that, unless generators have the ability to recover lost revenues for reducing generation in response to congestion management needs, generators have no incentive to follow dispatch orders. SMUD contends that the Commission needs to develop congestion management principles that ensure that market participants will receive fair market value for facilities that they have owned and operated for many years.

Importance of Scale in Congestion Management. A number of commenters argue that the achievement of an appropriate scale by an RTO will be important to the effective management of congestion.⁴⁹⁵ LG&E states that the Commission should require RTOs to be of sufficient size to be capable of meaningfully addressing congestion. It believes that if a proposed RTO's ability to address congestion would be impaired by its size or configuration, then the Commission should either refuse the RTO's application or should condition approval on attaining the necessary size and configuration to manage regional congestion issues. Industrial Consumers state that, although congestion management can be addressed with non-market solutions such as transmission loading relief procedures, it is far better to internalize the problem within an RTO with an appropriate scope and configuration. Minnesota Power notes that, currently, it can have transactions curtailed by two different procedures, NERC Transmission Loading Relief and MAPP Line Loading Relief. It claims that an RTO will provide transmission users with region-wide, standard, congestion management.

The Midwest ISO states that an appropriately sized RTO will be able to relieve congestion on a broad scale. However, it claims that its own redispatch options will be limited by the failure of border companies, such as FirstEnergy and AEP, to join it. Also, it notes that longer term congestion relief involves the construction of transmission facilities. It claims that, if border companies are not members, the Midwest ISO will not have the ability to coordinate required transmission construction by those entities. Also, the Midwest ISO Participants state that new transmission facilities required to relieve constraints may involve both the companies of the Alliance RTO and the Midwest ISO Participants. The Midwest ISO Participants believe that, with planning and authority split between these two regional entities, these

facilities may not be optimally constructed or located.

Ontario Power, however, takes a different view. It claims that many of the advantages that would flow from expanding U.S. markets to include Ontario can be realized without requiring the Independent Electricity Market Operator (IMO) in Ontario to join a larger RTO at this time. Ontario Power believes that these advantages could be achieved by negotiating agreements between the IMO and other RTOs. Also, Central Maine states that if transmission line loading relief is performed on a market basis, many of the benefits that might result from merging existing ISOs could be realized without actually requiring those ISOs to merge.

Tri-State argues that the Commission should provide an incentive for non-participating transmission owners to join an RTO by allowing the RTO to use a pricing and congestion management structure that withholds the benefits of the RTO from entities that refuse to turn control of their transmission assets over to the RTO. Also, Vernon claims that non-participants can take unfair advantage of ISO-controlled facilities by scheduling their own loads over ISO grid facilities that parallel the non-participant paths, instead of scheduling them over their own wires. Vernon contends that having thus freed up their own wires, the non-participants can then put their facilities to various uses, such as to avoid the increased ISO grid congestion.

Congestion Management Between RTOs. Many commenters believe that effective congestion management must take into account effects that extend beyond the RTO's boundaries.⁴⁹⁶ NERC states that congestion management approaches that work within a particular region may not adequately deal with transactions that originate or terminate outside the region. NERC believes that as RTOs develop congestion management approaches, the Commission must require that they be compatible with what is happening elsewhere.

Industrial Consumers believe that congestion management, especially during emergency conditions, is an interconnection-wide responsibility. It asserts that, if multiple RTOs are allowed within an interconnection, congestion management must be coordinated across RTO boundaries. Industrial Consumers argues that an RTO can accomplish this only by

sharing data on system conditions (e.g., ATC calculations) with neighboring RTOs, agreeing to protocols for cross-boundary actions to mitigate congestion, and cooperating in a process to ensure fair compensation to generators that are redispatched.

UAMPS believes that if a state is involved in the consideration of various potential solutions to regional congestion, it will likely be more willing to accept that a particular proposal to construct new transmission within its borders is indeed the most efficient solution to a genuine problem, and to provide the necessary approvals for that construction.

Transcos and Congestion Management. Some commenters are concerned that, if a for-profit company owns transmission (e.g., a transco), it may not have the correct incentives to manage congestion efficiently.⁴⁹⁷ ISO-NE argues that if such a company seeks to operate transmission and markets as an RTO, it will have competing responsibilities and economic interests. ISO-NE believes that, given the company's economic motivations, market participants may have insufficient confidence in such a company's determinations of whether a transmission-expansion solution to congestion is preferable to a generation-based solution. EAL believes that compensating a wire-owning RTO on the basis of invested capital could lead to over-building of transmission. New Smyrna Beach is concerned that a for-profit transmission company will exhibit a bias toward transmission construction when other, more economical alternatives might exist. New Smyrna Beach states that the Commission should consider requiring the RTO to conduct a competitive bidding process when it determines that transmission construction, or an alternative, is needed to relieve transmission constraints.

Industrial Consumers asserts that transcos would compete head-on with generation companies wherever there is congestion. It thus believes that transcos-as-RTOs would have a serious conflict of interest if they have the authority over congestion management and over the decision whether to eliminate congestion with new generation or transmission facilities. Industrial Consumers believes that where new generation is a more cost-effective option than construction of new transmission facilities, the cheaper option should be built, and markets should be given the opportunity to make

⁴⁹⁵ See, e.g., LG&E, ComEd, Midwest ISO Participants, Midwest ISO.

⁴⁹⁶ See, e.g., NERC, Mass Companies, Industrial Consumers, Montana Commission, Indiana Commission, AEP.

⁴⁹⁷ See, e.g., ISO-NE, EAL, New Smyrna Beach, Industrial Consumers.

the choice. Industrial Consumers believes, however, that this will require that the markets have access to redispatch costs, congestion valuations (from a secondary market for capacity reservations), and other data on grid conditions. This is information that is better disclosed by a disinterested independent RTO than a self-interested transco or generation company.

Cal DWR questions whether either ISOs or transcos have an incentive to use transmission alternatives (such as demand-side management, load shedding, distributed generation, or generation) to reduce the overall cost of transmission. However, it believes that this problem may be more acute for a transco, for which revenues and return are directly tied to the use of their transmission assets.

However, other commenters claim that there is no basis for concerns that a transco will favor a transmission solution to constraints.⁴⁹⁸ Entergy contends that, if a generation solution is the most efficient way to resolve congestion, a new generator will likely realize that and try to locate in the appropriate area. Entergy states that an RTO's obligations as an open access transmission provider leave it with no choice but to interconnect with the new generator. Also, Entergy argues that an RTO will not have the unfettered ability to propose and build inefficient transmission solutions. It believes that review by state regulators with siting authority, and prudence review by the Commission, will make it difficult for an RTO to build inefficient and unnecessary transmission additions. Enron/APX/Coral Power and JEA believe that a transco may, in fact, be well suited for congestion management. Enron/APX/Coral Power states that placing responsibility for managing congestion in the RTO's hands complements their view that an RTO-Transco must be obligated to assume delivery risk (*i.e.*, deliver physically firm power) in exchange for being rewarded for cutting costs and increasing system throughput.

The Need for Flexibility in the Design of Market Mechanisms. Commenters in general showed considerable support for the NOPR's proposal to give RTOs considerable flexibility in experimenting with different market approaches to managing congestion.⁴⁹⁹ Mass Companies state that the NOPR's willingness to allow RTOs latitude to

develop local approaches to congestion management is particularly appropriate, given the difference in conditions in different parts of the country. CP&L believes that congestion management is an area where a one-size-fits-all solution would miss the mark and unnecessarily increase the cost of forming and operating an RTO. SRP believes that a flexible approach is needed because the use of market mechanisms for congestion management is in its infancy, and poorly designed market mechanisms can exacerbate problems and adversely impact reliability.

The Florida Commission states that the details of proposals for managing congestion using a market mechanism should be determined on a regional basis with endorsement by the state regulatory body. The Florida Commission recommends that the Commission continue to monitor discussions of these issues within NERC and not duplicate or foreclose their development and resolution at NERC.

Montana-Dakota recommends that the Commission not limit the experimentation with market mechanisms to the provision of firm transmission service. Montana-Dakota believes that there is potential to further improve transmission services by allowing RTOs the ability to implement congestion management methods for non-firm services rather than relying only on the use of TLR to curtail such services.

Many commenters express support for the proposal to allow RTOs flexibility in developing approaches to congestion pricing.⁵⁰⁰ Some, such as Florida Power Corp. and Desert STAR, believe that allowing flexibility in pricing may provide incentives for transmission owners to join or form an RTO. Florida Power Corp. argues that such flexibility allows transmission owners to deal with issues such as cost shifting, and believes that providing more specific guidance will only limit possible options.

However, the FTC cautions that the Commission should not allow its policy of flexibility to continue indefinitely. The FTC states that although experimentation with transmission congestion pricing alternatives to LMP may be appropriate at present, it does not believe that great uncertainty about the most effective approach to transmission congestion management need exist indefinitely. It suggests that the Commission may wish to establish a date in the not-too-distant future when it will undertake a comparative analysis

of the consumer costs and benefits of alternative transmission pricing regimes. The FTC states that if one or more approaches provide substantially superior results for consumers, the Commission may wish to initiate a rulemaking on policies to encourage RTOs to adopt these approaches. The Oregon Commission recommends that the Commission evaluate the effectiveness and efficiency of various congestion pricing experiments, and based on its evaluation, require RTOs to use the better methods. However, the Oregon Commission estimates that the process of refining congestion pricing methods may take a decade or more.

NERC states that there are strongly held, differing opinions throughout the industry on how congestion prices should be designed. NERC states that, while flexibility is one important consideration, the various regional solutions must be able to work together. It believes that the Commission can provide the leadership needed to bring the industry to closure on these issues. NERC notes that this may require the Commission to be more proscriptive, and it should not hesitate to do so. In this regard, Minnesota Power suggests that the Commission encourage neighboring RTOs with constrained interfaces to jointly develop constraint relief procedures including common constraint pricing where appropriate.

Timing of Implementation. With regard to the NOPR's proposal to allow RTO's up to one year after start-up to implement the congestion management function, commenters express a variety of opinions. Some indicate that one year is an appropriate additional time period.⁵⁰¹ Others, however, believe that it is essential that the RTO have some form of congestion management system in place when it begins operation.⁵⁰² SMUD and CMUA state that a significant deterrent to participating in the Cal ISO has been the fact that, in California, Cal ISO transmission is strictly a short-term transaction given that Cal ISO has not yet fully implemented FTRs. SMUD emphasizes that, without the hedge provided by FTRs, it cannot guarantee its customer-owners low cost or reliable transmission service. TANC believes that allowing an RTO to begin operations without a congestion management procedure in place greatly increases the opportunity for market power abuses as well as market inefficiency.

⁴⁹⁸ See, *e.g.*, Trans-Elect, FirstEnergy, Entergy.

⁴⁹⁹ See, *e.g.*, Mass Companies, SRP, CP&L, Southern Company, PJM/NEPOOL Customers, United Illuminating, Georgia Commission, JEA, Florida Commission, NYPP, Cinergy.

⁵⁰⁰ See, *e.g.*, PJM/NEPOOL Customers, United Illuminating, Florida Power Corp., Desert STAR, Oregon Commission, NERC.

⁵⁰¹ See, *e.g.*, Industrial Consumers, Allegheny, PGE, Entergy.

⁵⁰² See, *e.g.*, SMUD, Tri-State, CMUA, TANC, Desert STAR, Cinergy.

Duke states that, ideally, the permanent congestion management function should be in place on the first day of RTO operation. Then, Duke notes, it would not be necessary to incur the cost of implementing, and developing strategies and behavior appropriate to an initial system, only to have to incur additional costs and changes in behavior to adapt to a permanent system. However, Duke states that congestion management issues are complex and substantial information management systems must be put in place. Consequently, Duke believes one year from the time the RTO becomes operational may not be a sufficient length of time to implement the congestion management function.

Desert STAR states that the new approaches to congestion management called for by newly competitive markets will take additional time to work out and, therefore, the Commission should be willing to consider additional time on a case-by-case basis. However, in order to ensure reliable operation, Desert STAR believes some congestion management system must be in place when the RTO begins operation.

Some commenters believe that more than one year of additional time may be needed for the RTO to implement the congestion management function. NSP states that if the RTO has a state-estimator model with the necessary properties, it is possible that a congestion management system, of the type preferred by NSP, could be implemented within about 18 months from the time of project initiation. However, for regions without the necessary models, NSP expects the time-line would likely be three years from time of project initiation.

Montana Power believes that there will be many "growing pains" associated with implementation of RTOs that will take time to work out, especially in areas like the Pacific Northwest, which have no history of tight pool operation. Montana Power believes that allowing one-year for implementing a market mechanism for congestion management is a very aggressive schedule. Montana Power thus encourages the Commission to allow up to three years. Similarly, Avista states that, with the IndeGo experience in mind, it encourages the Commission to allow two to three years for implementation of this function, especially where it is demonstrated that the RTO will comply immediately with other characteristics and functions identified in the Commission's Final Rule.

The Florida Commission believes that the Commission should not impose any

arbitrary time period for implementation of congestion management. It states that NERC is working with the regions on this issue and FERC should monitor those activities before setting any deadlines, if at all. Also, JEA believes that requiring the congestion management function to be in place within one year from the start-up of RTO operation may be feasible only for those RTOs structured as transcos from the beginning.

Commission Conclusion. As we proposed in the NOPR, we conclude that an RTO must ensure the development and operation of market mechanisms to manage congestion. Furthermore, as we proposed, we will require that responsibility for operating these market mechanisms reside either with the RTO itself or with another entity that is not affiliated with any market participant.

We agree with the large number of commenters that believe that the use of market mechanisms to manage congestion is superior to the use of administrative curtailment procedures or other approaches that do not take into account the relative value of transactions that are curtailed and those that are allowed to go forward. In addition, we conclude that the RTO or an independent entity must assume an active role in developing and implementing any congestion market mechanisms, because the use of such mechanisms must necessarily be closely coordinated with the operational activities that the RTO performs on a day-to-day and, in many cases, moment-to-moment basis.

Some commenters argue that an RTO should not be allowed to operate a centralized market for congestion management. The commenters contend that, if such a market is operated by an RTO or other entity that is independent of the market, a robust market in forward contracts for energy will not develop. As a result, these commenters claim, society will never obtain the efficiency benefits that would otherwise flow from a marketplace in which buyers and sellers are able to trade actively among themselves. These commenters also argue that the price certainty provided by forward markets will be replaced with the uncertainty of prices that are determined after the fact.

We disagree with these commenters and see no reason why the RTO's operation of a market for congestion management should inhibit the ability of others to offer forward contracts for energy, or other market instruments that provide price certainty. We recognize that some of the market redispatch programs undertaken to date are

experimenting with various ways to manage congestion efficiently—including relying upon decentralized markets to effect the necessary redispatch.⁵⁰³ It is too early to tell if these decentralized markets will work efficiently. But given the short time frame in which system operators often must react to congestion situations, experience may ultimately show that markets for congestion management can achieve more efficient and effective results if they are centrally operated. Therefore, we will not deny here the RTO, or other independent entity, the opportunity to operate a market—either centralized or decentralized—for congestion management.

As we proposed in the NOPR, we will require the RTO to implement a market mechanism that provides all transmission customers with efficient price signals regarding the consequences of their transmission use decisions. We are convinced that efficient congestion management requires that transmission customers be made aware of the cost consequences of their actions in an accurate and timely manner, and we believe that this is best accomplished through such a market mechanism. Also, as we proposed in the NOPR, we believe that congestion pricing proposals should seek to ensure that (1) the generators that are dispatched in the presence of transmission constraints are those that can serve system loads at least cost, and (2) limited transmission capacity is used by market participants that value that use most highly. Although we agree with some commenters that price signals can also assist in determining the efficient size and location of new generation and grid expansions, we share the view of LIPA and others that price signals alone cannot be relied upon to identify all needed enhancements.

While we will not prescribe a specific congestion pricing mechanism, we note that some approaches appear to offer more promise than others. As we stated in our order approving the PJM ISO and reiterated in the NOPR, markets that are based on locational marginal pricing and financial rights for firm transmission service appear to provide a sound framework for efficient congestion management.⁵⁰⁴ A number of commenters express strong support for the LMP approach. As PJM notes in its comments, LMP assesses congestion charges directly to transmission customers in a manner consistent with

⁵⁰³ See, e.g., the market redispatch experiment of NERC (Docket No. ER99-2012-000).

⁵⁰⁴ See PJM, 81 FERC at 62,252-53.

each customer's actual use of the system and the actual dispatch that its transactions cause. In addition, LMP facilitates the creation of financial transmission rights, which enable customers to pay known transmission rates and to hedge against congestion charges. We further note that, where financial rights holders are entitled to receive a share of congestion revenues, the availability of such rights helps to address the concerns of commenters who fear that congestion pricing can lead to the over-recovery of transmission costs. The Commission recognizes, however, that LMP can be costly and difficult to implement, particularly by entities that have not previously operated as tight power pools.

The principal alternative to LMP advocated by commenters is an approach that manages congestion by means of physical transmission rights that are tradable in a secondary market. Under this approach, the RTO may be required to issue the transmission rights initially through an auction or allocation process. Market participants would then generally have to demonstrate ownership of sufficient rights in a constrained interface before they would be allowed to schedule firm service over the interface. Such an approach greatly reduces the role of the RTO in congestion management. While the approach of trading physical transmission rights in a secondary market may prove to be workable in regions where congestion is minor or infrequent, in other regions where congestion is more of a chronic problem, it may not be workable. Also, commenters such as NERA and Professor Hogan claim that the network interactions on complex electricity grids make it difficult to define physical transmission rights that will use the system fully and yet can be traded in decentralized markets. We expect RTOs and any affected stakeholders to consider carefully such issues as they formulate specific pricing proposals.

While our experience has shown that, in specific situations, some approaches to congestion pricing appear to have advantages over others, we have not yet identified one approach as being clearly superior to all others. Furthermore, the Commission recognizes that an RTO's choice of a congestion pricing method will depend on a variety of factors, many of which may be unique to that RTO. Therefore, we will allow RTOs considerable flexibility to propose a congestion pricing method that is best suited to each RTO's individual circumstances.

Some commenters appear to confuse the need to redispatch generators to maintain reliability with the need to take specific actions to relieve congestion. Commenters generally agree that the RTO should have clear authority to order redispatch for reliability purposes. However, for congestion management, we conclude here that the RTO should attempt to rely on market mechanisms to the maximum extent practicable. We recognize, of course, that there may be times when even well-functioning markets will fail to provide the RTO with the options it needs to alleviate a specific instance of congestion. In those cases, the RTO must have the authority to curtail one or more transmission service transactions that are contributing to the congestion. Although the act of curtailing a transaction may sometimes require the redispatch of generation, we clarify that we are not requiring the RTO to redispatch any generators exclusively for the purpose of managing congestion.

In the NOPR, we stated that a workable market approach to congestion management should establish clear and tradeable rights for transmission usage, promote efficient regional dispatch, support the emergence of secondary markets for transmission rights, and provide market participants with the opportunity to hedge locational differences in energy prices. Most commenters agree that these are reasonable features of any congestion management proposal. However, Enron/APX/Coral Power believes that the RTO should not be allowed to provide a hedging instrument. It contends that the "monopoly wires business" should not be allowed to encroach on what it views as the highly competitive and innovative business of providing hedges against locational price differences of energy or capacity, or against price volatility of these or any other competitive products. In response, we note that, while decentralized markets may ultimately prove to be capable of providing such products, as these commenters claim, we do not yet have evidence to that effect. Therefore, in the interest of allowing RTOs flexibility to experiment with different market approaches, we will not prohibit the RTO from offering such products through markets that it may operate.

Finally, with regard to the timing of implementation of the congestion management function, we will adopt our proposal to allow the RTO to take up to one year after start-up to implement market mechanisms for managing congestion. Most commenters agree that some period of time is needed for implementation. However, a number

of them indicate that the RTO must have some form of congestion management system in place when it begins operation. We agree, and clarify that, upon start-up, the RTO must have in place effective protocols for managing congestion while preserving reliability. Because the NOPR did not make this point explicitly, we do so here.

3. Parallel Path Flow (Function 3)

In the NOPR, the Commission proposed to require that an RTO develop and implement procedures to address parallel path flow issues within its region and with other regions.⁵⁰⁵ The Commission noted that measures to address parallel path flow between regions may not necessarily be in place on the first day of RTO operation, and proposed to allow up to three years after start-up for this function to be implemented.⁵⁰⁶ The Commission sought comments on whether such an additional implementation time period is warranted, and whether three years is an appropriate additional time period.

Comments. Virtually all commenters support the NOPR's proposal to require that an RTO develop and implement procedures to address parallel path flow issues as a separate function.⁵⁰⁷ Industrial Consumers states that parallel path flow-related disputes will diminish as a result of RTOs addressing this issue.⁵⁰⁸ But PGE notes that grandfathering existing transmission contracts may impede the RTO's ability to address loop flow.

Many commenters assert that parallel path flow and congestion management issues are closely related to one another since both the issues involve identification of power flows resulting from a specific transaction.⁵⁰⁹ Therefore, they argue that any solution to parallel path flow should recognize

⁵⁰⁵ The terms "parallel path flow" and "loop flow" are sometimes used interchangeably to refer to the unscheduled transmission flows that occur on adjoining transmission systems when power is transferred in an interconnected electrical system.

⁵⁰⁶ FERC Stats. and Regs. ¶ 32,541 at 33,743-44.

⁵⁰⁷ See, e.g., ComEd, East Texas Cooperatives, EPSA, Industrial Consumers, LG&E, NASUCA, NSP, PJM, Southern Company and Williams. However, Cinergy argues that parallel path flows should not be considered as a separate function but should be considered as a characteristic under the scope and regional configuration because that will allow an RTO to address congestion management issues along with parallel path issues.

⁵⁰⁸ Industrial Consumers also notes that the first sentence in the proposed regulation should be modified to read as "RTO must develop and implement procedures to address parallel path flow issues within its region and with other regions *in the interconnection within which it resides.*" (Suggested change underlined)

⁵⁰⁹ See, e.g., EPSA, Florida Power Corp., FTC, Georgia Transmission, LG&E, Mass Companies, NSP and PJM.

this close relationship. For example, Industrial Consumers believes that an RTO can take preemptive actions against potential curtailment situations to manage congestion resulting from loading of chronically constrained transmission interfaces due to loop flow. PJM suggests that the use of redispatch solutions like LMP not only is more efficient and beneficial to a competitive market, but is preferable to curtailing transactions under TLR to address congestion due to loop flow. South Carolina Authority is convinced that over the long run the problem of parallel path flow needs to be addressed as a planning issue, focusing on appropriate reinforcements to constrained transmission lines.

Many commenters recommend that an RTO should encompass as large a region as possible so that it can "internalize" most of the loop flow within its region.⁵¹⁰ However, others argue that the loop flow issue can be solved satisfactorily only if it is addressed at the interconnection level.⁵¹¹ They believe that while a large RTO will "internalize" most of the parallel path flows within its region, parallel path flows between RTOs will remain. Some other commenters are convinced that cooperative efforts among regional entities works best when it comes to resolving issues such as parallel path flow issue.⁵¹² NERC notes that it is in the process of developing the needed information system to address the parallel path flow issue on an interconnection basis and urges the Commission to direct the RTOs to work closely with it to coordinate efforts to resolve this issue. Southern Company and Industrial Consumers support NERC's initiative in solving the loop flow issue. Cleveland states that the national grid should be viewed as a single electrical system which calls for a universal approach rather than a regional approach to resolve the loop flow issue. The universal approach, Cleveland argues, will not only improve the integrity and reliability of the national grid but also eliminate the need for any policy shift in the future.

Commenters from Western System Coordinating Council (WSCC) assert that the loop flow issue in their region was solved by the adoption of WSCC

Flow Mitigation Plan (Plan) that provides for controlling unscheduled flows through the use of phase shifting transformers.⁵¹³ SRP suggests loop flow in WSCC should continue to be addressed at the WSCC level and not at the RTO level because WSCC may end up with four or more RTOs. PG&E recommends that the establishment of property rights such as FTRs be explored as a means to solve loop flow issues, on the basis that developing property rights will ensure the most efficient use of the transmission lines. Enron/APX/Coral Power urges RTOs in the Eastern Interconnection to move toward the Western model. NASUCA believes that RTOs should perform a cost-benefit analysis of controlling loop flows with phase shifting transformers.

Most commenters support the NOPR's proposal for an additional implementation time period of three years for coordination among RTOs.⁵¹⁴ They argue that the proper resolution of loop flow presents a number of complex issues that may require negotiations and agreements among neighboring RTOs and that the additional time period will give them an opportunity to coordinate their efforts. Allegheny supports an additional time period for implementation of this function but urges the contract path methodology be replaced at a faster pace than three years. Industrial Consumers notes that an additional time period of three years is necessary for NERC to solve the loop flow issue at the interconnection level. However, Florida Power Corp. and Florida Commission observe that the severity of parallel path flow varies from region to region and therefore opposes setting an arbitrary time limit for the implementation of this function. Duke likewise believes that the deadline for the implementation of this function should be determined by the Commission on a case-by-case basis.

Commission Conclusion. We reaffirm our preliminary determination that an RTO should develop and implement procedures to address parallel path flow issues within its region and with other regions. Most commenters agree that the formation of RTOs, with their widened geographic scope of transmission scheduling and expanded coverage of uniform transmission pricing structures, provide an opportunity to "internalize" most, if not all, of the effect of parallel path flow in their scheduling and

pricing process within a region. NERC notes that it is in the process of developing the needed information system to address parallel path issues on an interconnection basis, and we will direct RTOs to work closely with NERC, or its successor organization, to resolve this issue. As noted by Industrial Consumers, parallel path flow-related disputes will diminish as a result of RTOs addressing this issue.

Commenters from Western System Coordinating Council (WSCC) state that they adopted the WSCC Flow Mitigation Plan (Plan) to address parallel path flow issue in their region. SRP suggests that parallel path flow in WSCC continue to be addressed at the WSCC level and not at the RTO level because WSCC may end up with more than one RTO. We will not here make any judgments on the merits of WSCC's Plan as a solution for parallel path flow issues. However, we clarify that this rule does not prevent addressing parallel path flow issues on a larger-than-single-RTO basis. In fact, we require RTOs to develop and implement procedures for addressing parallel flow issues with other regions.

In the NOPR we proposed that the RTO have measures in place on the date of initial operation to address parallel path flow issues within its own region. We also noted that measures to address parallel path flow issues between RTO regions may not necessarily be in place on the first day of RTO operation. We proposed to allow up to three years after start-up for this function to be implemented. Most commenters support the NOPR's proposal for an additional time period of three years. A few commenters⁵¹⁵ prefer a case-by-case approach. Since severity of the parallel path flow varies from region to region, some parts of the Nation may choose to resolve inter-regional parallel path flow issues sooner than the required three years. Consequently, we will adopt our proposal in the NOPR that the RTO have measures in place to address parallel path flow issues in its region on the date of initial operation. We also adopt three years as an adequate time period for implementation of measures to address parallel path flow issues between regions.

We recognize that these measures to address parallel path flows combined with the requirement that the RTO be the sole provider of transmission services over facilities that it owns or controls will eliminate or diminish the ability of transmission users to choose among different contract paths owned by different service providers within the

⁵¹⁰ See, e.g., LG&E, Michigan Commission, NASUCA, New Smyrna Beach, NSP, PJM and South Carolina Authority.

⁵¹¹ See, e.g., Cleveland, East Texas Cooperatives, Georgia Transmission, Industrial Consumers, NY ISO, Southern Company, TEP. Industrial Consumers note that several other issues need to be addressed at the interconnection level and not at the regional level. They are ATC calculation, inadvertent flows and congestion management.

⁵¹² Central Maine Reply at 9; NYPP Reply at 10.

⁵¹³ See, e.g., PG&E, Seattle, SRP and TEP.

⁵¹⁴ See, e.g., Cal ISO, Desert STAR, Entergy, Industrial Consumers, NECPUC, NERC, NY ISO, PGE, SRP, Tri-State, TVA, UtiliCorp and WPSC. Cleveland also argues that a similar grace period should be given for the implementation of function # 5. (TTC and ATC Calculation). Cleveland at 14.

⁵¹⁵ Florida Power Corp., Florida Commission and Duke.

RTO region. However, these users will have the ability to move power anywhere within the RTO at a single rate and under a single set of terms and conditions. We believe this is pro-competitive and represents one of the fundamental benefits that is envisioned by the Rule. As we noted in the NOPR, the creation of large RTOs that can internalize most, if not all, of the effect of parallel path problems through their scheduling and pricing actions provides a unique opportunity to resolve a major operating concern that has caused problems on both the Eastern and Western Interconnections and which is a significant impediment to promoting efficient competition in generation markets.⁵¹⁶ Therefore, in reviewing the competitive implications of a proposed RTO application under section 203, we believe that any inability of transmission customers to choose among different contract path suppliers within an RTO will be outweighed by their enhanced ability to reach numerous buyers and sellers of electricity throughout the region.

4. Ancillary Services (Function 4)

The fourth proposed minimum function is that the RTO must serve as the supplier of last resort for all ancillary services required by Order No. 888.⁵¹⁷ This supply obligation for the RTO is necessary because only the single grid operator will be able to provide certain ancillary services, not all transmission customers may be able to self-supply (some own generation, others do not), and because it typically is more efficient for the RTO to provide some ancillary services for all transmission users on an aggregated basis.

In carrying out this function, the Commission proposed that all market participants would have the option of self-supplying or acquiring ancillary services from third parties. In addition, the RTO must have the authority to decide the minimum required amounts of each ancillary service and, if necessary, the locations at which these services must be provided; must be able to exercise direct or indirect operational control over all ancillary service providers; must promote the development of competitive markets for ancillary services whenever feasible; and must ensure that its transmission customers have access to a real-time balancing market.

Comments. Supplier of Last Resort. Comments on whether an RTO should serve as a supplier of last resort are

mixed. A large number of commenters support the Commission's proposal, as written.⁵¹⁸ Detroit Edison believes that the RTO should serve as the sole supplier of ancillary services to transmission customers and that the RTO should be permitted either to purchase services directly from generation suppliers or to purchase generation resources for this purpose. First Energy believes that the RTO's obligation as the supplier of last resort for ancillary services cannot be eliminated, since it is the basis of reliability.⁵¹⁹

On the other hand, a few commenters suggest that the Commission allow flexibility. Duke believes that an RTO should always have the responsibility for ensuring that transmission customers have arranged adequate ancillary service and that those services are delivered. They suggest that where a competitive market for ancillary services exists, the RTO should not be required to provide such ancillary services as a supplier of last resort.⁵²⁰ And a number of commenters take issue with one or more aspects of the proposed requirements, although many of these commenters generally support the proposal.

For example, some commenters suggest that more information is needed. Southern Company suggests that the Commission allow NERC to finalize an ancillary services policy before mandating changes to ancillary service requirements.⁵²¹ Professor Hogan suggests further investigation into developments in ancillary services.⁵²²

Other commenters believe that the focus of the proposal should be narrowed. Los Angeles suggests that an RTO should be the "safety net" of last resort for providing generation-based ancillary services. As such, the RTO would not play a significant role in the energy market and can remain essentially indifferent to energy market issues. PG&E believes that an RTO could set appropriate rules for ancillary services but would not itself procure

such services from the marketplace absent clearly defined emergency situations or in its role as provider of last resort. Avista states that while a transitional "supplier of last resort" role may be appropriate, an RTO should generally not become deeply involved in any of the markets for generation services.

A number of commenters suggest that the obligation to provide ancillary services should be expanded to include more or different sellers. MidAmerican believes that each control area should retain responsibility for the provision of ancillary services and should be allowed to self-provide or acquire necessary ancillary services in the most economical means it sees fit to meet performance compliance standards. East Texas Cooperatives suggests that the Commission require both transmission owners and the RTO to offer ancillary services at cost-based rates unless a seller can demonstrate a competitive market in a particular ancillary service. PPC and Desert STAR also believe that the role of provider of last resort of ancillary services would better rest with local control areas or independent generators that can supply ancillary services. Steel Dynamics requests that the final rule require generation-owning members of RTOs to maintain Commission approved cost-based tariff schedules for ancillary services. Georgia Transmission believes that any RTO members that are capable of providing ancillary services should be the providers of "first resort," and the ability to acquire such services from different providers would enhance competition in these markets.

While not specifically objecting to the RTO being the supplier of last resort for ancillary services, some parties suggest that the Commission should allow other mechanisms to work.⁵²³ California Board urges the Commission to allow consideration of other means for ensuring that the need for ancillary services is addressed. It recommends that the final rule reflect a requirement that the RTO filings must indicate how default provision of ancillary services will be accomplished without necessarily requiring the RTO to be the provider of last resort. Enron/APX/Coral Power advocates a form of performance-based ratemaking in which the RTO would have an incentive to perform its ancillary service function as efficiently and economically as possible. Florida Commission recommends that an RTO only be responsible for providing non-competitive ancillary services and

⁵¹⁸ See, e.g., Entergy, Industrial Consumers, NECPUC, Cal ISO, EPSA, FirstEnergy, LG&E, PacifiCorp, Empire District, EME, Southern Company, UtiliCorp, PGE, PNGC, PSNM, TDU Systems, Nevada Commission.

⁵¹⁹ See also Florida Power Corp.

⁵²⁰ See, e.g., NASUCA, Seattle, CalPX, Mass Companies.

⁵²¹ Southern Company notes that NERC's Interconnected Operations Services Working Group is currently addressing the ancillary services that should be required in a competitive environment and has issued a proposed policy for public comment and review.

⁵²² NWCC recommends that additional research regarding the application of ancillary services to wind and other intermittent generation technologies be conducted.

⁵¹⁶ See FERC Stats. and Regs. ¶ 32,541 at 33,744.

⁵¹⁷ FERC Stats. and Regs. ¶ 32,541 at 33,744.

⁵²³ See, e.g., CMUA, LPPC, California Board, San Francisco, Oneok, SMUD, Avista, Sithe, Seattle.

should require users to purchase or self-provide the other competitive services.

Similarly, FTC suggests that the Commission consider arrangements in which the RTO's primary role is to provide a market mechanism for transmission customers to acquire ancillary services for themselves. It argues that this method may reduce costs by allowing customers to customize their purchases of ancillary services to better fit their specific needs.⁵²⁴ Some commenters suggest that final RTO regulations expressly recognize the administration of an ancillary service exchange as an alternative to the provider-of-last-resort obligation that is imposed on a RTO under the proposed regulations.⁵²⁵ For example, ISO-NE believes that a competitive market for ancillary services is a superior supply mechanism, and ISO-NE suggests that the text of proposed § 35.34(j)(4) be amended to read:

An RTO must develop and maintain a market or other contractual arrangements for the supply of all ancillary services required by Order No. 888, FERC Stats. & Regs. ¶ 31,036 (Final Rule on Open Access and Stranded Costs), and subsequent orders.

Comments were also sought on the circumstances under which an RTO's obligation as supplier of last resort could be eliminated.⁵²⁶ Several commenters believe that the supplier of last resort obligation can be eliminated once a viable competitive market develops within the RTO region.⁵²⁷ For example, WPSC suggests that an RTO must continue to fulfill the role of supplier of last resort for these services or a power exchange must be available to supply these services. WPSC believes that it would be difficult to predict the circumstances under which the market for ancillary services is sufficiently robust that the RTO's role as supplier of last resort may be eliminated. WPSC believes that it would be a mistake to eliminate that role in any market where the generation market concentration levels as measured by the Herfindahl-Hirschman Index exceed 1,800. TDU Systems states that it is not aware of a market in any of the ancillary services that is now sufficiently competitive to warrant elimination of an ancillary service from this obligation. However, TDU Systems acknowledges that there may never be a competitive market for certain ancillary services and that an alternative mechanism must be created.

⁵²⁴ See also Empire District.

⁵²⁵ See, e.g., Cinergy, APX, EAL, NY ISO, JEA.

⁵²⁶ FERC Stats. and Regs. ¶ 32,541 at 33,745.

⁵²⁷ See, e.g., WPSC, APS, Florida Commission, Duke.

The NOPR also asked for comments on whether a different set of ancillary services requirement for RTOs is needed because RTOs will not own generating resources. Comments on this issue were mixed.

Sithe and several other commenters⁵²⁸ generally believe the Commission's initial set of guidelines on ancillary services is reasonable, and that a new set of ancillary services requirements for RTOs is unnecessary. LG&E adds that, as already is the case under the open access tariff, an RTO should be allowed to choose to add to the list of ancillary services in recognition of local or regional conditions. MidAmerican believes that while no additional or revised ancillary services are required, an RTO must ensure that sufficient transmission capacity is available to allow delivery of backup supply, planning reserves and the existing six ancillary services.

On the other hand, Los Angeles believes that a different set of ancillary services requirements than those required currently from a vertically integrated utility should apply to an RTO which does not own generation resources. They envision an ultimate industry structure of complete desegregation of generation and transmission assets so that any incentive (either real or perceived) for the transmission provider to act in a discriminatory manner is eliminated.

NSP requests that the Commission refer to the draft NERC policy that discusses the role of an operating authority as an unbundled procurement agent for community ancillary services. They describe this document as a good "guidepost" for the Commission to follow in the RTO NOPR, and for the establishment of additional ancillary services such as system blackstart and frequency responsive reserve.⁵²⁹ Desert STAR and Cal ISO agree that additional blackstart ancillary service may be required. TDU Systems believes that RTOs should be required to offer backup service and an additional load following service. It describes backup service as required to meet contingencies during periods following those covered by the OATT's reserve services, and load following service as required to complement the OATT's minute-to-minute regulation service with a service matching hour-to-hour variations in load. Industrial Consumers recommends that the Commission remove Schedule 4 (energy imbalance service) from any tariff administered by an RTO. They

suggest that this service be provided by the real-time balancing market as proposed in the NOPR.

Self-Supply Option. Nearly all who commented on the self supply option generally agree that, where feasible, all market participants should have the option of self-supplying or acquiring ancillary services from third parties.⁵³⁰ Some commenters strongly endorse the self-supply model. For example, APS believes that it should be the aim of the RTO to have each transmission customer self-supply its generation-related ancillary service requirements to the fullest extent practical. Los Angeles suggests that the role of the RTO should be limited to ensuring that the transmission customer has adequately provided for the necessary ancillary services for each transaction, and the RTO provide such services only in the event of non-compliance. It believes that the RTO should develop specific rules and protocols that would support the self-provision of ancillary services. Some commenters, including PJM/NEPOOL Customers and LG&E, suggest that it is important for the development of a competitive market in ancillary services that RTO customers not be required to purchase them from the RTO, and that an RTO must not prohibit or interfere with the ability of all market participants to have the option of acquiring competitive ancillary services or providing such services through buy/sell transactions from customer-owned generation.

On the other hand, FirstEnergy states that the Commission should be very cautious that policies that encourage self-supply of ancillary services do not compromise the very ability of the RTO to ensure reliable and secure network operation. It maintains that the provision of "self-supplying" ancillary services is untested, the infrastructure needed is as yet undeveloped, and the process of providing them could potentially lead to abuses. FirstEnergy identifies this issue as one of the reasons that NERC is pushing for mandatory compliance requirements.⁵³¹ It believes that an RTO must have the ability to evaluate and accept/approve those NERC-certified sources that reliably contribute to support the grid.

Authority to Determine Amounts and Location of Ancillary Services. Most commenters generally support the proposal that the RTO have the

⁵³⁰ See, e.g., CMUA, Cal ISO, LG&E, PG&E, PJM/NEPOOL Customers, PPC, APX, Metropolitan, MidAmerican, NSP, Seattle, SMUD, Desert STAR, TDU Systems, Tri-State.

⁵³¹ FirstEnergy notes that NERC is developing certification and verification criteria for ancillary service providers.

⁵²⁸ See, e.g., PGE, TDU Systems, Cal ISO, Duke, Tri-State.

⁵²⁹ See also Eric Hirst.

authority to determine the quantities and, where appropriate, the location at which ancillary services must be provided.⁵³² In addition, CMUA suggests that the RTO be responsible for enforcing compliance with established standards.

PJM/NEPOOL Customers requests that RTO decisions regarding the amounts and locations of ancillary services consider both stakeholder input and NERC standards. It believes that this requirement would ensure that the RTO does not impose unnecessarily high ancillary service obligations that will inhibit the operation of the competitive market. In addition, PJM/NEPOOL Customers asks that the Commission ensure that the RTO exercises this authority only to the extent necessary for reliability purposes, since decisions regarding ancillary services could impact the competitive electricity supply market.

NYPP requests that the RTO's authority not be exclusive. It suggests that properly constituted local and regional reliability councils authorized by FERC should have the authority to establish criteria necessary to maintain the reliability of the transmission system including the reliability of discrete locations.

Duke notes that the Commission has previously recognized NERC's leadership role in developing concepts in the area of ancillary services.⁵³³ It encourages the Commission to recognize and adopt NERC's development of ancillary service definitions and reliability standards.⁵³⁴

Industrial Consumers and Steel Dynamics request that the Commission first approve the standards by which the RTO determines the requirements. They request that these standards include the development of "metrics," *i.e.*, standardized units of measurement such that the performance of each service can be verified. In addition, Industrial Consumers recommends modifying the requirement to ensure seamless application between multiple RTOs and for transactions that only go through an RTO. It suggests adding an additional requirement to § 35.34(j)(4)(ii):

The Regional Transmission Organization must support the minimum required amounts of each ancillary service for transactions between itself and other Regional Transmission Organizations in the interconnection and through itself.

⁵³² See, e.g., Industrial Consumers, PJM, Turlock, Cal ISO, Florida Power Corp., PJM/NEPOOL Customers, LPPC, PGE, SMUD, TDU Systems, NYPP, Tri-State, Nevada Commission.

⁵³³ Citing FERC Stats. & Regs. ¶ 31,036 at 31,705 (1996).

⁵³⁴ See also Eric Hirst.

Control Over Ancillary Services Providers. All commenters that commented on this subject believe that the RTO should be able to exercise some operational control, either directly or indirectly, over any supplier of ancillary services.⁵³⁵ SMUD supports the RTO establishing well documented and specific operating criteria and the ability to require compliance with such operating criteria, including monetary penalties and commission-approved sanctions. JEA believes that this control should be exerted only where pre-existing contractual rights are established.⁵³⁶

Some commenters would broaden the requirement. For example, FirstEnergy is concerned that limiting the RTO's control to ancillary services providers rather than all generation located within the RTO may compromise the RTO's ability to operate the transmission system reliably. It suggests that the Commission allow a greater flexibility for the RTO and all generation owners located within the RTO to develop an agreement for provision of ancillary services through the RTO that provides for the necessary requirements for voluntary generation participation in the ancillary services market including operational control if appropriate, and the necessary requirements for calling on ancillary services from connected generation necessary for the reliable operation of the transmission system.

On the other hand, PJM/NEPOOL Customers suggest that the RTO control be limited to those providers that the RTO will rely on to fulfill its obligation as supplier of last resort for ancillary services. It claims that control over additional generators is unnecessary and may affect the operation of the competitive market.

Metropolitan recommends that the Commission allow RTO indirect control of existing large hydroelectric plants to protect and facilitate use of existing systems that have been operational for a substantial period of time and to preserve the integrity of the FERC hydro license. It states that allowing indirect control would eliminate the need for costly installation of software and infrastructure.⁵³⁷

Promote Competitive Markets for Ancillary Services. Most commenters support the proposal in the NOPR that RTOs promote competitive markets for ancillary services.⁵³⁸ Seattle suggests that the RTO provide incentives to

ensure a robust, transparent market with many buyers and sellers of ancillary services. PJM/NEPOOL Customers states that it is important that the RTO not impede the development of competitive markets for ancillary services and that the RTO actually facilitate the development of these markets. However, it stresses that the RTO and incumbent transmission owners should not be permitted to have market-based rates for ancillary services until a viable competitive market for such services develops.⁵³⁹

Seattle advocates that the final rule grant RTOs the authority to administer spot markets for ancillary services and establish rules obligating all participants to meet uniform requirements. PG&E believes that the RTO should not be the sole purchaser of ancillary services. Instead, it should facilitate the development of bilateral markets for as many of the ancillary services as possible, thereby allowing market participants to self-provide those ancillary services.

Access to Real-Time Balancing Markets. In the NOPR, the Commission proposed that an RTO must ensure that its transmission customers have access to a real-time balancing market. We proposed that the RTO must either develop and operate such markets itself or ensure that this task is performed by another entity that is not affiliated with any market participant. The Commission noted that although system-wide balancing is a critical element of reliable short-term grid operation, this does not necessarily require that there be a moment-to-moment balance between the individual loads and resources of bilateral traders and load-serving entities and the schedules and actual production of individual generators. We also noted that unequal access to balancing options for individual customers can lead to unequal access in the quality of transmission service available to different customers, and that this could be a significant problem for RTOs that serve some customers who operate control areas and other customers who do not. The Commission proposed to give RTOs considerable discretion in how a real-time balancing market would be operated.

We invited comments on the use of market mechanisms to support overall system balancing and imbalances of individual transmission users. In addition, we invited responses to the following questions. Is it feasible to rely on markets to support a function that is so time-sensitive? Can such markets be

⁵³⁵ See, e.g., PJM, Cal ISO, Florida Power Corp., Cinergy, Los Angeles, PSNM, SMUD, Duke.

⁵³⁶ See also Cinergy.

⁵³⁷ See also NYPP, PSNM.

⁵³⁸ See, e.g., FTC, LPPC, Avista, APX, PJM/NEPOOL Customers, Seattle.

⁵³⁹ See also TDU Systems.

made to function efficiently if the RTO is not a control area operator? For the imbalances of individual transmission customers, should a distinction be made between loads and generators? Should customers have the option of paying for all imbalances in such a market or only imbalances within a specified band?

Several commenters hold the view that it is indeed feasible to rely on markets to support a balancing function that is time-sensitive,⁵⁴⁰ and many agree that access to a real-time balancing market would be of considerable benefit to market participants.⁵⁴¹ NERA claims that technical logic dictates that an electricity system have a central process to co-ordinate real-time physical operations. NERA argues that to the extent that this process is not based on markets, it must be based on less efficient command-and-control methods. NERA also claims that economic and commercial logic requires that a commodity market have short-term trading arrangements to bring market positions into agreement with physical reality, and argues that to the extent that market trading does not reflect physical reality, some non-market process must close the gap between the market and reality. NERA asserts that these two propositions imply that the best way to maximize the role of the market and minimize the role of non-market processes is to base real-time physical operations on a spot market and to allow market participants to use this market for commercial purposes to the extent they find this useful.

Enron/APX/Coral Power states that access to a real-time energy balancing market is central to assuring comparability in open access, and Industrial Consumers believes that this proposal is the beginning of a much needed "paradigm shift" in the manner in which ancillary services are defined and provided in the marketplace. Eric Hirst states that implementation of a real-time balancing market would permit FERC to eliminate the Order No. 888 requirement that transmission providers offer an energy imbalance service to transmission customers. He argues that elimination of energy imbalance service, with its awkward and arbitrary deadband and penalty payments, would be a pro-competitive change. Professor Hogan claims that without an efficient spot market and the associated transparent spot prices, it

will be much more expensive and difficult to arrange balancing and settlement for the increasing number of retail access programs in the states. East Texas Cooperatives agrees that real-time balancing markets are desirable but believe that simply commanding RTOs to promote the development of competitive markets for ancillary services provides no incentive for the RTO and its members to do so.

Also, two commenters argue that access to real-time balancing markets would eliminate some significant barriers to entry for non-traditional resources such as renewable and distributed energy.⁵⁴² In particular, EPA notes that providing such access would eliminate arbitrary energy imbalance penalties that are a major barrier to intermittent resources such as wind and solar energy.

Some commenters believe that the RTO itself should develop and operate a real-time balancing market.⁵⁴³ PJM/NEPOOL Customers believe that the development of such a market is an essential function of the RTO that will facilitate the further development of retail competitive supply markets. PJM states that a real-time balancing market can best be provided through a power exchange operated by an RTO. Commenters are divided as to whether the development of a real-time balancing market requires that the RTO be a control area operator. Several believe that such markets are possible whether or not the RTO operates a control area.⁵⁴⁴ Indeed, MidAmerican believes that, to function efficiently, these markets normally must operate in a region that is larger than a typical control area. However, others take an opposite view.⁵⁴⁵ FirstEnergy, for example, argues that the timing, dispatch and telecommunications infrastructure needed to operate a real-time balancing market today can only be done by a control area operator and then only for a combined load within a control area with ample generation resources under automatic generation control.

Some commenters provide detailed recommendations regarding the rules that should govern the RTO's operation of real-time balancing markets.⁵⁴⁶ Professor Hogan notes that the complex network interactions in an electric grid require that there be an entity that can

provide certain critical coordinating services, and that the most obvious example of such services is energy balancing. He states that the operator should offer an energy balancing redispatch service where market participants can make offers to buy and sell energy.

He believes that the best approach would be to run the balancing market as a "bid-based, security-constrained economic dispatch" with voluntary participation by generators and loads. Professor Hogan emphasizes that the RTO must not reject voluntary bids, stating that the natural extension of open access and the principles of choice would suggest that participation in the coordinated balancing market offered by the operator should be voluntary. He states that market participants can evaluate their own economic situation and make their own choice about participating in the operator's economic dispatch or finding similar services elsewhere. He believes that any other rule would require some form of discrimination, and adds that there should be a strong burden of proof for those who argue that it is necessary to restrict voluntary bids, or discard consideration of some bids. Professor Hogan claims that experience in PJM and elsewhere shows that his suggested approach can work.

However, several commenters take a very different view, claiming that the development of a real-time balancing market is not a viable option.⁵⁴⁷ For example, FirstEnergy is concerned that a real-time balancing market is not practical to implement. It claims that transmission customers do not yet have the real-time metering and associated communication needed to dispatch and match fluctuating loads to generation. FirstEnergy argues that it would be much better to tie this service to the NERC effort of certifying ancillary service providers for control of generation, and activate the service when the technology and installation can be accommodated. Seattle states that it performs its own real-time energy balancing and expects to continue to do so. Seattle opposes adding this function to an RTO because Seattle believes it will increase the overhead costs of the organization. Seattle believes that market participants that require this service should contract with third parties that stand ready to provide it. Florida Power Corp. states that, given the complexity of implementing short term transmission service in general, it is difficult to imagine that a market for

⁵⁴⁰ See, e.g., Duke, PJM, Illinois Commission, Cal ISO, NERA.

⁵⁴¹ See, e.g., Enron/APX/Coral Power, Eric Hirst, NYPP, Powerex, East Texas Cooperatives, Industrial Consumers, Professor Hogan.

⁵⁴² See EPA and Project Groups.

⁵⁴³ See, e.g., PJM, PJM/NEPOOL Customers, Professor Hogan, NERA.

⁵⁴⁴ See, e.g., Tri-State, Illinois Commission, MidAmerican, Duke.

⁵⁴⁵ See, e.g., PJM/NEPOOL Customers, Southern Company, FirstEnergy.

⁵⁴⁶ See, e.g., Professor Hogan, Allegheny.

⁵⁴⁷ See, e.g., Seattle, FirstEnergy, Florida Power Corp.

energy imbalance service could be developed. It argues that if the market is limited to the generators needed for control, the development of market mechanisms will depend on resolving issues such as the mitigation of potential market power. Florida Power Corp. suggests that an RTO could contract with generators to perform this balancing function using a mechanism that is market-like in that generators would be selected based on their bids to perform the function over some designated period of time, albeit not on an hourly basis.

Several commenters believe that control areas or RTOs should not be the sole provider of energy imbalance services,⁵⁴⁸ while others argue that the role of RTOs should be limited to that of a supplier of last resort.⁵⁴⁹ UtiliCorp states that, in addition to serving as a supplier of last resort, the RTO must ensure public access to real-time balancing information. SMUD argues that any burden on the RTO that falls outside of the core function of ensuring regional transmission reliability will add cost and complexity to an already costly and complex endeavor. SMUD recommends that the Commission should limit its focus on generation to the role that generation-related service plays in promoting reliable transmission. Desert STAR and FirstEnergy believe that the Commission should give deference to RTOs regarding the development of markets for real-time balancing.

FirstEnergy believes that, ultimately, ancillary service provision must be based on a free-market pricing mechanism, and Southern Company believes that if a real-time balancing market is desired in a region, it will develop without a mandate. FirstEnergy asserts that the detrimental effects of regulated and capped ancillary service markets have been observed in the California and PJM markets. Also, APX believes that the Commission should let the market, not the RTO, provide the trading arrangements in the power industry. APX asserts that efficiency in the competitive market comes from the de-centralized trading activity of self-interested buyers and sellers, and that competition will develop further when market participants self-provide their ancillary services which they acquire in forward contract markets. In APX's view, the RTO should not provide a centrally optimized dispatch because a central dispatch will discourage, if not eliminate, the commitment of forward contracts in the energy market and

replace the price discovery of forward markets with *ex post* pricing. To the extent that the RTO must acquire ancillary services, including balancing services, APX believes that the RTO should acquire them from a market created by market participants, and not create its own markets. NERA, however, states that this argument ignores the fact that preventing the ISO from operating balancing markets does not eliminate the network interactions and real-time events that are inherent in any electricity network. Rather, according to NERA, it merely forces the ISO to manage these interactions and events by less efficient and more intrusive non-market means. NERA contends that if the objective really is to maximize the role of competitive market forces and minimize the extent to which the monopoly ISO determines the outcome, the ISO should operate market-clearing mechanisms that reflect network interactions and real-time events as accurately as possible. Similarly, ISO-NE claims that it does not understand how operating a market in which (as in New England, currently) an RTO does not buy and sell the pertinent commodities can constitute "taking a position" in those markets such that its operation is perceived as biased. ISO-NE believes that because it does not own market assets or commodities, an ISO-type RTO is exceptionally well situated to run a fair and non-discriminatory market. ISO-NE states that the linkages among transmission operation/dispatch, generation commitment/dispatch, and economic and market forces strongly support the integration of a physical market with an RTO's operations. Nevertheless, ISO-NE states that other financial power markets are welcome and can co-exist in the same region with an RTO market.

Several commenters offered their views as to whether unequal access to balancing options leads to unequal access in the quality of transmission service available to different customers, and whether this is a significant problem when RTOs serve some customers that operate control areas and other customers that do not.⁵⁵⁰ A number of commenters believe that the present system does lead to undue discrimination.⁵⁵¹ Enron/APX/Coral Power states that both the NERC and *pro forma* tariff rules are inequitable and discriminatory in that large customers rarely will be significantly out of

balance due to the law of large numbers. Enron/APX/Coral Power states that such customers are given great flexibility to balance their scheduled deliveries and load, while smaller customers are much more likely to exceed the 1.5 percent deviation band, making them immediately subject to penalties. Enron/APX/Coral Power believes that by offering real-time balancing to all transmission customers, the NOPR promises to redress this inequity. TDU Systems recommends that, pending the development of competitive balancing markets, the existing inequity between control area operators and other users be partially redressed by enlarging the deadband for imbalances to be repaid or received in kind to no less than five percent of scheduled amounts. It also recommends that the penal character of these charges should be reduced to a ten percent premium, except in cases of abuse.

PJM/NEPOOL Customers argue that, to the extent current control area operators wish to maintain access to inadvertent energy accounts to pay back imbalances and avoid penalties, other transmission customers must have the same opportunity. In the alternative, it recommends that all users be required to cash-out through the RTO balancing process. Utility Engineers recommends implementing a pricing plan for inadvertent interchange by participants of the RTO, where the price for inadvertent interchange is geographically differentiated to reflect losses and constrained transmission paths. They claim that such a pricing plan would need a continuous auction, which could be achieved through establishing a pricing formula.

With regard to providing access to inadvertent energy accounts, other commenters argue that there are valid reasons for distinguishing between customers that are control areas and those that are not. FirstEnergy argues that no other entity, other than control areas, can or should have that access to inadvertent accounts. It claims that, if market participants are provided with the authority to "go inadvertent" as control area operators currently have, the strain on the grid would drastically degrade system reliability, requiring much higher reserve capacity requirements. FirstEnergy believes that marketers would "borrow" from the grid during high price time periods and make whole on their borrowing during low price time periods, thus distorting the true price signal. Florida Power Corp. notes that in addition to balancing generation against load, control area balancing also includes a requirement for contributing to the maintenance of

⁵⁴⁸ See, e.g., Southern Company, Tri-State.

⁵⁴⁹ See, e.g., UtiliCorp, Avista, APX.

⁵⁵⁰ See, e.g., Enron/APX/Coral Power, LG&E, PJM/NEPOOL Customers, FirstEnergy, TDU Systems, Florida Power Corp.

⁵⁵¹ See, e.g., Enron/APX/Coral Power, PJM/NEPOOL Customers, TDU Systems.

system frequency. In contrast, it notes that the non-control area transmission customer's balancing requirement is limited to the directly measured load it serves. Florida Power Corp. also claims that, if a system of payments was substituted for the inadvertent payback system presently used, control area operators would simply be circulating large sums of dollars between themselves to accomplish the same result at a higher administrative cost. LG&E suggests that the Commission treat such technical issues separate from the RTO NOPR and work in conjunction with NERC's parallel efforts in this area. Also, Florida Commission believes that inadvertent energy accounting between control areas should continue to be allowed within the operating standards of NERC.

With regard to any requirement that loads and resources must be in balance from moment-to-moment, Professor Hogan and Eric Hirst believe there is no need for individual loads and generation to balance their schedules separately, and PJM/NEPOOL Customers states that balancing should be required only to ensure that generators deliver the amount scheduled and committed. Professor Hogan argues that individual balancing requirements both complicate the task for the RTO and provide a device to reinforce market power. Eric Hirst states that the RTO's costs of providing or absorbing imbalance energy should be charged equitably to those that under-generate and over-consume, with compensation to those that over-generate and under-consume. He states that this will result in charges and payments netting roughly to zero in each hour. However, Enron/APX/Coral Power believes that any RTO proposal should include development of an *ex post* energy balancing market in which buyers and sellers are given a finite amount of time after the market has closed to find others with offsetting positions.

Regarding the imbalances of individual transmission customers, commenters disagree as to whether a distinction should be made between loads and generators. MidAmerican and Florida Power Corp. believe that loads and generators should be treated differently. MidAmerican contends that it is much easier to control generators than it is to control load, and in the future managing imbalances will become more complex in that control from the load-side will involve the response of potentially thousands of entities that may or may not respond as quickly as central generation. MidAmerican states that a distinction

exists between loads and generators both in magnitude and response time. Florida Power Corp. claims that load and generators are not always similarly situated. It states that the nature of energy imbalance service depends on whether a generator and the load that it serves are in the same control area or are in different control areas. Eric Hirst, TDU Systems, and Duke believe that, in general, the market rules and principles should be the same or comparable for generators and loads, although TDU Systems believes that loads may be less likely than generators to abuse the system by leaning on it. Eric Hirst states that the use of imbalance markets would eliminate the asymmetry between generation and load in FER's definition of energy imbalance.

Finally, the NOPR also asked whether customers should be able to pay for all imbalances in a market or only imbalances within a specified band. Duke believes that it is appropriate to let the market participants determine how imbalances will be determined and paid. PJM/NEPOOL Customers believes that the RTO should provide transmission users with as many service offerings as possible, including the ability to opt for different balancing pricing proposals. Florida Power Corp., however, believes that there should only be one method of settling the imbalance market. It claims that complexity and opportunities for gaming increase with options for settlement.

MidAmerican believes that transmission customers should pay for all energy imbalances caused by the mismatch of scheduled energy and actual load. It recommends that imbalance charges be based on market prices at the time the imbalance occurred, and should include a penalty, in appropriate circumstances, to deter future imbalances. MidAmerican contends that if transmission customers are allowed to avoid payment within a specified bandwidth, gaming of the transmission system will occur.

PJM/NEPOOL Customers and Professor Hogan, however, argue that the RTO should not be allowed to impose balancing penalties on transmission users. Eric Hirst states that RTOs should maximize the use of price signals rather than penalties to encourage appropriate behavior on the part of generators and loads, and Professor Hogan states that such prices should reflect the marginal cost for power. Eric Hirst believes that penalties should be imposed only to counter the perverse incentives that are created when metering or billing procedures require prices to be calculated over time intervals that do not correspond to those

used to measure generation and consumption quantities. Using the example of the California ISO, he states that mismatches between ten minute prices and hourly quantities provide unintended incentives to generators to ignore ISO dispatch instructions or to ignore their schedules. He claims that aligning the time periods for price determination and billing would eliminate these perverse incentives. He adds that, where penalties are needed, they should be closely tied to the costs incurred by the ISO.

TDU Systems argues that if markets for balancing services are fully competitive, transmission users should be able to use them to deal with any amount of imbalance. TDU Systems recommends that until such markets are fully competitive, it may be necessary to restrict such purchases to a deadband to prevent abuse. It believes that any such deadband should be less restrictive than that of the *pro forma* tariff. In that regard, it recommends that the minimum within-band allowance should be no less than the greater of two megawatts or five percent for loads or capacities up to 200 MW, with declining percentage tolerances as loads and capacities increase in size.

Commission Conclusion. We conclude that an RTO must serve as the provider of last resort of all ancillary services required by Order No. 888 and subsequent orders.

Since some commenters interpreted the "supplier" of last resort obligation as proposed in the NOPR to require that the RTO be the direct supplier of ancillary services,⁵⁵² we have made a minor change to the requirement by substituting the term "provider" for "supplier." We clarify that this obligation requires that the RTO have adequate arrangements in place for the provision of ancillary services.

The ancillary services adopted in Order No. 888 were defined using the control area and its operator as the basis because a majority of transmission service was provided by control area operators and they controlled the generation facilities that supplied ancillary services. We note that since we are not requiring the RTO to be a single control area operator, we can not require an RTO that owns no generation to be the direct *supplier* of ancillary services. Therefore we will give the RTO and its participants flexibility in developing adequate arrangements for the provision of ancillary services to all transmission

⁵⁵² See, e.g., LPPC, Los Angeles, Georgia Transmission, JEA, PPC. A direct supplier of ancillary services either owns or operates generation.

customers that request service over the facilities under RTO control.

The RTO could fulfill its ancillary services obligations through a variety of mechanisms, including contractual arrangements, indirect or direct control of specified generation facilities, or market mechanisms. However, regardless of the method of provision, the ancillary services must be included in the RTO administered tariff so that transmission customers will have access to one-stop shopping for transmission service.

We conclude that all market participants must continue to have the option of self-supplying or acquiring ancillary services from third parties subject to any general restrictions imposed by the Commission's ancillary services regulations in Order No. 888 and subsequent orders. In such instances, the RTO must determine if the transmission customer has adequately obtained these services. The Commission believes that allowing self-supply provides a possible competitive check on the RTO to ensure that to the extent it does provide the services, it acquires them at lowest cost.

In the NOPR we asked whether additional or revised ancillary services are needed. While a completely unbundled and competitive environment may require a modification to the ancillary services required by Order No. 888, comments suggest that an immediate change is unnecessary. We will not, at this time, make changes to the ancillary services described in Order No. 888. However, we will allow an RTO to propose other services in recognition of local or regional conditions.

We conclude that the RTO must have the authority to decide the minimum required amounts of each ancillary service and, if necessary, the locations at which these services must be provided. All generators or other facilities that provide ancillary services must be subject to direct or indirect operational control by the RTO. The RTO must promote the development of competitive markets for ancillary services whenever feasible. To ensure the reliable operation of the system, an RTO must have authority to determine quantities and locations for ancillary services. The RTO should consider stakeholder input as well as established industry standards in determining these requirements. The Commission anticipates that some of the generation-based ancillary services could be acquired in short-term markets. This has been the approach taken by most of the ISOs that we have approved, and we see no reason that this would be different

for transcos or other types of RTO entities. Apart from establishing the general requirement to use competitive markets, the Commission will allow the RTO considerable flexibility in determining many of the detailed market design questions, with case-by-case review by us.

As we proposed in the NOPR, we conclude that an RTO must ensure that its transmission customers have access to a real-time balancing market that is developed and operated by either the RTO itself or another entity that is not affiliated with any market participant. We have determined that real-time balancing markets are necessary to ensure non-discriminatory access to the grid and to support emerging competitive energy markets. Furthermore, we believe that such markets will become extremely important as states move to broad-based retail access, and as generation markets move toward non-traditional resources, such as wind and solar energy, that may operate only intermittently.

Some commenters believe that implementation of real-time balancing markets presents technical problems that may prevent RTOs in some areas of the country from making such markets available to market participants. For example, some argue that it is difficult if not impossible for an RTO that is not a control area operator to operate an efficient real-time balancing market. These commenters suggest that to the extent such markets are feasible and desirable in a particular region, the RTO, its stakeholders and market participants should be given the flexibility to develop markets in accordance with their needs and capabilities.

We are not convinced that, at this time, technical considerations preclude the development of a real-time balancing market for any potential RTO. As discussed elsewhere in this Final Rule, we are requiring each RTO to be the security coordinator for its region and to have, at a minimum, the authority to exercise a combination of direct and functional control over facilities within its region. Thus, even if an RTO is not a control area operator, it should have sufficient operational authority to ensure that a real-time balancing market can be implemented. With regard to the issue of flexibility, we believe that real-time balancing markets are essential for development of competitive power markets. Therefore, although we will give RTOs considerable discretion in how they operate real-time balancing markets, we will not allow implementation of such markets to be discretionary.

Our conclusions regarding provision of real-time balancing markets are similar to our conclusions regarding markets for congestion management; that is, we will not prevent an entity other than an RTO that is unaffiliated with market participants, from seeking to offer transmission customers a real-time balancing market. However, because this function is so time-sensitive and requires such close coordination with the actual dispatch, experience may ultimately show that it cannot be performed to a high degree of efficiency unless it is made a part of the RTO's central or hierarchical dispatch activities. Also, we do not agree that an RTO's operation of a real-time balancing market will interfere unduly with the efforts of others to establish markets in forward contracts for energy.

We asked in the NOPR whether customers should have the option of paying for all imbalances in a real-time balancing market or only imbalances within a specified band. Based on the comments received, we decline to give a generic solution for all RTOs in this rule. An RTO may propose one approach or the other but should explain how it proposes to overcome any disadvantages of the approach selected.

In the NOPR, we noted that unequal access to balancing options can lead to unequal access in the quality of transmission service, and that this could be a significant problem for RTOs that serve some customers who operate control areas and other customers who do not. We conclude that control area operators should face the same costs and price signals as other transmission customers and, therefore, also should be required to clear system imbalances through a real-time balancing market. We believe that providing options for clearing imbalances that differ among customers would be unduly discriminatory.

Finally, we asked in the NOPR whether, for the imbalances of individual transmission customers, a distinction should be made between loads and generators. We conclude that, for the purpose of determining cost responsibility for imbalances, no distinction needs to be made. The system-wide balance between load and generation is affected comparably by changes in load and changes in generation. Therefore, the cost of an imbalance is unaffected whether the imbalance is determined ultimately to be the responsibility of load or of generation. However, commenters point out certain differences between loads and generators (such as in the time needed to respond to an operator's

instructions) that are important from the standpoint of system operation. These differences can be relevant to the determination of the appropriate penalties to assess to loads and generators that fail to submit accurate schedules. Thus, for purposes of assessing penalties for inaccurate schedules, we conclude that a penalty mechanism that treats loads and generators differently may be appropriate.

5. OASIS and Total Transmission Capability (TTC) and Available Transmission Capability (ATC)

In the NOPR, the Commission proposed that an RTO must be the single OASIS site administrator for all transmission facilities under its control and independently calculate TTC and ATC. The Commission stated that the most controversial aspect of OASIS operation is the calculation and posting of ATC⁵⁵³ and noted that there is widespread dissatisfaction with the reliability of posted ATC numbers. To alleviate this problem, the Commission proposed that the RTO become the administrator of a single OASIS site for all transmission facilities over which it is the transmission provider.⁵⁵⁴ The NOPR outlined three levels at which an RTO could be involved in ATC calculations. At Level 1, the RTO would post ATC values received from transmission owners. At Level 2, the RTO would receive raw data from transmission owners and itself calculate ATC values. At Level 3, the RTO would itself calculate ATC values based on data developed partially or totally by the RTO.

In the NOPR, the Commission envisioned that RTOs would operate at Level 3 to ensure that ATC values are based on accurate information and to minimize the opportunities for manipulation.⁵⁵⁵ The Commission also proposed that: (1) An RTO must formulate a validation system to check any ATC data supplied by others; (2) in the event of a dispute over ATC values, the RTO's data should be used pending the outcome of the dispute resolution process; and (3) the RTO must formulate the operating standards (subject to regional and national reliability requirements) underlying ATC calculations.⁵⁵⁶

Comments. Most commenters who address the subject agree with the Commission's observations regarding dissatisfaction with ATC/TTC data.

⁵⁵³ FERC Stats. and Regs. ¶ 32,541 at 33,747.

⁵⁵⁴ *Id.* at 33,748.

⁵⁵⁵ *See id.*

⁵⁵⁶ *Id.*

Moreover, most commenters on the subject endorse the proposal that an RTO must be the single OASIS site administrator for all transmission facilities under its control.⁵⁵⁷ Some commenters, however, are opposed to mandating the RTO as the OASIS site administrator. For example, Central Maine argues that it should not be precluded from operating its own site because as a "wires-only company" it has an incentive to operate an efficient site in order to maximize use of transmission capacity. EEI asserts that OASIS operation can occur independently of formation of an RTO and that the tasks and problems of OASIS operation will not become naturally easier to solve with the creation of an RTO.

Most commenters also support the Commission's proposal to have the RTO independently calculate ATC and TTC.⁵⁵⁸ In addition, a number of commenters emphasize that independent and disinterested RTOs could be trusted and empowered to maintain reliable ATC data and calculate accurate values.⁵⁵⁹ Moreover, several commenters are concerned with consistency across RTOs and contend that RTOs must also coordinate ATC values with adjacent regions and with the NERC regional reliability councils.⁵⁶⁰

Many commenters concur with the Commission's conclusions about the different levels of RTO involvement in ATC calculations. These commenters believe that Level 1 is insufficient for reliable and trustworthy data and that an RTO should independently calculate ATC values. Several commenters, however, disagree about the appropriate timing for Level 3 compliance. Some commenters, such as Cinergy, argue that upon commencement of operation, an RTO should be required to perform all studies and analysis needed for accurate

⁵⁵⁷ *See, e.g.*, NASUCA, WPSC, EAL, NERC, Industrial Consumers, Entergy, Mass Companies, JEA, LG&E, NY ISO, NJBUS, Sithe, TAPS, How Group, Southern Company, PG&E, PJM, UtiliCorp, Williams, Cinergy, Oneok, East Texas Cooperatives, Cal DWR, Tri-State, Seattle, New Smyrna Beach, RUS, Cinergy, Nevada Commission, and Enron/APX/Coral Power.

⁵⁵⁸ *See, e.g.*, Sithe, RUS, TAPS, PG&E, SMUD, Cal DWR, New Smyrna Beach, East Texas Cooperatives, WPSC, EAL, NERC, NASUCA, Seattle, Georgia Transmission, First Rochdale, Tri-State, Industrial Consumers, Enron/APX/Coral Power, Cinergy, Oneok, PJM, Williams, Empire District, PJM/NEPOOL Industrial Customers, Entergy, Mass Companies, Nevada Commission, NJBUS, and LG&E.

⁵⁵⁹ *E.g.*, FMPA, East Texas Cooperatives, NJBUS, Empire District, Entergy, Oneok, First Rochdale, Seattle, EAL, Sithe, WPSC, Sithe, PG&E, SMUD, New Smyrna Beach, and PJM/NEPOOL Customers.

⁵⁶⁰ *See, e.g.*, Industrial Consumers, Seattle and WPSC.

ATC values consistent with Level 3. APX supports each RTO reaching Level 3 as quickly as possible. Enron/APX/Coral Power asserts that upon commencement of operation, an RTO should operate at Level 2 and, as it gains operational experience, migrate to Level 3. SMUD supports RTO operation at Level 3 but is concerned about the significant costs associated with developing data.

JEA is opposed to any RTO structure that gives an RTO complete authority over ATC calculations for transmission that JEA will continue to own. JEA asserts that transmission owners are in the best position to assess the capabilities of their own transmission system. Therefore, absent formation of a transco, JEA does not support relying on an RTO for ATC and TTC calculations because JEA argues that ownership and control of the assets would be split between two or more entities whose interests are not always the same.

Both Cal ISO and NY ISO argue that the final rule should provide flexibility in the OASIS requirements to accommodate network systems like the Cal ISO and the NY ISO in which transmission service is not explicitly reserved. In addition, numerous commenters argue that the Commission should expand the minimum requirements to have every RTO employ a single set of OASIS practices and terminology.⁵⁶¹ They note that consistency in OASIS procedures will allow seamless trades across RTOs.

How Group also focuses its comments on the standardization of transmission transactions. It notes that without some level of standardization only a limited number of market participants who learn all of the differences between RTOs can perform transactions that span multiple RTOs. How Group proposes that each RTO establish a coordinating committee with neighboring RTOs and transmission customers in order to: (1) Coordinate the naming of interconnected facilities, sources, sinks, paths, points of receipt and/or delivery between the RTO and its neighbors; (2) coordinate the sharing of necessary data for the calculation of transmission capability on interconnected paths; and (3) foster coordination with neighbors in adopting standardized business practices. It also suggests that continued industry-wide coordination is necessary to formulate common definitions for types of transmission and ancillary services, curtailment priorities, and timing

⁵⁶¹ *See, e.g.*, Williams, EPSA, Cinergy, Empire District and PJM/NEPOOL Customers.

requirements for arrangement of transmission services.

Only one commenter expressed concern about the proposal to use the RTO's ATC values in the event of a dispute. Southern Company contends that the existing transmission owner's data are preferable to the RTO's data. Southern Company argues that existing transmission owners have experience in operating the regional transmission facilities and, therefore, are best qualified to determine ATC values.

Some commenters raise other OASIS-related issues that were not addressed in the NOPR. For example, commenters argue that: (1) All reservations and scheduling, including that for network service, should occur on the OASIS; (2) sanctions should be levied against transmission providers that skew their ATC values; and (3) the power flow methodology rather than the contract path model should be used for scheduling.⁵⁶² A few commenters address issues relating to Capacity Benefit Margin (CBM). NASUCA argues that administration of CBM should be a required function of RTOs and that a uniform methodology for calculating CBM is needed. Similarly, Idaho Commission asserts that requiring the posting of CBM on OASIS with a narrative explanation of its derivation would be beneficial. Empire District states that the Commission should provide better guidance about how to calculate CBM.

Commission Conclusion. After considering the comments, we continue to believe that an RTO must be the single OASIS site administrator for all transmission facilities under its control. As numerous commenters note, independent RTOs can be trusted to maintain an OASIS site with reliable and current data that is easy to use. In addition, a single OASIS site for each region instead of multiple sites will enable transactions to be carried out more efficiently.

However, in response to those who argue for flexibility in OASIS requirements, we clarify that this requirement does not mean that each RTO must itself operate the OASIS for its region. Our concern is that there be no more than one OASIS site for the facilities under the RTO's control, and that the RTO ensure that the OASIS site operator have the same attributes of independence we require for an RTO. Thus, we will allow an RTO the flexibility to contract out OASIS responsibilities to another independent entity, if justified. More specifically, we

do not intend to keep an RTO from participating in a "super-OASIS" jointly with other RTOs.

We reaffirm that an RTO should operate at what the NOPR characterizes as Level 3 for ATC/TTC calculations, which requires the RTO itself to calculate ATC values based on data developed partially or totally by the RTO. Most commenters believe that Levels 1 and 2, where the RTO would accept the transmission owners' ATC calculations or data, are insufficient for reliable and trustworthy ATC values. Level 3 ensures that ATC values are based on accurate information and consistent assumptions. When data are supplied by others, the RTO must create a system for tests and checks that ensure customers of coordinated and unbiased data. We also agree with commenters who recommend that RTOs coordinate ATC values with adjacent regions.

We recognize that the NOPR was silent on the appropriate timing for Level 3 compliance. Commenters suggested that: (1) An RTO should reach Level 3 compliance upon commencement of operation; (2) an RTO should reach Level 3 as quickly as possible; or (3) an RTO should operate at either Level 1 or 2 upon commencement of operation and as it gains operational experience, migrate to Level 3. We conclude that an RTO OASIS site, including ATC calculations, must be fully operational at Level 3 upon commencement of service. All parties to a transmission transaction need precise ATC values to make scheduling decisions.

We affirm that in the event of a dispute over ATC values, the RTO's values should be used pending the outcome of a dispute resolution process. Only one commenter, Southern Company, disagreed with this proposal and we are not persuaded by its arguments. Each RTO must develop procedures to validate its ATC values.

How Group and other commenters address issues relating to the standardization of transmission transactions. Standardization of transactions involves two separate concerns: (1) Many transactions will cross RTO boundaries; and (2) numerous customers will do business with multiple RTOs. Without standardized communications protocols and business practices, the costs of doing business will be increased as market participants will be required to install additional software and add personnel to transact with different RTOs and regions. Therefore, to promote interregional trade, standardized methods of moving power

into, out of, and across RTO territories will be needed.

We believe that standards for communications between customers and RTOs must be developed to permit customers to acquire expeditiously common services among RTOs. For example, we envision the creation of standardized communications protocols to schedule power movements and to acquire auction rights. These protocols would not standardize what the rights are, or the nature of the auctions. Instead, the focus of the communications protocols would be on how customers communicate their intentions to an RTO and how customers receive an RTO's responses.

We agree with How Group and others that certain business and communication standards⁵⁶³ are necessary, and we believe that these standards will facilitate the development of efficient markets. We believe, however, that these issues need further examination based on a complete record.

A few other commenters discussed issues that were not addressed in the NOPR. For example, commenters argue that: (1) All transmission transactions (reservations and scheduling) should occur on the OASIS; (2) sanctions should be levied against transmission providers that skew their ATC values; and (3) the power flow methodology for scheduling, rather than the contract path model, should be utilized. In addition, NASUCA, Empire District and the Idaho Commission raise issues relating to CBM. These issues are too detailed for this proceeding and we will not address them at this time. Commenters will have the opportunity to bring up these issues in response to specific RTO filings, as well as during OASIS Phase II proceedings and in the CBM docket (Docket No. EL99-46-000).

6. Market Monitoring (Function 6)

In the NOPR, the Commission proposed that RTOs perform a market monitoring function. Specifically, RTOs would be required to: (1) Monitor markets for transmission service and the behavior of transmission owners and propose appropriate action; (2) monitor ancillary services and bulk power markets that the RTO operates; (3) periodically assess how behavior in markets operated by others affects RTO operations and how RTO operations

⁵⁶³ We believe that the communications standards and protocols would, like the current OASIS, make use of: (1) The Internet for communications; (2) interactive displays using World Wide Web browsers; (3) file uploads and downloads for computer-to-computer communication; and (4) templates defining the file uploads and downloads.

⁵⁶² See, e.g., Ontario Power, Williams, NERC and EPSA.

affect those markets; and (4) provide reports on market power abuses and market design flaws to the Commission and affected regulatory authorities, including specific recommendations. In addition, the Commission asked a number of questions regarding the role of RTOs in market monitoring, the tools RTOs should use, and similar issues.

Comments. Commenters address a number of issues regarding the market monitoring function. The issues can be grouped into three general areas: (1) The need for and scope of a market monitoring function; (2) who should perform the market monitoring function and how it should be performed; and (3) what are the specific components or procedures of a market monitoring plan.

Need For and Scope of Market Monitoring. As a general proposition, a variety of commenters favor having RTOs serve as market monitors.⁵⁶⁴ Commenters, such as Blue Ridge, argue that RTOs should conduct market monitoring because they will be in the best position to deal with the growing volume of multiparty transactions and discern any manipulation or preferential treatment. Several commenters, such as the Florida Commission, note that the appropriate role for RTOs in market monitoring and the various aspects of the function will depend upon the nature of the RTO that is ultimately established. TEP claims that RTO market monitoring needs to be flexible given the costs involved in such a function. PP&L Companies believes that RTO market monitoring should focus on properly structuring business rules to foster efficient transactions and gathering statistical information to make available to the Commission or other enforcement agencies. EEI and Allegheny recommend that RTO market monitoring identify market design flaws and propose solutions that lead to greater efficiency, competitiveness and reliability.

A number of commenters support having the RTO should serve as the "first line of defense" for detecting design flaws and market power abuses.⁵⁶⁵ Cal ISO suggests that the RTO serve as a first line of defense in conjunction with state commissions and local regulatory authorities in the region, particularly in the operation of hourly and real-time markets where potential buyers may not have the ability to decline electric service, and where transmission and ancillary

services markets tend to have high concentrations. PJM believes that market monitoring by RTOs provides a continual check on market activities and accordingly, RTOs should have clear authority to investigate potential market power abuses or flaws and to compel market participants to produce relevant information. SMUD contends that although RTO monitoring should be the first line of defense, an independent RTO monitoring unit must not be a substitute for review by the Commission and other regulatory agencies.

In contrast, some commenters, such as Cinergy, argue that, if transmission markets realize the efficiencies envisioned in the NOPR, the commodity market should be able to regulate itself, with the Commission and the courts serving as backstops. SNWA cautions that RTOs may be too focused on safe and reliable operations to be a first line of defense. Some commenters, such as Metropolitan and Southern Company, claim that there is no benefit in having RTO monitoring replicate the costly regulatory responsibility that already exists in state and Federal agencies.

Several commenters propose an expansive RTO market monitoring role. NECPUC proposes that monitoring include mitigation of both market flaws and market power. East Texas Cooperatives and SMUD believe that RTO market monitoring should include remedying market abuse. Project Groups believes that an RTO should monitor energy and ancillary services markets and their interplay, and develop indices and criteria to evaluate activities and behaviors that may reflect market power abuse. Advisory Committee ISO-NE suggests that the RTO monitor transmission and ancillary services markets to identify design flaws and market power, and to administer or propose remedial actions. Dyrnergy claims that monitoring should include oversight of transmission owners' behavior. EPSA proposes that the RTO also document any significant market impacts attributable to application of reliability rules.

Some commenters support limits on market monitoring by the RTO. Commenters, such as Southern Company and Entergy, argue that RTO monitoring should not reach to any market the RTO does not operate, nor should it encompass market power abuse and the effect of existing structural conditions on the competitiveness of electricity markets. Entergy adds that the RTO will not be in a good position to monitor markets it does not operate. Several commenters claim that the purpose of monitoring should be to look for market flaws, not

act as policeman looking for bad behavior.⁵⁶⁶ Desert STAR recommends that any proposed remedy be restricted to market flaws within the RTO's area of operation. Enron/APX/Coral Power argues that evaluation of the structure of power markets and policing market power lies outside of an RTO's core competencies as the operator of the transmission system. Tri-State opposes RTO monitoring of power markets because it would add to the complexity and cost of RTOs and impermissibly involve the RTO in issues about generation market power. NY ISO opposes monitoring to the extent that it encompasses the RTO playing an investigative and enforcement role. Nonetheless, in its view, the RTO could mitigate evident market power problems on a prospective basis by applying pre-approved remedies.

SiThe recommends that RTOs not have the authority to compel the provision of commercially sensitive data and should instead rely on nonproprietary information to monitor markets. PG&E contends that commercially sensitive information should not be released to anyone except in accordance with Commission-approved rules. PP&L raises concerns regarding the ability of the RTO market monitoring organization to guarantee confidentiality of commercially sensitive information supplied to it. Seattle argues that any claims of commercial sensitivity must be tempered by the need to create an efficient, self-policing, transparent market for nondiscriminatory transmission services.

Various commenters would limit the RTO market monitoring function to information gathering.⁵⁶⁷ They argue that the NOPR proposal is overly broad, too extensive and open-ended, and a potentially burdensome requirement. SiThe argues that the application of mitigation measures by the RTO could have real commercial impacts on market participants that often cannot easily be measured or repaid after the fact; therefore, market participants should have an opportunity to review and comment on monitoring procedures prior to their implementation. Seattle claims that the Commission should take a minimalist approach by facilitating market monitoring through greater public information disclosure. PG&E believes that the RTO should not regulate the functioning of the energy market. Duke supports RTO identification and description of alleged market abuses to appropriate authorities

⁵⁶⁴ See, e.g., New York Commission, South Carolina Authority, Mass Companies, LG&E, ISO-NE, TAPS, SMUD, NECPUC, WPSC, Project Groups and Tri-State.

⁵⁶⁵ See, e.g., Metropolitan, DOE, CMUA, NASUCA and Project Groups.

⁵⁶⁶ See, e.g., Desert STAR, CRC and Tri-State.

⁵⁶⁷ See, e.g., CP&L, TDU Systems, PP&L and PG&E.

through the regulatory framework that exists today.

Other commenters question the need for or otherwise oppose an RTO market monitoring function, in general, as a form of back door regulation.⁵⁶⁸ They contend that RTO monitoring will be unduly burdensome, overtaxing and costly to the ratepayers. Los Angeles and Salomon Smith Barney argue that RTO monitoring may interfere with the proper relationship between the RTO and its customers, which they claim should be focused solely on providing nondiscriminatory open access transmission services. UtiliCorp argues that the assignment of market monitoring functions to a commercial entity such as a transco (other than those functions concerned strictly with transmission pricing) may raise antitrust concerns both for the transco and its customers.

Commenters differ on whether market monitoring should continue indefinitely. East Texas Cooperatives believes that continuous RTO market monitoring is necessary because, in its view, antitrust laws and complaints to the Commission provide only a slow, after-the-fact remedy. Entergy recommends that any RTO self-monitoring be allowed to terminate after a fixed period, subject to Commission approval. Industrial Consumers suggests that market monitoring be limited to the period when the risk of discriminatory conduct is greatest. Los Angeles claims that, once the Commission determines that generation markets are workably competitive, market forces should be allowed to discipline the markets. If an RTO market monitoring function is required, PSE&G suggests a five-year sunset provision.

Who Should Perform Market Monitoring and How Should it Be Performed. Many commenters address the issue of whether the RTO should perform market monitoring depending on the form of the RTO (*i.e.*, whether the RTO is a for-profit or a not-for-profit organization). Most commenters raise concerns about and generally oppose a for-profit RTO monitoring markets.⁵⁶⁹ The commenters generally argue that, due to its economic and business interests, a for-profit RTO cannot objectively monitor itself. CP&L submits that a for-profit RTO may be a competitor of other market participants in the provision of congestion relief and ancillary services, which would make

unbiased monitoring of those markets difficult. TDU Systems would limit a for-profit RTO's role to data collection. Other commenters recommend that for-profit RTOs employ a fully independent organization to monitor market conditions.⁵⁷⁰ A few commenters, however, support for-profit RTOs serving as market monitors.⁵⁷¹ Entergy claims that market monitoring conducted by a transco could be as effective as for any other type of RTO as long as procedures are in place that ensure its independence.

Commenters also address whether an RTO that is an ISO needs to insulate its market monitoring function from other RTO functions to ensure independence and objectivity. A number of commenters generally believe it is appropriate for ISOs to internally monitor market activities either through staff devoted to the function or through a committee of ISO members assigned to the function.⁵⁷² They argue that an ISO, which would be free of commercial interests, can be trusted by market participants, and therefore should not have to undertake costly establishment of autonomous monitoring units. Mid-Atlantic Commissions note that PJM ISO's monitoring unit is a neutral body that has access to and maintains confidentiality of market sensitive data in accordance with sharing arrangements with each of the states in the region. California Board contends that, if the internal unit is independent and has the ability to report and/or consult with state and Federal authorities without needing additional approval, those regulators are likely to respect the opinions and recommendations of the market monitoring unit. CalPX suggests that RTOs and separate power exchanges coordinate their market monitoring functions and jointly conduct research to lower costs. EPSA suggests that the information and market data, if collected by an independent and unbiased RTO, could be relied upon by market participants in formulating business strategies, and by regulators for purposes of reviewing and approving modifications to regulated aspects of RTO structures and operations.

Most commenters, however, would require an ISO (*i.e.*, a not-for-profit RTO) to make its market monitoring function more independent. Pennsylvania Commission contends that an independent ISO is absolutely necessary

to perform market monitoring functions. EEL points out that while an RTO's independence may ensure that its recommendations do not favor particular market participants, this does not ensure that it will monitor its own performance objectively. In its view, an ISO should use outside experts within the monitoring committee or on an ad hoc basis to address concerns about objectivity. Similarly, PG&E contends that experience has shown that an ISO's rules and actions may interfere with the proper functioning of the market. Industrial Consumers contend that an RTO's operations must be sufficiently transparent that it is the market participants that do the real monitoring. FTC suggests that internal RTO monitoring could be problematic if the internal monitoring unit is given enforcement powers, because this could both devolve into re-regulation and raise conflict of interest issues. FTC recommends that the Commission's RTO rules explicitly make clear that self-monitoring controlled by an RTO does not create an antitrust exemption for the RTO and its participants.

Los Angeles believes that market monitoring should be conducted by an independent body. CP&L, however, believes that delegation to a private party is questionable, where its objectivity may also be challenged on grounds of conflict of interest, particularly, if the delegated authority includes the ability to impose sanctions and penalties. Oregon Commission believes that RTOs should appoint a local committee to use RTO data to monitor the market for ancillary services because RTOs, as major buyers and sellers of such services, will want to protect their market shares. The Commission should consider establishing its own regulatory advisory bodies to monitor markets. DOE also claims that the Commission should avoid reliance upon RTO monitoring to the exclusion of the Commission's own monitoring efforts. Alliant believes that moving responsibility for monitoring market power to another organization would allow the RTO to focus on the many technical demands that will be placed on it. Metropolitan believes market monitoring should occur on two levels: an internal group responsible for data gathering and publication and frequent preliminary analysis of anomalous conduct; and formal analyses performed by a group or committee independent of RTO management whose results and recommendations would not require RTO approval.

LG&E proposes that the RTO make its monitoring findings public and refer

⁵⁶⁸ See, *e.g.*, Industrial Consumers, Williams, Southern Company, PSE&G, Arizona Commission, Georgia Transmission and East Kentucky.

⁵⁶⁹ See, *e.g.*, Dynegy, South Carolina Authority, Industrial Consumers and East Texas Cooperatives.

⁵⁷⁰ See, *e.g.*, PJM/NEPOOL Customers, Cal ISO, Tri-State and Metropolitan.

⁵⁷¹ See, *e.g.*, Entergy and Duke.

⁵⁷² See, *e.g.*, PJM, ISO-NE, NY ISO, WPSC and East

them to an appropriate regulatory body. Industrial Consumers opposes giving deference to the RTO's recommendations for correcting such market power abuses and flaws. Instead, it believes that stakeholders and market participants should use the RTO reports to make their own recommendations.

NYPP believes that structural solutions are matters for legislators, courts or regulatory agencies. In contrast, PJM believes that, if the market issue is a structural one, the RTO should be able to propose structural remedies to the Commission.

In the case of localized market power, MidAmerican submits that it would be inappropriate for the RTO to take corrective competitive actions in the case of localized must run generating unit market power. Similarly, PG&E contends that RTOs should allow temporary supply and price issues to be resolved by the competitive forces of the market, unless there is a threat to the physical supply of power or a Commission determination that markets are not workably competitive.

CalPX believes that monitoring and reporting should be simplified in order to reduce costs and to rationalize staff and committee work loads. Also, the RTO and power exchange compliance related staffs should jointly conduct research that is beneficial both to increase coordination and reduce costs. NY ISO submits that RTOs that are ISOs should not be required to establish costly and otherwise burdensome autonomous market monitoring units.

Many commenters address the issue of the appropriate role for the Commission and the state commissions in market monitoring. Commenters overwhelmingly believe that the Commission and state commissions have an important role to play, whether it is a primary role as market monitors, or a secondary role providing oversight of market monitoring activities by RTOs.

Some commenters believe that market monitoring is better handled by the existing statutory and regulatory agency frameworks than by RTOs.⁵⁷³ They suggest a continuing, if not mandatory, role for the Commission and other Federal and state authorities in conjunction with any market monitoring undertaken by RTOs.⁵⁷⁴ PP&L Companies argues that, in *Gulf States Utilities Co. v. FPC*,⁵⁷⁵ the Supreme Court made it clear that the Commission

is charged with serving as the first line of defense to protect and preserve competition in wholesale power markets.

TDU Systems and Sithe contend that regulatory commissions cannot abdicate to RTOs the responsibility to ensure that wholesale electric markets are free of market power. Many commenters see RTOs serving to forward any claims of market abuse and market power to the various federal and local regulatory agencies consistent with their respective jurisdictions. PJM and LG&E see the Commission reviewing remedies and approving penalties and sanctions. Desert STAR and CRC see the Commission acting as a backstop to an RTO's ADR process or mitigation plan. EEI suggests that RTOs regularly inform the Commission about monitoring results, which will enable it to respond quickly to problems not resolved by the RTO. SoCal Cities suggest that RTOs share responsibility to remedy structural defects in the market or impose general sanctions for market power abuse with appropriate state and federal agencies, but not duplicate their responsibilities such as implementation of the FPA. CalPX believes that there is a decreasing role for regulatory oversight as a result of a progression toward greater RTO self-regulation.

Florida Power Corp. and Nevada Commission suggest close coordination of RTO market monitoring with state regulators. Nevada Commission also suggests that RTOs collaborate their monitoring efforts with neighboring RTOs, as well as audit the records of those parties who violate the RTO's rules. Project Groups recommends adding an eighth minimum function under which RTOs provide data support for states' policies, monitoring the competitive impacts of emissions regulations, verifying compliance with state generation portfolio standards.

NARUC claims that the states need to be heavily involved in RTO market monitoring and that the Commission should work with the states to make utility codes of conduct more effective. In its view, such collaboration is the most effective means of monitoring market power in generation, since the RTO would have information for the region on transmission planning, generation expansion and transmission constraints, and state commissions would have utility specific data and information on local operations. NARUC argues that such collaboration is critical because state commissions are responsible for both evaluating local markets to assure competitiveness and for licensing electric supplies, and abusers of market power can inhibit

competition and distort the prices of locally regulated services. NASUCA similarly claims that market participants, state and federal regulatory agencies, and state consumer advocates periodically review the indices and screens to be used for RTO market monitoring. The RTO should periodically issue confidential reports to federal and state regulatory authorities and state consumer advocate offices, that describe the state of the markets and the results of matters under investigation.

A number of state commissions suggest a continuing oversight role over RTO monitoring by the Commission and the states.⁵⁷⁶ Oregon Commission recommends that the Commission establish its own regulatory advisory bodies to monitor ancillary services markets. For a for-profit RTO, it recommends that a regional oversight committee perform this function with the Commission reviewing any oversight committee reports.

Commenters also address a number of issues related to the ability of RTOs to perform self-assessments. A number of commenters believe that RTOs are capable of objective analysis. NY ISO contends that an ISO will have no incentive to distort the results of its analysis. Cinergy recommends that RTOs be limited to monitoring the behavior of the markets they administer because of the ready access to relevant information. Los Angeles comments that, if the RTO is not primarily responsible for providing ancillary services, it should not be burdened with surveying that market.

Other commenters oppose RTOs monitoring the markets that they operate because of conflict of interest concerns.⁵⁷⁷ EEI argues that independence from market participants does not ensure that the RTO will be able to monitor its own performance objectively, e.g., a non-profit RTO may not have sufficient incentives to minimize the costs under its control. Oregon Commission comments that RTOs cannot be entrusted to monitor ancillary services markets, where they will be providing services and have incentives to protect market share. Industrial Consumers contends that market participants must perform monitoring and, accordingly, an RTO's operations should be fully transparent. SNWA and PG&E claim that the RTO

⁵⁷³ See, e.g., Salomon Smith Barney, South Carolina Commission, PG&E, Enron/APX/Coral Power and Duke.

⁵⁷⁴ See, e.g., SMUD, Tri-State, Cinergy, TDU Systems, EPSA, Industrial Consumers, CMUA, PJM/NEPOOL, Customers, NY ISO, ISO-NE and DOE.

⁵⁷⁵ 411 U.S. 747 (1973).

⁵⁷⁶ See, e.g., Florida Commission, New York Commission and Michigan Commission.

⁵⁷⁷ See, e.g., Florida Power Corp., CMUA and DOE.

should establish an independent body to monitor and evaluate its performance.

Some commenters, such as Salomon Smith Barney and Michigan Commission, oppose the RTO monitoring markets where the RTO takes a market position because the RTO plays the dual role of seller of services and policeman. Alliant contends that an RTO will be competing with generation providers in congestion management and have an incentive to build transmission facilities. Similarly, CP&L contends that a for-profit RTO may compete with others in providing ancillary services, and therefore any proposal by the RTO monitor for remedial action raises serious conflict of interest concerns. Industrial Consumers suggests that, even in markets where the RTO is the supplier of last resort, the RTO should not have quasi-regulatory powers.

Commenters also address the issue of whether RTOs should be required to provide periodic assessments of markets they do not participate in or operate, thereby assessing the effect of existing structural conditions on the competitiveness of their region's electricity markets. Some commenters oppose this proposal. Tri-State opposes an RTO monitoring of power markets because it would not only violate the Commission's goal of separation between transmission and power sales, it would also add a level of complexity and cost to the operation of the RTO. Justice Department believes that the RTO cannot reasonably be expected to monitor activities with which it has no involvement. Justice Department therefore recommends that the Commission consider requiring each separate electric power trading institution to monitor any market that it operates.

On the other hand, a number of commenters favor extending RTO monitoring responsibility to markets they do not operate. PJM/NEPOOL Customers argues that the independence of the RTO would enable market participants and the Commission to have confidence in the RTO's assessments. ISO-NE favors RTOs monitoring power markets. NASUCA recommends that RTOs monitor bulk power markets, capacity markets, transmission rights markets, ancillary services markets and any other potentially competitive markets. FTC suggests that, where an RTO is smaller than one of the major interconnects, the Commission may wish to encourage all the RTOs within each of the interconnects to coordinate their efforts to examine the effects of market rules or variations between RTOs in market

rules on the volume and price of inter-RTO transactions. Cal ISO also sees collaborative market monitoring and assessment by neighboring RTOs and at the national level.

Florida Power Corp. recommends that an RTO that is an ISO be required to make regular assessments as to whether it has sufficient operational authority to ensure its ongoing ability to provide reliable, open access transmission service on a comparable basis to all customers—nonetheless, the RTO should not be self-regulating.

For those regions where the real-time balancing function is performed by an ISO, Advisory Committee believes that the ISO should monitor market power in generation markets. SoCal Edison claims that, where markets are not yet workably competitive, the RTO, with Commission approval, should ensure that prices are just and reasonable through appropriate temporary mechanisms such as price caps. PG&E counters that, in no case, should RTOs be permitted to use control of a power exchange for unilaterally capping prices set by the market.

Many commenters address the issue of how the RTO should report, if at all, its monitoring activities. The Commission did not propose to establish detailed standards on the format and content of monitoring reports, noting that such matters are best left to the RTO. We asked commenters to address whether reporting should be limited to when a specific problem is encountered, or whether periodic reporting on the state of competition and transmission access would be more appropriate.

Commenters express mixed views on reporting requirements. CRC supports the concept of RTOs reporting to the Commission regarding RTO design flaws, and New York Commission suggests that RTOs report on market power abuse as well. Florida Power Corp. submits that, if market monitoring is necessary, it should be performed by the RTO reporting and filing appropriate information with state and Federal regulators. Project Groups wants the provision of data to support state programs pertaining to the monitoring of the competitive impacts of emissions regulations. Project Groups argue that RTOs would be uniquely positioned to support data collection for verification of green marketing claims and compliance with information disclosure requirements and portfolio standards. EEl opposes a Commission mandate for RTOs to track generation source and emissions data. EEl recommends the RTO voluntarily undertake this task to meet specific state compliance

requirements provided appropriate safeguards protect competitively sensitive information. EEl expresses concern regarding the possibility that the RTO would have authority to collect and disclose information from a generation source where the state has not imposed such a requirement.

Several commenters favor issuance of monitoring reports at regular intervals. Project Groups believes that RTO monitoring units should issue public reports on their activities and findings, including annual reports on the general state of the market. Metropolitan supports reporting at regular intervals from an external monitoring source; however, during initial startup, more frequent reporting is advisable to assist participants' understanding of the market operation. East Texas Cooperatives believes that RTOs should prepare periodic reports to the Commission with the precise form left to the discretion of the RTO.

California Board contends that regular reports on market performance should issue at least on a yearly basis, and include all relevant data that can be made publicly available. NASUCA contends that, to further create trust in the RTOs' ability to effectively and objectively monitor the market, RTOs should periodically issue reports describing the state of the markets that it is monitoring, items under investigation by the RTO, and any results from completed investigations. In its view, market participants, state and federal regulatory agencies and state consumer advocates should participate in the development and periodic review of the indices and screens the RTO will use to monitor the operation of the markets. Reports should be provided to state and federal regulatory authorities as well as state consumer advocate offices, on a confidential basis, to enable them to independently assess whether additional investigation is merited. Cal ISO submits that the Commission should specify regular reporting requirements for the RTO's monitoring unit. PJM believes that RTOs should periodically report results of monitoring activities to the Commission and state agencies.

Components of a Market Monitoring Plan. Commenters address various issues regarding particular elements of a market monitoring plan. Many commenters address the issue of whether RTOs should be allowed to impose penalties and sanctions. Most commenters would limit the RTO's ability to impose penalties or sanctions. Many of them argue that such authority should remain the province of the

regulatory and antitrust agencies.⁵⁷⁸ Justice Department claims that RTOs lack experience either in detecting exercises of market power or in making recommendations on correcting market power problems. SPRA questions whether the imposition of sanctions by the RTO may conflict with the Supremacy Clause of the Constitution and whether affected public power bodies could only consent to such sanctions if they do not create indefinite or uncertain liabilities. PP&L argues that, because it will be judge and jury, the RTO must demonstrate competitive harm before taking any market action. Some commenters, such as CP&L, note that a for-profit RTO may not be objective in imposing sanctions because it competes with other market participants. Other commenters, such as Salomon Smith Barney, claim that RTOs should be limited to extracting ordinary commercial penalties when market participants fail to follow the market's rules. EPSA claims that RTOs should be empowered to intervene in a market within the strict confines of the Commission's oversight only when a situation has the potential to become catastrophic. Mass Companies opposes allowing a private RTO or one that is operated by a non-stakeholder board to enforce violations of market standards and impose sanctions and penalties.

Canada DNR claims that it will be problematic for Canadian entities subject to the jurisdiction of Canadian provincial and Federal energy regulators also to be subject to an RTO that has its disciplinary authority backstopped by the Commission. In its view, the issue will not be resolved by simply having the appropriate Canadian regulator serve as the regulatory backstop to the RTO for each Canadian entity because the Canadian regulator may take a different position than the Commission.

A few commenters support authority for RTOs to impose penalties and sanctions. Among them, CalPX believes that RTO governing boards and power exchange market monitoring committees must be able to take appropriate action either by referral to regulatory agencies or directly through applicable sanctioning authority. It views this as critical for self-policing and providing prompt remedies before problems detrimentally affect market results. ISO-NE believes that an RTO should have the ability to impose penalties and sanctions, but suggests that the RTO not act as an antitrust agency, in order to increase the acceptability of sanctions among participants.

The Commission specifically sought comment on whether penalties should be limited to violations of RTO rules and procedures, or whether the RTO should be allowed to impose penalties for the exercise of market power. More commenters oppose than support RTOs imposing sanctions and penalties for market power abuse. Among them, Allegheny and Metropolitan claim that this is a proper function of regulatory or antitrust authorities. Central Maine argues that the Commission cannot grant RTOs the authority to impose corrective actions without affording the affected public utilities with procedural due process. EEI believes that the RTO tariff may include RTO authority to impose fines or sanctions to ensure compliance with RTO rules in accordance with the costs imposed by their actions. Pointing to similar positions taken by Justice Department and FTC, EEI contends, however, that the RTO should not attempt to define or prosecute alleged exercise of market power because it is not a regulatory body or an antitrust agency authorized to take such actions. It also suggests that limited additional authority might be granted during the transition to restructured markets to permit the RTO to deal effectively and timely with identified market design flaws, software errors, or other unanticipated situations that could be costly if no action is taken.

Cinergy also argues that the RTO should not be allowed to take corrective action against individual market participants. It believes that claims of market abuse and the exercise of market power should be forwarded to the Commission to address consistent with its jurisdiction. Similarly, MidAmerican recommends that RTO penalties be limited to (1) willful violations of material RTO directives related to the operation of regional transmission facilities, Commission approved RTO standards for transmission facility operations, and material provisions of RTO agreements that conflict with the RTO transmission tariff, and (2) violations of RTO transmission tariff provisions relating to operating reserves and energy imbalances. NASUCA recommends that compliance with RTO rules be enforced with penalties and sanctions imposed through a collaborative process involving all market participants, regulatory agencies and consumer advocates. However, the Final Rule should specify that any actions taken by the RTO cannot substitute for penalties or other remedies which may stem from independent investigations by governmental authorities. Similarly,

ISO-NE and SNWA generally would impose sanctions based on a participant's engaging in patterns of conduct defined in the RTO's rules or its tariff.

NYPP, DOE, and LG&E generally concur that RTO sanctions and penalties should only be levied for violations of RTO rules and procedures, whereas penalties and sanctions for market power abuses are matters for the regulatory and antitrust agencies, legislators, or the courts. Florida Power Corp. argues that, since an RTO does not have authority to grant or terminate market-based rate authorizations premised respectively on the absence or presence of market power, the RTO should therefore have no role in passing judgement or imposing penalties for the exercise of market power.

On the other hand, some commenters, such as East Texas Cooperatives, are more comfortable with RTO imposition of penalties and sanctions for market power abuse. PJM recommends that RTOs be able to take corrective action to ameliorate market abuses or flaws and to seek Commission approval to add penalties and sanctions to its market monitoring plan. NECPUC recommends that market monitoring be expanded to include formalized mitigation and sanction rules in connection with market design, implementation flaws and market power. NY ISO claims that RTOs should mitigate evident market power problems, on a prospective basis, by applying pre-approved remedies. CRC submits that RTOs investigate whether market power abuse results from a design flaw and report the results to the Commission for approval of its mitigation plan. WPSC sees RTOs being effective because they will have access to real-time data on system conditions and should be given authority to take appropriate corrective action immediately to respond to market abuses.

Some commenters also want sanctions against market participants for reliability rule violations. PSNM claims that RTOs should defer to existing mechanisms where they exist (such as the WSSC's Reliability Management System RMS, and NERC Reliability Standards and Measures) for sanctions against market participants for poor performance, rather than create new monitoring and sanction systems for RTOs. Similarly, Desert STAR submits that any RTO should be allowed to pass the reliability performance standards sanctions on to participants who do not comply. SMUD concurs that an important aspect of enforcing reliability standards is ensuring that the RTO has sufficient authority to police and

⁵⁷⁸ See, e.g., Entergy, Duke, PG&E, PSE&G, PJM/NEPOOL Customers and Williams.

investigate the markets they administer, and assess fines and other appropriate penalties, or resolve disputes amongst market participants as to any alleged market abuse.

A few commenters also address the Commission's questions about how much discretion the RTO should have in setting penalties (e.g., should the RTO's penalty authority be limited to collecting liquidated damages). Nevada Commission submits that RTOs should be allowed to impose specific penalties and sanctions for non-compliance with RTO rules based on liquidated damages and not punitive damages. Cal ISO and Metropolitan believe that penalties should be limited to liquidated damages. Cal ISO argues that for cases of repeated or intentional violations or serious abuses of market power, the RTO should seek relief, including imposition of punitive damages, from the Commission or other appropriate agencies such as the Justice Department. Metropolitan argues that liquidated damages sought by an RTO should be approved by the Commission. And Duke opposes the RTO assuming the role of market monitor and enforcer; therefore, it recommends that terms and conditions for any penalties the RTO might impose should be agreed upon by contract during the RTO development process.

On the other hand, WPSC claims that the RTO should have the discretion to determine the amounts of adequate sanctions and penalties to discourage anti-competitive conduct. Whether the RTO has acted properly can always be reviewed after the fact through a dispute resolution procedure either through the Commission or the Justice Department. NASUCA contends that sanctions and other penalties should be large enough to be an effective deterrent. It suggests that a for-profit RTO may have incentives to impose unjustified penalties and should be required to allocate all revenue derived from sanctions and penalties in a way that benefits customers. SMUD offers that, since liquidated damages are a mere proxy designed to make a victim whole for a transgression, they do not really serve as a deterrent to market abusive conduct.

Several commenters address whether the SEC model of regulating stock exchanges, i.e., requiring extensive and sophisticated market monitoring of stock exchanges, should be applicable to RTO market monitoring. Some commenters, such as EEI and PP&L, do not believe the model is applicable. EEI claims that monitoring scheme in the securities industry is an exception because in most industries the market

participants bring competitive problems to the attention of antitrust authorities. Site also opposes any emulation of the NASD or NYMEX model of self-regulation at this time because of the limited amount of market experience to date.

PJM/NEPOOL Customers and Cal ISO, however, contend that the RTO monitoring function should be similar to that of a stock exchange because the RTO is designed to ensure that the exchange of electricity can occur readily and easily in a competitive marketplace.

Commission Conclusion. In the NOPR, the Commission proposed that RTOs perform a market monitoring function. Many commenters raise a number of issues regarding market monitoring. The issues largely encompass the following concerns: the need for and scope of a market monitoring function; who should perform this function and how it should be performed; and what are the specific components or procedures of a market monitoring plan.

The Commission recognizes that the market monitoring concept is new and not yet well-refined, either at the Commission or within existing ISOs. We also acknowledge the apprehensions of some parties that market monitoring by an RTO could intrude into markets and affect their behaviors. The Commission, however, is engaged in finding ways to understand market operations in real-time, so that it can identify and react to any problems that are preventing the most efficient operations. It also has a responsibility to protect against anticompetitive effects in electricity markets.⁵⁷⁹ If we are to satisfy this goal, we must systematically assess whether our policies and decisions are consistent with this responsibility. Market monitoring is an important tool for ensuring that markets within the region covered by an RTO do not result in wholesale transactions or operations that are unduly discriminatory or preferential or provide opportunity for the exercise of market power. In addition, market monitoring will provide information regarding opportunities for efficiency improvements.

However, in light of the different forms of RTOs that could be developed by market participants and the varying types of markets an RTO may be operating within its region, different market monitoring plans are likely to be appropriate for different RTOs. Consequently, after careful consideration of the comments, the

⁵⁷⁹ See *Gulf States Utilities v. FPC*, 411 U.S. 747, 578-59 (1973).

Commission will require that RTO proposals contain a market monitoring plan that identifies what the RTO participants believe are the appropriate monitoring activities the RTO, or an independent monitor, if appropriate, will perform. We believe that such approach will provide those proposing an RTO sufficient flexibility to design a monitoring plan that fits the corporate form of the RTO as well as the types of markets the RTO will operate or administer. We have revised the regulatory text for the RTO market monitoring function to reflect our decision to allow this flexible approach.

Although we decline at this time to prescribe a particular market monitoring plan or the specific elements of such a plan, the RTO must propose a monitoring plan that contains certain standards. The monitoring plan must be designed to ensure that there is objective information about the markets that the RTO operates or administers and a vehicle to propose appropriate action regarding any opportunities for efficiency improvement, market design flaws, or market power identified by that information. The monitoring plan also must evaluate the behavior of market participants, including transmission owners, if any, in the region to determine whether their behavior adversely affects the ability of the RTO to provide reliable, efficient and nondiscriminatory transmission service. Because not all market operations in a region may be operated or administered by the RTO (e.g., there may be markets operated by unaffiliated power exchanges), the monitoring plan must periodically assess whether behavior in other markets in the RTO's region affect RTO operations and, conversely, how RTO operations affect the efficiency of markets operated by others. Reports on opportunities for efficiency improvement, market design flaws and market power abuses in the markets the RTO operates and administers also must be filed with the Commission and affected regulatory authorities.

In developing its market monitoring plan, the RTO should identify the markets that will be monitored, i.e., transmission, ancillary services or any other market it may develop (e.g., congestion management). With regard to those markets, the monitoring plan should examine the structure of the market, compliance with market rules, behavior of individual market participants and the market as a whole, and market power and market power abuses. The monitoring plan should also address how information will be used and reported. The monitoring plan

should indicate whether the RTO will only identify problems and/or abuses or whether it also will propose solutions to such problems. We note that sanctions and penalties may be appropriate for certain actions such as noncompliance with RTO rules. However, the monitoring plan should clearly identify any proposed sanctions or penalties and the specific conduct to which they would be applied, provide the rationale to support any sanctions, penalties or remedies (financial or otherwise) and explain how they would be implemented. With regard to the reporting of market monitoring information, the monitoring plan should indicate the types and frequency of reports that will be made and to whom the reports will be sent. Under the FPA, the Commission has the primary responsibility to ensure that regional wholesale electricity markets served by RTOs operate without market power. An appropriate market monitoring plan must provide an objective basis to observe markets and, if appropriate, provide reports and/or market analyses. Market monitoring also will be a useful tool to provide information that can be used to assess market performance. This information will be beneficial to many parties in government as well as to power market participants. This includes state commissions that protect the interests of retail consumers, especially where they are overseeing the development of a competitive electric retail market. We note, however, that the market monitoring function for the RTO does not limit the ability of each state within the RTO's region or other authorities to decide the nature and extent of its own market monitoring activities.

We are not requiring a plan that necessarily involves the collection of data the RTO would not collect in its ordinary course of business. We believe that the information collected through the RTO market monitoring plan will reflect data that the RTO will collect or have access to in the normal course of business (e.g., bid data, operational information). In light of our requirements that the RTO have operational control over the transmission facilities transferred to it and the RTO be the security coordinator for its region, the RTO will be in the best position to perform (or provide information to another entity, if appropriate, for it to perform) objective monitoring functions for the markets that the RTO operates or administers in the region.

In response to commenters' arguments that RTO market monitoring results in an impermissible shift of Commission

authority to other entities, we emphasize that performance of market monitoring by RTOs is not intended to supplant Commission authority. Rather it will provide the Commission with an additional means of detecting market power abuses, market design flaws and opportunities for improvements in market efficiency. Further, because market monitoring plans will be required to be filed with and approved by the Commission as part of an RTO proposal, we will retain the ability to determine what, how and by whom activities will be performed in the first instance.

Because we believe market monitoring is essential, we decline to set any sunset date for monitoring at this time. However, as bulk power markets evolve and become more competitive, we may revisit the need for the type of monitoring the Rule requires.

7. Planning and Expansion (Function 7)

In the NOPR, the Commission proposed that the RTO planning and expansion process must satisfy certain standards. Specifically, RTOs would be required to: (1) Encourage market-motivated operating and investment actions for preventing and relieving congestion; and (2) accommodate efforts by state regulatory commission to create multi-state agreements to review and approve new transmission facilities, coordinated with programs of existing Regional Transmission Groups (RTGs) where necessary. We suggested that RTOs be designed to promote efficient use, which requires efficient price signals such as congestion pricing, and efficient expansion of their regional grid, which requires control over planning and expansion. We specifically proposed that the RTO have ultimate responsibility for both transmission planning and expansion within its region. If the RTO is unable to satisfy the planning and expansion requirement when it commences operation, we proposed that the RTO must file a plan with specified milestones that will ensure that it meets this requirement no later than three years after initial operation. In addition, the Commission sought comment on whether three years is an appropriate amount of time for implementation of this function.⁵⁸⁰

Comments. Encourage Market-Motivated Operating and Investment Actions for Preventing and Relieving Congestion. Many commenters support the Commission's proposal to require that an RTO must ensure the development and operation of market

mechanisms to plan and refinance transmission system expansion. As part of this an RTO should provide all transmission customers with efficient price signals that show the consequences for their transmission use decisions.⁵⁸¹

Some commenters, such as JEA and Williams believe that this role is best performed by for-profit entities because system expansion decisions must be driven by economic considerations. Entergy also contends that a transco will not create any bias in the method of grid expansion.

Los Angeles agrees that an RTO should rely upon market signals and market solutions in assessing all feasible options (e.g., construction of new generation, redispatch of existing generation, grid expansion) to assure the least-cost option is pursued. NASUCA also argues that the Commission should mandate that RTOs use least-cost planning on a region-wide basis for transmission system expansions and upgrades. It notes that the larger the region over which least-cost planning is conducted, the more economically efficient the outcome is likely to be. If market solutions do not develop or are not timely, Los Angeles believes that the RTO must have the power to resolve the transmission problem. LG&E proposes that RTOs be permitted to use competitive bidding as a means to meet new transmission investment needs.

EPA believes that RTOs should adopt a resource planning process with sufficient flexibility to consider non-traditional resources and to assign appropriate values to their unique benefits. EPA further believes that RTOs should be encouraged to take into account environmental costs and benefits that are not reflected in resource prices.

Puget suggest that the Commission should recognize that the concept of RTOs may contain some elements that do not enhance the reliable operation of the transmission grid. Puget requests that the Commission should address more fully how it will mitigate the effects of the severance of generation and transmission planning and operation and how it plans to ensure maximum reliability at the lowest integrated costs.

NASUCA recommends that the Commission require RTOs to develop a baseline regional transmission expansion plan that would identify the regional system's ability to meet essential NERC reliability criteria and

⁵⁸¹ See, e.g., United Illuminating, Wyoming Commission, Industrial Consumers, Champion, NSP, PG&E, Williams, LG&E, FTC and APX.

⁵⁸⁰ FERC Stats. & Regs. ¶ 32,541 at 33,751-53.

isolate potential constraint areas of the existing system where upgrades may be necessary or additional generation desirable. Such a baseline plan could provide a valuable tool to market participants in signaling the best locations for new generation projects. Entergy proposes the use of a regional transmission plan that includes a regional transmission planning summit process involving all stakeholders.

TAPS, however, questions whether market-based mechanisms to expand the transmission grid will emerge readily from an efficient short-term transmission pricing regime that accounts properly for the costs of congestion. TAPS asserts that, while efficient congestion pricing is an important component of a well-designed transmission regime, it is not the answer to the concerns that have been raised regarding the lack of economic and regulatory incentives to expand the transmission grid.

Many commenters agree that RTOs should be responsible for conducting the studies necessary to assess the need for new transmission system enhancement.⁵⁸² However, some commenters argue that the role of the RTO should be to facilitate market investment by others in new transmission and generation, not to lead the market by making its own plans for new facilities. For example, Seattle suggests that the RTO should generate information on the locations, frequencies and costs of congested paths to guide capital investment. It believes that the RTO need not make capital investments directly; rather it should seek market mechanisms, such as requesting bids for needed capacity, to encourage investments. EME states that performance of this role requires accurate accounting for the impact of congestion and new generation, and proper allocation of costs to those that require such costs to be incurred.

To ensure that transmission expansion decisions are not biased, ComEd proposes that RTO functions be performed by two linked organizations that together make up a "Binary RTO." ComEd envisions that the Binary RTO would consist of for-profit independent transmission companies (ITCs), each operating a large aggregation of existing transmission systems, under the oversight of an independent, not-for-profit Regional Transmission Board (RTB). The ITCs will identify transmission additions, upgrade opportunities, and prepare long-range plans which would be reviewed by the

RTB and subsequently integrated in an RTB-wide planning system.

Powerex believes that it is better to eliminate congestion at its source through facilities upgrades, if economically and environmentally feasible, than to attempt to manage congestion on a long-term basis through congestion pricing schemes.

Many commenters support the concept that RTOs must be responsible for transmission planning and that single-system planning should be the objective of the RTO planning process.⁵⁸³ Commenters differ, however, on the extent of the RTO's role in the planning process. Some commenters, such as Powerex, argue that the RTO must have control over transmission service, planning, system impact studies and facilities studies, and the authority to determine the need for, and require the implementation of, transmission upgrades by member utilities. Other commenters, such as LIPA and H.Q. Energy Services, propose that, in the absence of transmission expansion proposals from current or proposed market participants, the RTO should have the responsibility for assessing whether transmission improvements are needed and, if a need is found, the RTO should have the authority to order such expansion.

Some commenters such as NY ISO, on the other hand, express concern that exclusive authority by the RTO over transmission planning is overly restrictive. NY ISO claims that entities which are responsible for coordinating transmission expansion, but which lack authority to make enforceable planning decisions, can nevertheless achieve the Commission's primary transmission expansion-related goal, *i.e.*, ensuring that investments in new transmission facilities are coordinated to ensure a least-cost outcome that maintains or improves existing reliability levels.

H.Q. Energy Services objects to NY ISO's arguments as being merely concerned with preserving its so-called "two-tier" governance system which provides NY ISO transmission owners with significant authority, or veto power, over interconnections with generating facilities and over decisions related to transmission system planning and expansion. H.Q. Energy Services does not believe that the two-tier approach is appropriate unless the RTO has ultimate decision-making authority.

Many commenters agree with the proposal that an RTO must be ultimately responsible for all

transmission expansions and upgrades.⁵⁸⁴ These commenters claim that transmission operations must be conducted on an independent and fair basis and must be undertaken by an impartial entity if transmission services are to be offered on a truly non-discriminatory basis. They argue that vesting the RTO with the ultimate responsibility for expanding transmission systems eliminates the conflict that is inherent in vesting these responsibilities with an entity that also has commercial interests that are competing with users of the system.

Although SMUD supports having the RTO be responsible for transmission planning and expansion, it cautions that, in such a paradigm, people that have no responsibility to the ratepayers will be deciding planning and expansion issues. Therefore, SMUD argues that the Commission needs to scrutinize the recovery of the costs of such expansion to ensure that such expansion decisions and costs are prudent, just and reasonable.

Several commenters agree that the RTOs can and should play a significant role in the transmission planning and expansion process.⁵⁸⁵ Some of these commenters, such as NYPP and Mass Companies, however, do not believe that the Commission should require that RTOs have authority to order a transmission owner to modify or expand its transmission system. Nevada Commission believes that transmission owners should be allowed to assist an RTO in the development of grid planning criteria and could take the lead in such grid planning with RTOs performing more of an overview role. Professor Joskow states that the transmission owners, operating through a sound RTO/ISO transmission planning process should be expected to be the primary, but not necessarily the exclusive, source of network enhancement initiatives. WEPSCO argues that transmission owners should be integrated into the RTO regional transmission plans where they can be improved and expanded to meet regional needs most efficiently. Turlock contends that the RTO's authority over the transmission system it operates must be limited to that system. Turlock argues that the RTO should not have the ability to force expansion of lower voltage or tangentially related facilities which are beyond the area of its responsibility, even if those other facilities might have a small but

⁵⁸⁴ See, *e.g.*, San Francisco, SoCal Cities and CMUA.

⁵⁸⁵ See, *e.g.*, NYPP, Industrial Customers, Mass Companies and Nevada Commission.

⁵⁸³ See, *e.g.*, PNCC, Wisconsin Commission, EAL, Entergy, PJM, Minnesota Power and Montana-Dakota.

⁵⁸² See, *e.g.*, EME and Seattle.

theoretically possible impact on the RTO's facilities.

CP&L supports a coordinated planning approach which would be similar to the planning approaches identified in the Midwest ISO and the Alliance RTO filings, where the RTO would have responsibility for review of the transmission plan, but the individual transmission-owning entities would provide the necessary input to facilitate the development of the comprehensive RTO transmission plan. East Kentucky argues, however, that an individual transmission owner should be able either to require or to veto the building of a particular RTO facility.

MidAmerican disagrees with the proposal that the RTO have the ultimate responsibility for both transmission planning and expansion in the region. MidAmerican claims that existing regional transmission groups (RTGs) have clear and prominent roles in transmission expansion decisions in which planning for transmission improvements are coordinated through collaborative processes that already involve many interested stakeholders in the widest fashion possible.

MidAmerican states that throughout the MAPP region there is broad support for continuing transmission planning and expansion decisionmaking as a collaborative function and that the existing collaborative processes adequately accommodate RTO participation.

Central Maine believes that RTOs/ISOs can and should play a significant role in the transmission planning and expansion process, but disagrees with the Commission's proposal to give ISOs ultimate responsibility for transmission planning and expansion. Central Maine does not object to ISOs having oversight responsibility in these areas, but Central Maine believes that the planning and engineering functions should be a shared responsibility between utilities and RTO, *i.e.*, the Commission should consider utility planners as a satellite to the ISO/RTO similar to satellite function served by utility control centers in monitoring, switching and dispatching. Central Maine states that the Commission should grant individual transmission owning utilities an equal voice in determining the technical aspects of transmission planning and expansion.

Although Big Rivers believes that, as proposed in the NOPR, the RTO should be the default provider of transmission planning and expansion, it agrees with NRECA that incumbent transmission owners should have the first opportunity to build required transmission system expansion with

RTO ability to facilitate needed construction by others.

Some commenters suggest specific tasks and functions that the RTO should perform or have the ability to require as part of the transmission planning and expansion function.⁵⁸⁶ For example, SRP proposes that at a minimum, each RTO should have the authority to: (1) Direct transmission owners to study and evaluate system performance and to develop plans to solve known reliability or adequacy problems; (2) revise or combine elements of transmission owners' plans to achieve the most efficient and reliable transmission expansion plan; (3) approve or reject any component of the RTO transmission plan developed by a transmission owner; and (4) approve facility additions by third parties.

Accommodate Efforts by State Regulatory Commission to Create Multi-State Agreements to Review and Approve New Transmission Facilities. Many comments concur that multi-state agreements are to be encouraged and that the RTO should be designed to work within that structure.⁵⁸⁷ Commenters, including NSP and Nevada Commission, encourage the Commission to provide an active role for RTOs to participate with state and local government in the siting and licensing of new facilities. PJM states that a cooperative relationship between RTOs and the states is essential to effective transmission expansion planning. In PJM's view, states are more likely to trust the planning decisions of RTOs that have no commercial interest in transmission and generation expansion than decisions made by transmission-owning entities, which have commercial interests.

Cinergy recommends that the final rule include a Commission commitment to proceed aggressively to establish a forum to encourage coordination of RTO planning and expansion among states through multi-state certification agreements and multi-state regional planning boards. Cinergy notes, however, that the creation of a forum or agency to review grid planning and expansion that would consider the public interest beyond the constraints of state boundaries may require federal legislation. If so, the Commission should be aggressive in its dialogue with Congress to obtain the requisite legislative relief.

The Kentucky Commission suggests creating a voluntary "Joint Board on Regional Transmission Siting" to

develop and review standards for transmission expansion. The Joint Board would include participation from the Commission, state commissions, RTOs, and other interested parties. The Joint Board would also convene ad hoc committees to review specific transmission expansion proposals. Pennsylvania Commission also prefers a joint Federal-state approach towards regulating RTO site approvals, expansion, innovation and customer service. It notes that a joint Federal-state approach has been used with success in other areas, such as the Susquehanna River Basin Commission, the Delaware River Basin Commission and the Joint Pipeline Office which regulates the Trans-Alaska Pipeline System.

Illinois Commission recommends that accommodation of multi-state efforts be expanded to include the possibility of multi-state regional regulatory oversight organizations. Such organizations could be instrumental in coordinating regional solutions to regulatory and policy issues.

Otter Tail expresses concern that multi-state agreements may not actually add to the efficient use and expansion of the interstate transmission system due to a danger that these types of agreements could be mired in state-versus-state political conflict and become unworkable, to the detriment of transmission owners, generators, and ultimately customers. Industrial Consumers also does not believe that requiring an accommodation with "multi-state agreements" is necessarily productive. It states that nothing now prevents such coordination among states, yet there is no obvious evidence that this will work. Industrial Customers believes that states will always reserve the right to veto a project that may be partially situated within their jurisdiction, regardless of the benefits elsewhere.

East Texas Cooperatives believes that retention of state public utility commission authority over siting (and other necessary approvals) is necessary to control the risk of overbuilding because RTOs will have no real incentive to limit facility construction.

Commenters generally express support for the proposal that the RTO build on existing RTG processes.⁵⁸⁸ For example, Industrial Consumers urges that the Commission require existing RTGs to merge their functions with the RTOs because RTGs should not be allowed to develop an institutional

⁵⁸⁶ See, e.g., Project Groups, LIPA and SRP.

⁵⁸⁷ See, e.g., Illinois Commission, DOE and New Smyrna Beach.

⁵⁸⁸ See, e.g., Wisconsin Commission, Industrial Customers and SRP.

culture that diverges from the goals and objectives of RTOs.

New Smyrna Beach and Oneok claim that market participants will undoubtedly benefit from a multi-state siting process for transmission because it may make siting of new generation easier if there is more certainty that related transmission siting decisions will be made on a timely basis with one-stop shopping.

Several commenters address the role of the Commission in the RTO planning and expansion process. Detroit Edison and Wolverine Cooperative support the establishment of the Commission as the primary channel of certification for transmission siting, construction, and expansion. Detroit Edison states that regional reliability organizations and the RTOs in each reliability region should be permitted to determine necessary changes and additions in transmission with input from transmission owners, control area operators, and other interested parties. It is vital, it states, that a single administrative agency resolve issues related to the siting of transmission facilities on a regional basis and have the authority to approve transmission expansion plans on a timely basis. Detroit Edison believes that the Commission should fill the important role of sole regulator over transmission siting and construction, just as it currently does in approving the siting and construction of natural gas pipelines, and it urges the Commission to work to gain such authority.

Pennsylvania Commission recommends that, if an RTO determines that transmission expansion is necessary, it should file with the Commission to demonstrate that need. Once the Commission determines a need exists within the RTO, the RTO should then file with the appropriate states for a determination of the siting issues. Pennsylvania Commission believes that vesting authority for determining the need for transmission expansion with the Commission solves several problems that are certain to arise in state forums. Federal determination of the need for transmission expansion obviates the burden of filing with multiple jurisdictions and possibly receiving conflicting determinations.

Otter Tail states that Commission should seriously consider whether the public interest would be better served through adoption of a transmission siting policy that is similar to review of interstate natural gas pipelines.

NY ISO claims that in many cases transmission expansion is delayed or blocked entirely by environmental and other transmission siting regulations. Nevertheless, NY ISO supports the

NOPR's proposal that RTOs participate in efforts to create multi-state transmission expansion agreements.

East Kentucky believes that there needs to be some regulatory oversight authority for facilities that are deemed necessary by an RTO planning staff. East Kentucky proposes that this regulatory authority be the Commission or a regional regulatory authority.

Conlon recommends that the Commission have the necessary authority to enforce reasonable siting request, or critically needed future transmission lines could be delayed causing a reliability risk. Granting the right of eminent domain to transcos or ISOs in Federal legislation would be another approach. This could be accomplished by the Commission recommending to Congress that it have the right of eminent domain.

LG&E believes that it is important that state authority over system expansion not impede necessary improvements that enhance the efficiency of the regional grid that is, or will be, subject to RTO control. Ultimately there may be a need for a congressional solution to the current balkanized system for authorizing grid expansion. In its comments, the East Central Area Reliability Council explicitly calls for such legislative action based on its concern that transmission facility expansion requests will fail as they become bogged down in multiple state reviews. LG&E shares this concern. Still, until such time as the statutory framework for transmission expansion is amended, LG&E believes that RTOs represent an opportunity for coordinating regional transmission expansion needs among transmission owners and state authorities.

Project Groups maintains that RTOs should be required to coordinate and lead in the development of comprehensive least cost regional plans for assuring short-and long-term system reliability, and they must coordinate the actions necessary for implementing timely system upgrades and additions pursuant to those plans. For example, RTOs must be given the authority to petition state and local regulators for necessary siting authorizations, including certificates of need or public necessity and environmental permits, as well as the authority to order construction of facilities sited and permitted under state regulatory authorities. The Commission should encourage state reliance on RTO-approved plans as the primary basis for the exercise of eminent domain powers under state law.

Puget notes that state condemnation powers granted to utilities are usually

limited for the benefit of the citizens of the state in which the utility operates. It is not clear that a state utility can delegate its state condemnation power to a regional RTO. Therefore, the final rule should expressly address how state condemnation authority can be legally exercised by a regional RTO.

NASUCA maintains that the RTO regional planning efforts must not displace state government siting authority. NASUCA states that the final rule should specifically recognize state statutory authority to regulate siting of transmission facilities. For other planning and expansion matters, the Commission should require RTOs to establish a process to ensure that the RTO obtains input from state government agencies with respect to the regional transmission plan. Nevada Commission states that it is imperative that the RTO coordinate transmission siting and planning with state agencies. Tri State believes that states should continue to fulfill their traditional roles in siting transmission facilities. However, it notes that it may be necessary for the states to consult with the RTO on transmission facility certification since the RTO will be charged with overall responsibility for transmission planning and will be required to work cooperatively with states and other regional groups.

CP&L supports state and local governments retaining the authority for certification and siting of new transmission facilities. These government agencies are closer to the local residents who will be affected and can best evaluate the great number of factors that must be considered in approving transmission routes.

Several commenters address the issue of eminent domain authority as a component of the transmission planning and expansion function. East Kentucky believes that the issue of eminent domain needs to be addressed for not only RTOs, but also for the entire open access transmission network. East Kentucky questions whether an entity, if required by an RTO or the Commission to construct a transmission facility, has eminent domain authority that is sufficient to allow the entity to acquire all property rights necessary to construct the required facility. Consequently, East Kentucky argues that, as a general proposition, Congress needs to grant federal eminent domain authority to any entity that is required by the Commission or any form of RTO to build a facility so that such entity can acquire private property rights under Federal law. Because it believes that siting of transmission has become the principal impediment to transmission

expansion, EPSA also advocates that the RTO should be delegated sufficient authority to direct transmission owners or others to exercise their eminent domain authority, as necessary, to implement transmission system expansion plans independent of the source of funds or the beneficiary of the project. Under current law, this authority must come from the states. Thus, EPSA also advocates the passage of Federal legislation that vests the Commission with primary jurisdiction over major transmission planning and siting decisions, perhaps subject to a requirement that the Commission consult with a regional siting authority or a consortium of affected state siting boards.

Central Maine disagrees and recommends that the Commission should reject EPSA's comments. Central Maine notes that, if a state government intends that an RTO have the power of eminent domain, the state legislature will grant it. Central Maine argues that RTOs should not be granted the power to do something indirectly that they may not do directly. Consequently, it believes that EPSA must pursue its proposal through the enactment of state legislation.

Whether Three Years Is an Appropriate Amount of Time for Implementation of This Function. Several commenters support the Commission's proposal to allow up to three years to implement the planning and expansion function.⁵⁸⁹ Some commenters, however, believe that three years is too short.⁵⁹⁰ South Carolina Authority suggests a five-year period. Florida Commission believes that it is premature to set any time limit for implementation of the planning and expansion function.

On the other hand, several commenters believe that three years is too long a period.⁵⁹¹ Most of these commenters believe that the planning and expansion is such an important function that its implementation should not be delayed at all. NYC suggests that implementation should not be delayed more than a year. SRP argues that the uncertainty that currently exists about who ultimately will be responsible for building and paying for new transmission facilities is causing delays in upgrades. According to SRP, requiring the RTO to perform this function upon commercial operation will eliminate this uncertainty.

Industrial Customers also argues that any delay should not be used as an excuse to stall the construction of any facility for which the need has been established. SRP suggests that, if a delay in implementation is permitted, the RTO should be required to identify the entity responsible for financing and building transmission expansion prior to the RTO assuming such responsibility.

Commission Conclusion. We reaffirm the NOPR proposal that the RTO must have ultimate responsibility for both transmission planning and expansion within its region that will enable it to provide efficient, reliable and non-discriminatory service and coordinate such efforts with the appropriate state authorities. In carrying out this overall responsibility, the Commission has concluded that the NOPR's three separate requirements for RTO planning and expansion must also be satisfied or, in the alternative, the RTO must demonstrate that an alternative proposal is consistent with or superior to these three requirements. Specifically, an RTO must satisfy the requirement to: (1) Encourage market-motivated operating and investment actions for preventing and relieving congestion; (2) accommodate efforts by state regulatory commissions to create multi-state agreements to review and approve new transmission facilities, coordinated with programs of existing Regional Transmission Groups (RTGs) where necessary; and (3) file a plan with the Commission with specified milestones that will ensure that it meets the overall planning and expansion requirement no later than three years after initial operation, if the RTO is unable to satisfy this requirement when it commences operation.

As noted above, the RTO should have ultimate responsibility for both transmission planning and expansion within its region. The rationale for this requirement is that a single entity must coordinate these actions to ensure a least cost outcome that maintains or improves existing reliability levels. In the absence of a single entity performing these functions, there is a danger that separate transmission investments will work at cross-purposes and possibly even hurt reliability. We also recognize that the RTO's implementation of this general standard requires addressing many specific design questions, including who decides which projects should be built and how the costs and benefits of the project should be allocated.⁵⁹² As with other requirements of the Final Rule, we propose to give

RTOs considerable flexibility in designing a planning and expansion process that works best for its region. It is both inevitable and desirable that the specific features of this process "should take account of and accommodate existing institutions and physical characteristics of the region."⁵⁹³ We emphasize that, as the transmission provider in the region, the RTO is required to provide service under a tariff that is consistent with or superior to the Commission's *pro forma* tariff, and that tariff obligates the transmission provider to expand and modify its system to provide the services requested under the *pro forma* tariff.⁵⁹⁴ Because an RTO may not own all of the facilities it operates, we clarify that nothing in this Rule relieves any public utility of its existing obligation under the *pro forma* transmission tariff to expand or upgrade its transmission system upon request. Accordingly, we shall evaluate each RTO proposal to ensure that the RTO can direct or arrange for the construction of expansion projects that are needed to ensure reliable transmission services.⁵⁹⁵ However, the Commission reiterates, as discussed below, its strong preference for market-motivated operating and investment actions.

We further note that the pricing mechanisms and actions used by the RTO as part of its transmission planning and expansion program should be compatible with the pricing signals for shorter-term solutions to transmission constraints (*i.e.*, congestion management) so that market participants can choose the least-cost response. Otherwise, their choices may reflect less efficient outcomes for the marketplace. For example, if the price of expansion overstates its cost (or the price of congestion management understates actual congestion cost), market participants likely will continue congestion management solutions to a transmission constraint when

⁵⁸⁹ *Id.* at 33,752.

⁵⁹⁴ *See, e.g.*, Section 15.4 of the *pro forma* tariff which requires the transmission provider to use due diligence to expand or modify its transmission system to provide requested services. Also, Section 28.2 of the *pro forma* tariff requires the transmission provider to plan, construct, operate and maintain its transmission system in order to provide network service, and to endeavor to construct and place into service sufficient transmission capacity to deliver network resources to network customers on a basis comparable to its own use of the transmission system.

⁵⁹⁵ We note that existing ISOs have addressed similar issues successfully. For example, the PJM ISO is responsible for expansion planning, but the transmission owners remain obligated to undertake upgrades necessitated by the plan. 81 FERC ¶ 61,257 at 62,275 (1997).

⁵⁸⁹ *See, e.g.*, Tri State, SoCal Edison and PNM.

⁵⁹⁰ *See, e.g.*, NECPUC, Duke and South Carolina Authority.

⁵⁹¹ *See, e.g.*, Champion, NYC, Turlock, SRP, TDU Systems and Industrial Customers.

⁵⁹² FERC Stats. and Regs. ¶ 32,541 at 33,751-52.

expanding the system to relieve congestion is more efficient.

Market-Motivated Actions. Planning new generation or new transmission requires a coordinated approach to ensure reliability and efficient congestion management. However, this does not necessarily imply that all transmission expansions must be centrally planned by the RTO. Where feasible, an RTO should encourage market approaches to relieving congestion. A market approach will require providing all transmission customers with access to well-defined transmission rights and efficient price signals that show the consequences of their transmission usage decision. If the RTO's market approach is successful, the decisions of where, when and how to relieve congestion will be driven by economic considerations.

Most commenters agree with the NOPR proposal that RTOs should rely upon market signals and market solutions in assessing all feasible options (e.g., construction of new generation, redispatch of existing generation, as well as expansion of the transmission grid) to assure that the least costly option is pursued. If an RTO can facilitate market-motivated decisions, several commenters point out that its planning role may largely be limited to extreme circumstances where continuing congestion in an area threatens reliability. However, we also recognize that different market approaches to relieving congestion are still in the early stages of development. Similarly, while market approaches to expansion are the subject of much discussion, they are also in the early stages of development.⁵⁹⁶ It is not the intent of the Commission either to mandate a market approach to the exclusion of an executive decision by the RTO or to mandate any particular market approach.

Nevertheless, if any market-driven approach is to be successful, there must be accurate price signals that reflect the costs of congestion and expansion costs. As we stated in the NOPR, accurate

price signals are the link between current usage and future expansion. Therefore, as discussed in more detail in Section III.E.2 Congestion Management, every RTO must establish a system of congestion management that establishes clear rights to transmission facilities and provides market participants with price signals that reflect congestion and expansion costs. In implementing its planning and expansion responsibility, an RTO must ensure that its decisions are not unduly discriminatory and produce efficient outcomes.

The Commission reaffirms its statement in the NOPR that independent governance of the RTO is a necessary condition for nondiscriminatory and efficient planning and expansion. While accurate price signals can signal the need for expansion, such expansion may not be achieved if an RTO operates under a faulty governance system (e.g., a governance system that allows market participants to block expansions that will harm their commercial interests).

Multi-State Agreements and RTGs. The final rule fully recognizes the statutory authority of the states to regulate siting of transmission facilities. Currently, state and local governments and regulatory agencies have exclusive authority over the siting process. Therefore, an RTO's planning and expansion process must be designed to be consistent with these state and local responsibilities.

RTOs must accommodate efforts by state regulatory commissions to create multi-state agreements to review and approve new transmission facilities. The Commission encourages the development of multi-state agreements or compacts to review and approve new transmission facilities. This would expedite transmission construction and eliminate duplicative (and possibly conflicting) reviews by multiple states. To facilitate any voluntary actions taken by our state colleagues, we will require that the RTO planning and coordination system must be able to accommodate the possible emergence of new regional regulatory systems.

Existing RTGs have clear and prominent roles in transmission expansion decisions in which planning for transmission improvements are coordinated through collaborative processes. To avoid duplicative efforts, the RTO process must build on existing RTG planning processes. Over time, since the RTO will have ultimate responsibility for planning the entire transmission system within its region, we expect that the functions of an RTG will be assumed by an RTO to avoid unnecessary duplication of effort.

Three-Year Implementation. If the RTO is unable to satisfy the planning and expansion function when it commences operation, it must file a plan with the Commission with specified milestones that will ensure that it meets this requirement no later than three years after initial operation. Recognizing that the planning and expansion function may require coordination among multiple parties and regulatory jurisdictions, we do not require this function to be in place at the initial operation of the RTO. We continue to believe that three years is a reasonable deadline for creating an operational planning and expansion system. Therefore, we will not extend this deadline or the requirement to file a plan with the Commission with an implementation timetable. This time period could be affected by the RTO's scope, the number of states and market participants, and implementation costs; however, the urgent needs of the electricity markets make us disinclined to extend these deadlines.

However, the delay should not stall the construction of new or enhanced facilities for which needs have been established, unless the RTO makes a positive decision that the facility is not in the best interests of the region. Delaying transmission expansion could result in significant market inefficiencies as well as unacceptable risks to reliability given the long regulatory and construction lead times required to build new facilities.

8. Interregional Coordination (Function 8)

In Order No. 888, the Commission identified eleven principles it would use to assess Independent System Operator (ISO) proposals submitted to the Commission.⁵⁹⁷ One of these principles required that the ISO develop mechanisms to coordinate with neighboring control areas to ensure reliability and the provision of transmission services that cross system boundaries. The RTO NOPR encouraged transmission entities to consider ways to reduce impediments to transactions among themselves,⁵⁹⁸ but a coordination requirement was not included explicitly in the RTO NOPR. Several commenters pointed out that there was no explicit coordination requirement proposed in the RTO NOPR and recommended including a function for RTOs similar to the coordination principle in Order No. 888.

⁵⁹⁷ Order No. 888, FERC Stats. and Regs. ¶ 31,036 at 31,730-32.

⁵⁹⁸ FERC Stats. and Regs. ¶ 32,541 at 33,758.

⁵⁹⁶ For example, TDU Systems and other commenters suggest that, by promoting competition for new construction, the RTO can minimize construction cost and also reduce its own risk profile. For example, an ISO in Victoria, Australia (VPX), which operates, but does not own transmission assets, uses competitive bidding for new transmission facilities. At the Regional ISO Conference in Richmond, Virginia on June 8, 1998, Raymond Cox described how VPX's strategy resulted in a number of bidders competing for the right to build, own and operate new facilities. He concluded that the "result of this competition was a lower price to the consumers of Victoria than would have resulted from regulated transmission service by the largest incumbent provider." Transcript at 86, Docket PL98-5-006.

Comments. Several commenters identify coordination with other regions as a necessary element that should be added more explicitly to the RTO functions.⁵⁹⁹ These commenters express this need as either required to ensure reliability or necessary for bulk power markets to operate over sufficiently large areas. For example, NERC states that the need for such coordination effort has increased as the management of short-term reliability of the interconnected bulk power system and the operation of increasingly competitive bulk power markets have become inseparable. Accordingly, NERC recommends that an additional function be added to the final rule that requires RTOs to integrate their market interface practices and reliability practices. It identifies OASIS standards, information sharing with neighboring RTOs, ancillary services requirements, parallel path flows, transmission loading relief, and interregional congestion management, as practices and standards that need to be integrated.

Duquesne states that efficiencies can be realized from coordinating and developing a seamless marketplace. It recommends that the Commission require RTOs to coordinate and plan for seamless and uniform transmission rules, scheduling systems and procedures, and reliability standards. In addition, Oneok suggests that the Commission encourage neighboring RTOs to form reliability compacts under which loop flow and other issues involving interregional reliability impacts can be resolved.⁶⁰⁰ Also, Wyoming Commission believes that the Commission should be flexible with respect to inter-RTO interaction and that it may be appropriate to address these issues later rather than in initial RTO filings.

Commission Conclusion.

Coordination of activities among regions is a significant element in maintaining a reliable bulk transmission system and for the development of competitive markets. In the NOPR, we discussed several region-to-region coordination activities in connection with the parallel path, congestion management, and expansion planning functions. However, the comments persuade us to add a more general interregional coordination requirement as one of the minimum RTO functions.

⁵⁹⁹ Many parties supported this requirement including NERC, Justice Department, NARUC, NASUCA, Oneok, PJM, Duquesne and Industrial Consumers.

⁶⁰⁰ ISO-NE, NY ISO and PJM recently signed a memorandum of understanding concerning interregional coordination activities.

We will require an RTO to develop mechanisms to coordinate its activities with other regions whether or not an RTO yet exists in these other regions.⁶⁰¹ If it is not possible to set forth the coordination mechanisms at the time an RTO application is filed, the RTO applicant must propose reporting requirements, including a schedule, for itself to provide follow-up details as to how it is meeting the coordination requirements of this function. We expect the RTO to work closely with other regions to address interregional problems and problems at the "seams" between the RTOs. Therefore, as recommended by NERC and others, we will add the following regulatory text to our RTO Final Rule functions:

(8) *Interregional Coordination:* The Regional Transmission Organization must ensure the integration of reliability practices within an interconnection and market interface practices among regions.

An RTO proposal must explain how the RTO will ensure the integration of reliability and market interface practices. An RTO may ensure the integration of these practices either by developing integration practices itself or by cooperating in the development of integrated practices with an independent entity that covers all regions or, for reliability practices, covers an entire interconnection. The term, interconnection,⁶⁰² refers here to any one of three large U.S. transmission systems. The Eastern Interconnection covers most of the area east of the Rocky Mountains in the United States and Canada. The Western Interconnection covers an area that is mostly west of the Rocky Mountains in the United States and Canada, as well as a small portion of Mexico. The Electric Reliability Council of Texas (ERCOT) Interconnection covers much of Texas.

This provision does not mean that all RTOs necessarily must have a uniform practice, but that RTO reliability and market interface practices must be compatible with each other, especially at the "seams." RTOs must coordinate their practices with neighboring regions to ensure that market activity is not limited because of different regional practices.

⁶⁰¹ This is similar to the existing ISO Principle #10 in Order No. 888 for single control area ISOs: "An ISO should develop mechanisms to coordinate with neighboring control areas."

⁶⁰² "Interconnection" is a term used by the North American Electric Reliability Council and others to refer to an interconnected alternating current transmission system. Engineering considerations require all generators connected to any one interconnection to operate in a coordinated manner, that is, synchronously.

We understand, as NERC pointed out in its comments, that the reliability and market interface practices are becoming highly interrelated. The reliability practices affect how markets interface with each other, and the market interface practices affect reliability. For example, TLR and congestion management are both used to unload an overloaded transmission interface, and these two practices must work together. We consider congestion management and TLR are best used as sequential steps to unload a line, with congestion management used first to unload a line in a market-oriented manner, and TLR used to unload a line in a fair manner when either congestion management is unavailable or an emergency condition requires immediate action. We therefore list below TLR as a reliability practice and congestion management as a market interface practice, understanding that these and other practices listed affect both reliability and markets.

The integration of reliability practices involves procedures for coordination of reliability practices and sharing of reliability data among regions in an interconnection, including procedures that address parallel path flows, ancillary service standards, transmission loading relief procedures, among other reliability-related coordination requirements in this Final Rule.

The integration of market interface practices involves developing some level of standardization of inter-regional market standards and practices, including the coordination and sharing of data necessary for calculation of TTC and ATC, transmission reservation practices, scheduling practices, and congestion management procedures, as well as other market coordination requirements covered elsewhere in this Final Rule.

F. Open Architecture

In the NOPR, the Commission stated its commitment to a policy of "open architecture" and proposed to require that RTOs be designed so that they can evolve over time. The Commission noted that there should be no provision in any RTO proposal that precludes the RTO and its members from improving their organization to meet market needs.⁶⁰³ The Commission sought comments regarding the open architecture policy in general and the flexibility needs of RTOs in particular.

Comments. Virtually all commenters support the NOPR's open architecture concept and recommend that an RTO have the ability to evolve over time as

⁶⁰³ FERC Stats. and Regs. ¶ 32,541 at 33,753.

it gains operating experience.⁶⁰⁴ They endorse the principle of flexibility to accommodate the changing needs of the market.⁶⁰⁵ WEPCO notes that open architecture should permit flexibility and urges the Commission not to require an RTO to be the only control area operator in the region.⁶⁰⁶ Ontario Power states that the open architecture policy should enable RTOs to accommodate Canadian entities in the future. Oglethorpe observes that open architecture policy would allow RTOs to utilize existing infrastructure and avoid high transition costs.

However, Central Maine and Southern Company argue that the flexibility implied by open architecture should not be used *carte blanche*. For example, there should be limits to an RTO's evolution process because transmission owners have some fundamental rights, such as: (1) The right to terminate their participation in the RTO; (2) the right to switch to another RTO; (3) the right to merge RTOs; (4) the right to recover their costs and a return on investment; and (5) the right to protect their assets and employees from damages and injuries.

LG&E states that the flexibility inherent in the open architecture concept should be applied fairly to all market participants, including those transmission owners that have already committed to existing or proposed ISOs. For example, a member of an existing ISO should be allowed to move to another RTO.

Industrial Consumers perceives a potential downside to the open architecture policy in that it may give existing IOUs a license to continue their opportunistic behavior rather than facilitating true market transformation. Therefore, Industrial Consumers argues that it supports the notion of flexibility inherent in the open architecture policy only in the absence of market power. Illinois Commission argues that the pace of evolutionary improvement of RTOs should not remain in the hands of vertically integrated utilities because their interest in structural change may

not be consistent with the public interest.

Cinergy, EPSA and Georgia Transmission state that the flexibility implied by open architecture should not be used to support deviations from minimum characteristics and functions. However, CP&L believes that the proposed minimum characteristics and functions are too stringent and do not allow for much flexibility that a changing market needs.⁶⁰⁷ Georgia Transmission supports the Commission's commitment to providing regulatory flexibility to allow RTOs to evolve.

Many commenters state that the open architecture concept is so broad that it will prevent stakeholders from developing meaningful RTO proposals. To bring some certainty to the negotiating parties to an RTO proposal, CP&L recommends that the Commission find that some necessary and reasonable limitations on modifications to RTOs are permissible, and these can be overridden only by unanimous consent or a supermajority vote.⁶⁰⁸ MidAmerican states that the Commission should accept RTO proposals that contain stated limitations, such as a transmission owner's right to withdraw from an RTO. MidAmerican argues that such limitations are consistent with the Commission's open architecture policy and would prevent transmission owners from being discouraged to join RTOs. To promote certainty, Entergy notes that the Commission should establish a general policy of grandfathering previously approved RTOs and not altering their requirements except in extraordinary circumstances.⁶⁰⁹

Southern Company is concerned that RTOs could evolve in ways that are undesirable to the participants that initiated its formation. Therefore, it argues that the parties should have some assurance that certain key provisions of an RTO would not change in the name of RTO evolution. For example, functions, boundaries, transmission rate design, and allocation of transmission revenues should not be amended by the RTO except by vote of the transmission owners, at least for the duration of a specified transition period. Southern

Company contends that the transmission owners will then know what they are "getting into" when they join an RTO.

Many commenters recommend that the Commission should not mandate the ultimate organizational form of the RTO given the electric industry's current state of structural flux and the uncertainty of the future. These commenters argue that the Commission's open architecture policy should encourage market participants to develop transmission institutions that are effective in meeting the needs of the marketplace. FirstEnergy and NU state that there is a range of organizational and functional forms—power pool (tight and loose); gridco, transco, marketco—which can accomplish the Commission's goal of improving the efficiency of the transmission grid, and only time and market forces should determine which form is best suited for a specific region of the country. Southern Company believes that there should be no requirement that would prohibit an RTO with no transmission ownership to transform into one that owns transmission (*i.e.*, change from an ISO to a transco).

PJM urges the Commission to clarify that RTOs can propose improvements to the RTO independently of its members to meet changing market needs. PSE&G is opposed to giving such authority to RTOs because it believes that the market participants rather than RTOs should drive changes in the structure and operation of electric markets.⁶¹⁰ Cal ISO recommends that the Commission's open architecture policy should support the creation of a structure that facilitates the addition of new participants, both within and outside of the existing RTO boundaries. Illinois Commission urges the Commission to modify the proposed paragraph 35.34(k) of proposed regulations to include an affirmative expectation that RTOs *will* change to meet new competitive market needs and to improve over time.

Commission Conclusion. As proposed in the NOPR, we adopt the principle of open architecture in order that the RTO and its members have the flexibility to improve their organizations in the future in terms of structure, geographic scope, market support and operations to meet market needs. We will require that the RTO design have the ability to evolve over time. In addition, we will provide flexibility to allow RTOs to propose changes to their enabling agreements to meet changing market, organization and policy needs.

⁶⁰⁴ See, e.g., APX, Arizona Commission, Cal ISO, Central Maine, Consumers Energy, CP&L, Connecticut, Desert STAR, DOE, Duke, Entergy, EPSA, FirstEnergy, Florida Commission, Georgia Transmission, Illinois Commission, Industrial Consumers, LG&E, NERC, NPCC, NSP, NU, NY ISO, Oglethorpe, PJM, Seattle, Southern Company, SMUD, SRP, TDU Systems, TEP, Tri-State and WEPCO.

⁶⁰⁵ NSP states that the configuration of electric markets will be much different five or ten years from now.

⁶⁰⁶ WEPCO notes that costs savings associated with creating large, efficient electricity markets will dwarf the savings attained by reducing the number of operators through control area consolidation.

⁶⁰⁷ CP&L and Southern Company state that the Commission should establish basic RTO guidelines through a policy statement rather than by a rule. They contend that the rules under the NOPR are too prescriptive, and will stifle the development of new RTOs.

⁶⁰⁸ CP&L notes that participants in Midwest ISO identified certain conditions that could be altered only by the transmission owners, including revenue distribution, pricing methodology and withdrawal rights.

⁶⁰⁹ Entergy at 42.

⁶¹⁰ PSE&G Reply Comments at 6-7.

Open architecture will permit RTOs to evolve in several ways, as long as proposed changes continue to satisfy RTO minimum characteristics and functions. As a first example, open architecture will allow basic changes in the organizational form of the RTO to reflect changes in facility ownership and revised corporate strategies. As noted by Southern Company, an RTO that initially does not own any transmission facilities might acquire ownership of some or all of those facilities. With an open architecture design, the RTO's enabling agreements should anticipate and facilitate changes of this nature.

Second, open architecture design accommodates change in the geographical scope of RTOs. Electric markets are evolving quickly and future market trading patterns cannot be foreseen at the time of RTO organization. An open architecture design will enable an RTO to grow geographically and possibly merge with another RTO as changes in markets suggest a realignment of organizations to meet evolving market needs.

Third, market support is another area that benefits from open architecture design. For example, an RTO may not initially operate a PX to support a regional spot market, but later determine that the establishment of a PX would provide additional benefit in its region. With open architecture, the RTO can propose to add a PX function (or a PX monitoring function) to its design. Open architecture design ensures that such future developments that are beneficial to the marketplace are not foreclosed.

Fourth, open architecture design accommodates changing operational needs. Most commenters agree that, as RTOs gain operating experience, some changes will become necessary. Cal ISO acknowledges that it had to make significant changes to its tariff and operational practices as it gained operating experience, and it believes further modifications are likely to be identified as additional experience is gained regarding evolving competitive markets.

Finally, as noted in the NOPR, technological change make changes in RTO design inevitable and desirable. Accommodating that change will require flexibility and adaptability in the RTO organization; open architecture will permit design modification to keep pace with technology.

Some commenters argue that the flexibility implied by open architecture design should not be interpreted to mean unfettered ability on the part of the RTO to modify its structure or

processes. We agree. Although under our open architecture policy the RTO will have the ability to propose whatever changes it believes are appropriate to meet the evolving needs of the RTO and the region, any such proposals or changes to existing agreements, which will be changes to the RTO's jurisdictional rate schedule(s) and contracts, will be subject to Commission review and approval under the FPA. The Commission will consider the merits of any changes to an approved RTO on a case-by-case basis. Interested parties will have the opportunity to comment on any such proposal. This process will enable all parties and the Commission to guard against proposed changes that are likely to stifle competition.

G. Transmission Ratemaking Policy for RTOs

We have concluded that the success of the Commission's efforts to have effective and efficient RTOs is dependent in large measure on the feasibility and vitality of the stand-alone transmission business. For that reason, and to promote economic efficiency, the RTO transmission ratemaking policies of the Commission are an important factor of RTO success. In light of the restructuring of markets and market institutions that is taking place, we now believe that it will be helpful to inform the industry about what we consider to be appropriate and inappropriate transmission pricing practices for RTOs, and about a framework for RTOs to propose efficient and fair pricing reform. Accordingly, we provide guidance below on a number of fundamental ratemaking issues.

We believe that it is critically important for RTOs to develop ratemaking practices that: eliminate regional rate pancaking; manage congestion; internalize parallel path flows; deal effectively and fairly with transmission owning utilities that choose not to participate in RTOs; and provide incentives for transmission owning utilities to efficiently operate and invest in their systems. In particular, the Commission encourages RTOs to develop and propose innovative ratemaking practices, particularly with respect to efficiency incentives. We therefore devote a significant portion of the discussion in this section of the Final Rule to performance-based regulation (PBR) and other RTO transmission ratemaking reforms.

In addition to the guidance offered here, we have added regulatory text (section 35.34(e)) with regard to PBR and other RTO transmission ratemaking

reforms,⁶¹¹ which now identifies a select list of innovative transmission rate treatments. The Commission will consider such innovative rate treatments for entities that file proposals under the new section 35.34 and that meet the minimum characteristics and functions required in the Final Rule. The Applicant must explain how the proposed rate treatment would help achieve the goals of RTOs, including efficient use of and investment in the transmission system and reliability benefits to consumers; provide a cost-benefit analysis, including rate impacts; and explain why the proposed rate treatment is appropriate for the RTO proposed by the Applicant. This means that filings under section 35.34(e) must be complete and fully explained; must demonstrate that the resulting rates are just, reasonable, and not unduly discriminatory or preferential; must identify how the rate treatment promotes efficiency and what benefits result; and must demonstrate that the rate treatment does not impede the RTO from meeting the minimum characteristics and functions required under this Final Rule. The Commission encourages properly developed transmission pricing proposals from RTOs that comply with the guidance set forth below and the amended regulatory text.

We agree with those commenters that urge the Commission to reform its transmission pricing policies to reflect new realities of the industry. For example, a number of commenters point to the unbundling requirements of Order Nos. 888 and 889, the vertical de-integration of generation and transmission for some utilities, the advent of wholesale and retail competition in energy markets, entry into markets of a range of new players, including independent generators and marketers, and other developments as a signal that the Commission's traditional cost-of-service ratemaking practices for transmission assets should be reevaluated. Some commenters suggest that the advent of competitive power markets necessitates a more robust transmission network as well as enhanced operating capabilities of the network, compared to the previous era of vertically integrated utilities providing service in monopoly franchise areas. They argue that the Commission's traditional transmission ratemaking practices are unlikely to support such a robust transmission network and enhanced operating capabilities.

⁶¹¹ We have adopted and expanded the regulatory text proposed by Edison Electric Institute in its comments (see EEL, Appendix E).

To put our concerns about transmission pricing in perspective, the NOPR said that "the Commission expects RTOs to reform transmission pricing, and in return we propose to allow RTOs greater flexibility in designing pricing proposals."⁶¹² The NOPR also said that our willingness to provide flexibility in reviewing pricing proposals dates back to the Transmission Pricing Policy Statement, issued by the Commission in 1994. In the Policy Statement, we identified five principles that transmission pricing proposals should conform to, including the principle that pricing proposals should meet the traditional revenue requirement. In order that this principle not undermine innovative pricing proposals, the Policy Statement noted that non-conforming pricing proposals would be considered, but that such proposals would have to satisfy additional factors, *i.e.*, promote competitive markets and produce greater overall consumer benefits. In the five years since the Policy Statement was issued, we have approved five ISOs with innovative transmission pricing, but otherwise have received few innovative transmission pricing proposals. We believe that, as a general matter, sensible pricing reform that could promote competition and efficiency in other contexts will achieve maximum benefits only when applied on a regional, rather than a single-system basis. This is true because of the inability of single systems to capture such efficiencies, but sensible pricing reform is one of the efficiencies that will likely flow from RTOs. And while we do not think the Policy Statement has been an impediment to transmission pricing innovation, we now believe, based on the myriad comments we received, that the Commission should now provide greater specificity on appropriate transmission pricing reforms by RTOs.

The rationale for providing greater specificity on transmission pricing for RTOs and amending the regulatory text at this time is three-fold. First, we recognize that transmission pricing issues are some of the most complex issues facing the industry. Second, a potential barrier to the development of RTOs, at least RTOs that span multiple transmission systems, is the difficulty that stakeholders have had reaching consensus on transmission pricing. This is not surprising, given that transmission pricing reform to accommodate regional needs and usage patterns can affect what customers pay for transmission service and how

transmission revenues are allocated among multiple owners of transmission within a region. Third, we are concerned that as we move to greater reliance on market forces, the incentives that market participants have to make efficient operating and investment decisions for both generation and transmission facilities are based in part on the price signals that flow from transmission pricing. That is, transmission pricing is a key determinant of the efficient operation of energy, ancillary service and balancing markets, and congestion management.

At the outset, we want to make clear that, contrary to the apprehensions of some commenters, the Commission is not proposing to "bribe" transmission-owning utilities to join an RTO. Rather, the Commission stated in the NOPR that it would consider innovative pricing proposals because we believed then, and now believe more strongly, that a reassessment of transmission pricing policy is warranted, given the fundamental changes in industry structure that have already occurred as well as those which may flow from the RTO Final Rule. In addition, as pointed out by Professor Joskow, delays in RTO formation occasion costs because of more limited competition in generation markets, and these costs may be avoided to the extent that the Commission considers transmission pricing reforms. Furthermore, as discussed below, since the costs of transmission are a small portion of total electric costs, getting transmission pricing right means that the industry will be able to capture significant net benefits from promoting competitive generation markets.

While the NOPR did not propose specific rules on transmission pricing reform, we believe it is now critical to provide further specificity to the industry. We recognize the need to establish clear and specific requirements for RTO development, provide certainty and clarity about our willingness to entertain transmission pricing reforms that are appropriate for RTOs, and assure utilities that they will not be penalized for RTO participation. To the extent consistent with ensuring that transmission rates are just, reasonable, and not unduly discriminatory, we believe transmission pricing disincentives to joining an RTO should be eliminated so that transmission-owning utilities will find RTO participation to be a dynamic business opportunity. Utilities that join RTOs should be accorded transmission pricing that reflects the financial risks of turning facilities over to an RTO and that reflects other changes in the structure of the industry. Those risks

may increase or decrease in particular instances. At the same time, we wish to make clear that the Commission is very concerned about potential impacts of market restructuring on the customers in "low-cost" states, and the Commission therefore intends to monitor the effects of RTO formation on such customers, specifically the potential for cost-shifting effects of RTO pricing proposals.

Traditional transmission pricing approaches reflect the industry structure as it existed when Order No. 888 was issued: a vertically integrated industry where transmission systems were designed primarily to meet the needs of local loads. Our primary focus, both in terms of access and pricing was comparability; that is, all transmission users should receive access under rates, terms and conditions comparable to those the transmitting utility applies to itself to serve its own customers. RTOs reflect a somewhat different approach, in which the transmission system must also be designed and operated to meet the needs of regional markets. It is not unreasonable to expect that, as the transmission system is restructured to meet these changing needs, significant pricing reform may be needed as well. Indeed, since a properly developed RTO will be designing methods to support regional congestion management and regional expansion, transmission pricing reform is inevitable.

We caution that we do not view transmission pricing reform as a program designed for the sole purpose of enhancing the revenues of transmission owners at the expense of transmission customers. Nor are we abandoning the fundamental underpinnings of our traditional transmission pricing policies, *i.e.*, that transmission prices must reflect the costs of providing the service.⁶¹³ While many aspects of transmission pricing reform are labeled incentive pricing, many are aimed at eliminating disincentives to the efficient use and expansion of regional transmission grids to support emerging competition in generating markets.

We view transmission pricing reform, not only as an important component of how stand-alone transmission companies can become viable and efficient network businesses, but also as an important means for transmission-owning utilities which maintain ownership but cede control of their transmission assets to an RTO to capture

⁶¹² FERC Stats. & Regs. ¶ 32.541 at 33.754.

⁶¹³ See, e.g., *Federal Power Commission v. Hope Natural Gas Co.*, 320 U.S. 591 (1944); *Bluefield Water Works & Improvement Co. v. Public Service Commission of West Virginia*, 262 U.S. 679 (1923).

the benefits of more efficient system operation and additional grid investment. We believe that the opportunities for pricing reform identified in this Rule should have no effect on an RTO's decision about how it will be structured. All RTOs, regardless of ownership structure, are therefore eligible to propose transmission pricing reforms that suit their strategic and economic objectives to the extent consistent with this Final Rule.

We also believe that the potential for any increase in transmission-related revenues available to transmission providers that are efficient and responsive in meeting the needs of their customers must be balanced by the potential for a decrease in profits if the transmission provider does not meet those needs. Moreover, a properly developed RTO can be expected to produce significant efficiencies, and we would expect that transmission owners, transmission customers and generation market participants will share in the economic benefits resulting from the efficient design and operation of the RTO.

As the industry begins the collaborative process of establishing RTOs, it is important that the Commission provide some certainty and specificity about the preferred types of transmission pricing reforms, and some certainty and specificity about the types of proposed transmission pricing reforms that appear more problematic. Accordingly, the remainder of this section discusses eight specific transmission ratemaking topics: pancaked rates; reciprocal waiving of access charges between RTOs; use of single system access charges; congestion pricing; service to transmission-owning utilities that do not participate in an RTO; performance-based regulation; other RTO transmission ratemaking reforms; and additional ratemaking issues.

1. Pancaked Rates

As described in the NOPR, the elimination of rate pancaking for large regions is a central goal of the Commission's RTO policy, and has been a feature of all five ISOs the Commission had approved. Rate pancaking occurs when a transmission customer is charged separate access charges for each utility service territory the customer's contract path crosses. The NOPR proposed that RTO tariffs not result in transmission customers paying multiple access charges to recover capital costs over facilities that it controls. The NOPR sought comments on the impact of the non-pancaked rate

requirement on voluntary RTO formation because of abrupt rate changes. It also sought comments on how the regional configuration may relate to these potential rate changes.

Comments. The overwhelming majority of the comments favor the proposed prohibition on pancaked rates,⁶¹⁴ although some commenters express concern over cost shifting. Some commenters, such as Minnesota Power, suggest that the cost shifting effect of non-pancaked rates would discourage voluntary RTO formation.

Some commenters suggest alternative approaches to the strict non-pancaked rate described in the NOPR. For example, WPSC advocates the use of flow-based, distance-sensitive rates as a replacement for pancaked rates. Allegheny argues that removing rate pancaking can cause disruptive shifts in rates and revenue requirements which are solved only temporarily with transitional rates. Allegheny proposes its form of locational marginal pricing method to solve this problem. NSP favors non-pancaked rates but notes that rates for the high-voltage system that differ from those for the low-voltage system may be an effective long-term rate strategy. MidAmerican recommends that the prohibition against rate pancaking be changed to allow transmission owners to charge a home-zone rate based on local cost determination and a wide-area charge outside the home area. MidAmerican argues that this approach would minimize cost shifting. The pancaked rate prohibition would change to: "promote wide-area transmission rates with due consideration to shifting of costs among transmission service providers and between state and federal delivery rates. Finally, Williams recommends that the Commission also consider other pricing methods such as those based on mileage or network usage and market-based rates, where possible, because it considers cost of service rates inefficient and unresponsive to the market.

A few commenters question an absolute prohibition against pancaked rates. AEP and Florida Power Corp. warn that a strict prohibition against pancaked rates may, at times, work against efficient solutions. There should not be a strict prohibition without regard to size or locational factors. Florida Power Corp. argues that this approach is consistent with the Commission's Transmission Pricing Policy Statement. Customers of both AEP and Florida Power Corp. dispute

⁶¹⁴ See, e.g., NASUCA, PJM, LG&E, Industrial Consumers and WEPCO.

this view.⁶¹⁵ Southern Company notes that an absolute prohibition against pancaked rates may hurt retail customers whose rates are supported by transmission revenue. Transmission owners should be assured in the final rule that they will be able to recover their full revenue requirement in the face of any pancaked rate prohibition. The Commission should, according to Southern Company, also clarify that a prohibition against pancaked rates does not prevent the use of zonal or other distance-sensitive rates. Desert STAR argues that a single region-wide rate may not be appropriate in a large region with legitimate cost differences among companies, and suggests that license plate rates may mitigate cost shifting but will not always eliminate it.

Commission Conclusion. In the NOPR, we described the elimination of rate pancaking as a central goal of our RTO policy. After receiving comments on the subject, mostly in favor of the proposed prohibition, we affirm that the RTO tariff must not result in transmission customers paying multiple access charges to recover capital costs.⁶¹⁶

Except for transactions within the ISOs now in place, transmission customers are faced with additional access charges for every utility border they cross. The distances need not be great to be assessed two, three or more access charges for a single transaction. This duplication can severely restrict the area in which generation can economically be secured. A main reason that an RTO can expand the marketplace for generation to a large region is that an RTO can implement non-pancaked rates for each transaction. A wider area served by a single rate means more generation is economically available to any customer which means greater competition for energy.

Some commenters warn that a blind adherence to non-pancaked rates can produce inefficiencies in some circumstances. Some argue that large distances and special conditions can add to transmission costs in a way not reflected in single system rates. They would leave open the option for distance-sensitive rates or completely new rate innovations that may not fit the strict definition of a non-pancaked rate. We are sensitive to some of these concerns, but we do not view a policy requiring non-pancaked rates as posing the problems that some commenters

⁶¹⁵ See New Smyrna Beach and Coalition of Alliance Users.

⁶¹⁶ Section 35.34(k)(1)(ii). However, see the discussion below regarding service to transmission-owning utilities that do not participate in an RTO.

describe. We take this opportunity to reaffirm that we will continue to be receptive to distance-sensitive rates and other rate features that can be supported.

2. Reciprocal Waiving of Access Charges Between RTOs

The elimination of pancaked rates within an RTO was intended to increase the efficiency of trade in that region. The NOPR furthered that concept by encouraging RTOs to agree among themselves to waive access charges on a reciprocal basis for transactions that cross RTO borders. If accomplished, this would have the effect of increasing effective trading areas. The NOPR sought comments on how the Commission could facilitate reciprocal waivers of access charges, and whether there are other impediments to inter-regional trade.

Comments. A majority of the commenters support the concept of a reciprocal waiver of access charges to encourage inter-regional trade.⁶¹⁷ Of those who support waivers, some, including Duke and SRP, specifically recommend that waivers be voluntary. Some supporters of waiving access charges note that it is not just the pancaked charges that inhibit inter-regional trade but also variations in business practices and procedures between RTOs. These commenters⁶¹⁸ recommend that the Commission ensure that such incompatibilities not be allowed to hamper trade between RTO regions.

Several commenters, both supporting and opposed to waiver of access charges, warn that the waivers proposed in the NOPR can cause cost shifting. Duke argues that cost shifting can be remedied by the structure of the rate. DOE and First Energy also express concerns about cost shifting. Southern Company generally opposes waivers of access charges unless transmission owners' revenues are protected.

Some commenters oppose waiving access charges between RTOs for reasons other than cost shifting concerns. South Carolina Authority claims that reciprocal agreements between RTOs waiving access charges are discriminatory and that independent monitoring groups would be needed to prevent gaming of reciprocity agreements. CP&L argues that waivers create a bias to sell outside of the RTO. Tri-State proposes the use of distance-sensitive export pricing mechanisms instead of waivers.

⁶¹⁷ See, e.g., Sithe, WPSC, Minnesota Power, Ohio Commission, and Midwest ISO Participants.

⁶¹⁸ See, e.g., Ontario Power and Oregon Office.

PP&L Companies claim that inter-regional trade solutions should be arrived at through a collaborative effort of stakeholders. NECPUC and Desert STAR argue that the Commission should grant deference to participants' solutions for inter-regional trade. Florida Commission argues that the Commission should wait until intra-regional trade barriers are dismantled before dealing with inter-regional trade.

Commission Conclusion. We asked in the NOPR for comments on the policy of allowing RTOs to reach reciprocal agreements to waive access charges for transmission that crosses an RTO border. Most commenters supported the approval of such waivers and some asked the Commission to further support inter-regional trade by requiring uniform practices and procedures among RTOs. Some commenters maintain that incompatible or varying procedures between RTOs can be as dampening to inter-regional trade as multiple rates.

We will continue to encourage reciprocal waivers of access charges between RTOs as long as they are reasonable in terms of cost recovery, cost shifting, efficiency, and discrimination. We also encourage terms and procedures that are compatible from region to region to the extent appropriate. Accordingly, we have added an RTO function to integrate reliability and market interface practices with other regions, as discussed above.

3. Uniform Access Charges

Each ISO approved by the Commission has struggled with the problem of cost shifting among the various individual transmission owners that make up the ISO. A single access rate would mean that the customers of low-cost transmission providers would see a rate increase and high-cost transmission providers would be concerned about not meeting their revenue requirements. The potential for cost shifting has been a stumbling block for several regions seeking to establish regional transmission organizations.

The Commission has allowed a flexible approach to this problem, and in each ISO approved by the Commission to date the solution has been to adopt a "license plate" rate for a transitional period of five to ten years before moving to a single uniform access charge. A license plate rate provides access to the regional transmission system at a single rate although that rate may vary based on where the customer is located.⁶¹⁹ The NOPR proposed to

⁶¹⁹ Consider that registering a car in one state, paying that state's fees, and obtaining a license

continue to employ a flexible approach, including the use of license plate rates. The NOPR requested comments on whether the license plate approach is appropriate for the long term.⁶²⁰

Comments. A clear majority of commenters favors the use of license plate rates in general, with a nearly even split between those that would allow license plate rates only for a transitional period⁶²¹ and those that would allow them as a permanent feature.⁶²² Of the approximately 64 commenters who addressed this subject, only about nine were clearly opposed to license plate rates for either the long term or for a transitional period. And several commenters advocate the use of license plate rates as a general concept but did not address directly the NOPR's question concerning their long-term use.⁶²³

Several commenters argued that the use of license plate rates should be for a transition period roughly coincident with the phase-in of retail competition. For example, Duke argues that license plate rates avoid cost-shifting, and will therefore make it easier for companies to collect their retail revenue requirements in jurisdictions without retail competition, where state regulators may disallow higher transmission rates.

Commenters that support license plate rates as a long-term solution argue that license plate rates are an aid to RTO formation.⁶²⁴ SoCal Edison claims that license plate rates avoid cost shifts, are administratively more efficient, provide a basis for efficient transmission operation, and provide incentives for system expansion. SoCal Edison favors their use in the long term.

Of those opposed to license plate rates in general, some suggest a different pricing methodology. CMUA prefers an integrated, two-part rate. The first part of the rate reflects the revenue requirement of the overall RTO (principally above 200 kV) and the second part reflects the local systems to the extent used. CMUA argues that license plate rates do not follow the rules of cost causation, do not promote needed enhancements and do not promote comparability in rates. Minnesota Power recommends a two-part rate with a demand component to

plate from that state, allows that car to be driven on the roads and highways of all other states.

⁶²⁰ FERC Stats. & Regs. ¶ 32,541 at 33,754.

⁶²¹ See, e.g., Montana Commission, Oglethorpe, Tri-State, FirstEnergy, Alliance Companies, AEP and DOE.

⁶²² See, e.g., Allegheny, Industrial Consumers, Northwest Council, APS, Desert STAR and SPP.

⁶²³ See, e.g., Kentucky Commission, Gainesville, Big Rivers, Puget and Ontario Power.

⁶²⁴ See eg., East Kentucky and PJM.

collect fixed costs and a variable component for losses. WPSC advocates the use of flow-based, distance-sensitive rates rather than license plate rates. APPA claims that license plate rates do not go far enough. A four part approach is suggested in their place: assure recovery of revenue requirement; honor existing contracts and phase in regional rates; sub-functionalize the grid by voltage; and, once trusted RTOs are in place, allow congestion rates above embedded costs and non-congestion rates below, all subject to a revenue requirement true-up. RECA recommends that zones for transmission access charges be formed based on cost and other differences, not on existing service areas. SMUD claims that Cal ISO's license plate rate encourages inefficient operation.

Some commenters provide more general reactions to the cost shifting problem. Wyoming Commission recommends that the Commission not codify a specific approach to license plate rates and other measures with cost-shifting ramifications but rather defer to regional and state processes to establish guidelines within a region. PSNM is concerned about the impact of the loss of existing contracts on its license plate rate calculation. Manitoba Board is concerned about shifting costs to low-cost, transmission-dependent areas. Platte River does not want its low costs averaged with higher cost systems. United Illuminating encourages the Commission to continue its flexibility in permitting different approaches in the recovery of sunk costs. Aluminum Companies argues that the Commission needs to offer more guidance on cost shifting and that rate increases due to cost shifting should be constrained to the benefits involved. Further, cost shifts should not be allowed unless competition is fostered.

Commission Conclusion. We conclude that the Commission should continue to provide flexibility with respect to RTO proposals for allocation of fixed transmission cost recovery. The Commission will permit RTO proposals to use license plate rates, as defined above, for several reasons. First, commenters overwhelmingly support the use of license plate rates, and demonstrated convincingly that problems associated with cost-shifting are not easily resolved by means other than the use of license plate rates. Second, the Commission is concerned that the potential for cost-shifting could act as an impediment to RTO formation, thereby denying all stakeholders the benefits that come from RTO membership.

Moreover, although license plate rates are not necessarily an ideal method for fixed cost recovery, we note that all ISOs have sought approval from the Commission for license plate rates, at least during their startup phase. No commenter has provided convincing evidence that the use of license plate rates by existing ISOs produces significant harms, although several commenters suggest various rate designs, including multi-part rates, as alternatives to license plate rates.

Although commenters overwhelmingly support the use of license plate rates, they are split on whether such rates should be used only for a transitional period, or whether the Commission should allow them as a permanent feature. This is a difficult issue. On the one hand, we are reluctant to require RTOs to suspend use of license plate rates after some arbitrary date certain at which time they will be required to transition to single system access rates; on the other hand, we are reluctant to announce generically that license plate rates may be a permanent feature of an RTO. Furthermore, the use of license plate rates could depend on idiosyncratic facts, e.g., the geographic makeup of the RTO, or the transmission cost differences in various subregions of the RTO.

We therefore believe that it is appropriate to allow RTOs to propose the use of license plate rates for a fixed term of the RTO's choosing. However, RTOs that propose the use of license plate rates must make clear how transmission expansion will be priced, that is, whether license plate rates or some other mechanism will be applied to the cost of new transmission facilities, and how such pricing affects incentives for efficient expansion. In addition, we will require that before the end of the fixed term, the RTO must complete an evaluation of fixed cost recovery policies based on the factual situation of the particular RTO, and file with the Commission its recommendations on any changes that should be instituted. We emphasize that we are not requiring that the RTO continue or abandon the use of license plate rates at that time, but we will require the RTO to justify its choice to continue or discontinue using license plate rates, or otherwise change the method for fixed cost recovery. We believe that this approach provides participants in RTOs significant flexibility, and is consistent with the principles articulated in the open architecture requirement for RTOs.

4. Congestion Pricing

Congestion pricing and congestion management are closely related. Comments on these issues have been treated jointly, and are summarized above in the discussion of congestion management.

Commission Conclusion. With respect to congestion pricing, the Commission emphasized that it intends to be flexible in reviewing pricing innovations, and sought comments on what specific requirements, if any, best suited the Commission's RTO goals. A number of commenters agreed with the Commission's conclusion in the NOPR that "markets that are based on locational marginal pricing and financial rights for transmission provide a sound framework for efficient congestion management."⁶²⁵

We reemphasize the basic principles for congestion pricing articulated in the NOPR, i.e., that proposals should "ensure that the generators that are dispatched in the presence of transmission constraints must be those that can serve system loads at least cost, and limited transmission capacity should be used by market participants that value that use most highly."⁶²⁶

We recognize that congestion pricing, especially when complex problems associated with parallel path flows are addressed, is in its infancy. Rather than prescribe a specific method, we encourage experimentation with reasonable congestion management techniques. We would expect that such experiments be consistent with the open architecture requirements of the rule, and that information from such experiments be made widely available to all interested parties, so that other RTOs can learn from each others' experience.

5. Service to Transmission-Owning Utilities That Do Not Participate in an RTO

The Commission asked commenters to discuss the treatment by an RTO of a non-participating transmission owner in a region if the transmission owner does not participate in its region's RTO.⁶²⁷ For example, we asked whether it would be appropriate to allow RTO members to provide transmission service at individual system rates to non-participating transmission owners located in the RTO region thereby denying non-participants the benefits of non-pancaked transmission rates.

Comments. Of those commenters that generally support the proposed strategy,

⁶²⁵ FERC Stats. and Regs. ¶ 32,541 at 33,742.

⁶²⁶ *Id.* at 33,754-55.

⁶²⁷ *Id.* at 33,759.

most argue that non-participants should not enjoy the benefits of non-pancaked rates.⁶²⁸ PG&E submits that the reasoning the Commission applied in Order No. 888 applies here (*i.e.*, in Order No. 888, the Commission rejected the claim that a reciprocity requirement required explicit Commission jurisdiction over the transmission customer finding that, as a matter of fairness, a public utility providing open access through a non-discriminatory tariff deserved the right to obtain comparable access over the transmission systems of its customers). Empire District is particularly concerned that utilities on the border of an RTO may receive many advantages of the RTO without accepting any of the burdens of participation, yet at the same time make it more difficult for competitors to service its load by staying out of the RTO.

Other commenters are conditional in their support. For example, Oneok wants the Commission to draw a hard line on non-participation and be willing to employ negative incentives; however, Oneok points out that denial of non-pancaked rates will be more costly to marketers and consumers. South Carolina Authority suggests that the Commission consider the extent to which the transmission owner is actually able to participate in an RTO before permitting denial of RTO service under non-pancaked rates. In the case of publicly owned utilities, there may be restrictions in the enabling act or charter, the applicable state constitution or the utility's bond covenant that effectively prohibit it from participating in a particular RTO. This would also apply if the RTO is not the product of the "region's RTO" involving all stakeholders in the designated region but is a business entity designed to advance the financial objectives of particular sponsors. Similarly, SPRA argues that, in the event that it is unable to immediately join an RTO, the RTO should recognize that SPRA has an OATT that provides for comparable treatment to the RTO. And New Smyrna Beach states that, although denial of non-pancaked rates to nonparticipants has merit, it may be a moot issue in Florida where FP&L's transmission is so extensive that pancaked rates would be a more costly alternative for marketers and consumers of electricity.

Other commenters believe the proposal is a flawed concept or otherwise oppose it. Avista and PPC argue that it is not appropriate to allow an RTO to provide transmission service

at individual system rates to non-participating transmission owners as such a policy would deny them the benefits of non-pancaked rates and defeat the central goal of its proposal. Metropolitan concurs that non-participating transmission owners should share in the benefits of non-pancaked rates. Southern Company and CP&L claim that the Commission cannot punish utilities that find it in the best interests of their stakeholders not to join an RTO. SMUD believes that RTOs must provide nondiscriminatory access to transmission it controls at cost-based rates to all customers, since they contribute to the RTO's cost recovery. SMUD argues that the Commission, through its NOPR has, in essence, found that pancaked rates are not just and reasonable and that they should be corrected; thus, the Commission cannot allow an RTO to charge pancaked rates in violation of the FPA section 205 prohibition on unjust or unreasonable rates.

Snomish, Turlock, Big Rivers and Dairyland all make similar arguments—charging higher pancaked rates to utilities that do not participate in the RTO is patently unfair, violates the Commission's duty to eliminate discriminatory rates, and would penalize consumers of customer-owned utilities who have no practicable choice about whether to participate in the RTO. Dairyland says that this could open the door to creation of RTOs that purposely do not accommodate non-public utilities. SRP posits that imposition of pancaked rates on non-participants in an RTO would effectively turn the Commission's stated policy goal of voluntary participation into an RTO mandate inviting years of litigation.

Two state commissions question the effectiveness of pancaked rate sanctions against non-participants. Indiana Commission contends that a recalcitrant utility may not perceive pancaked rates as detrimental and may not feel compelled to join an RTO. Illinois Commission feels that imposition of penalties involving restricted access to RTO transmission rates would either be self-defeating for the Commission or detrimental to the electricity consumers of the affected utility. In its view, the solution to this conundrum is for the Commission to abandon its unworkable voluntary approach to RTO participation, and utilize its authority under FPA sections 205 and 206 and examine its authority under FPA sections 202(a), 211 and 212 to mandate participation. However, Nevada Commission submits that the Commission must ensure that a transmission-owning utility that refuses

to join an RTO should not be allowed to derive any economic benefit from the existence of RTOs.

ISO commenters have diverse views on this issue. Desert STAR argues that a blanket ban on prohibiting a party that does not join an RTO from deriving any benefit from the RTO whatsoever may be too broad an approach. NYPP, citing *Associated Gas Distributors v. FERC*⁶²⁹ and *Richmond Power & Light v. FERC*⁶³⁰ for the proposition that the Commission cannot achieve indirectly what it cannot do directly, submit that the Commission cannot impose any coercive measure on or deny benefits to utilities that do not participate in an RTO. In addition, NY ISO argues that previously approved ISO's transmission-owning members should be eligible for whatever RTO participation incentives and benefits are ultimately adopted in this proceeding. On the other hand, PJM/NEPOOL Customers support denial of non-pancaked transmission rates to nonparticipants.

Canadian entities generally oppose imposition of pancaked rates against non-participants. Canada DNR contends that a decision not to participate in an international RTO by a Canadian jurisdiction should not place entities in that jurisdiction engaged in trade with the U.S. at a disadvantage relative to U.S. RTO participants. BC Hydro concurs that the decision to join an RTO should not be made a prerequisite for participation of Canadian provincial utilities or their affiliates to participate in the U.S. electricity market. CEA observes, however, that Canadian utilities see access to the U.S. market as a significant business opportunity that requires a transparent and open bulk transmission system operating in both directions. Grand Council *et al.* submits, however, that applying no penalties or incentives to Canadian utilities, while giving them unfettered access to U.S. markets without being subject to corresponding obligations, is inconsistent with the RTO concept. And H.Q. Energy Services submits that, if the Commission decides not to require RTO participation, it should strongly encourage voluntary participation by denying certain benefits such as the use of the system-wide tariff to nonparticipants.

Commission Conclusion. Regarding the question raised in the NOPR about whether a non-participating transmission owner in an RTO region should receive all the benefits of the RTO in its region, we share the concerns

⁶²⁹ 824 F.2d 981, 1024 (D.C. Cir. 1987).

⁶³⁰ 574 F.2d 610, 620 (D.C. Cir. 1978).

⁶²⁸ Montana-Dakota, Allegheny, PG&E, Tri-State, PNGC and Empire District.

of most commenters that transmitting utilities may receive the benefits of an RTO in its region without accepting any of the burdens of participation in the RTO. Accordingly, where a transmission customer of an RTO or the customer's affiliate owns, controls or operates transmission in the RTO's region, and is not participating in that particular RTO, we intend to permit that RTO to propose rates, terms, and conditions of transmission service that recognize the participatory status of the customer.

We do not intend that every such proposal will necessarily be accepted by the Commission. Each RTO must justify any proposal on a case-by-case basis. The proposal should recognize the various situations of non-participating transmission owners. As pointed out by commenters, some transmission owners may face legal obstacles to participation that may need to be taken into account in the proposal.

It is not our intent to permit an RTO to apply such a proposal to a non-participating transmission owner in another region. As discussed above, Empire District expressed concern about whether this provision would apply to a non-participating owner "on the border" of an RTO. We would permit an RTO to argue that the non-participant should be part of its RTO region based on engineering or other objective criteria.

An RTO will provide several benefits for parties in the region, including elimination of individual system rates. We asked in the NOPR whether it would "be appropriate to allow RTO members to provide transmission service at individual system rates to non-participating transmission owners located in the RTO region." (emphasis added)⁶³¹ SMUD argues that the Commission in its NOPR has found, in effect, that individual system rates are not just and reasonable and so cannot allow transmission-owning utilities in an RTO to charge individual system rates.

SMUD is incorrect. We have not made a generic determination that individual system rates are not just and reasonable in an RTO region. A non-participating public utility transmission owner in an RTO region may itself file a single company rate and argue that it is just and reasonable for use by its neighbors who join the RTO.

Instead of making a generic determination about these matters, we will permit an RTO and its transmission-owning public utility members to make the case that it is just and reasonable to charge individual

system rates to a transmission customer who is a non-participating transmission owner in its RTO region. We will decide each RTO proposal on its merits.

6. Performance-Based Rate Regulation

The NOPR suggested that, once RTOs are formed, performance based regulation (PBR) can facilitate good grid operation.⁶³² We noted that PBR can incorporate price/revenue caps, price incentives, or performance standards. The NOPR sought comments on how PBR should be applied to an RTO and whether it should be voluntary.

Comments. The vast majority of commenters favor PBR of some form to promote efficient operations by RTOs.⁶³³ And most commenters that favor PBR specifically state that PBR should be voluntary for RTO participants.⁶³⁴

Professor Joskow recommends that the Commission promote the view that PBR will eventually be required. He suggests that there is sufficient experience with PBR, such as in England and Wales. He argues that PBR should be based on a standard price cap that focuses not only on direct transmission service costs, but also focuses on the cost of congestion management, losses, ancillary services, reactive power, and connection of new generators. EEL notes that a price cap, based on a reasonable ROE revenue requirement, is the most widely used method. EEL argues that price caps reduce rate cases, give an incentive to improve productivity, and share productivity savings with customers. Brattle Group does not propose a specific PBR scheme but says that, at this point, approval should be case-by-case. Care should be taken that a PBR is not based on a single element, causing distortions elsewhere.

Other supporters have specific comments regarding the implementation of PBR. Entergy recommends that the Commission provide more specific guidance on the use of PBR. DOE warns that PBR should not be allowed to prevent a PMA that is a part of an RTO to under-recover its revenue requirement. New Smyrna Beach and Oneok only support PBR if there is a downside as well as an upside potential associated with transmission performance. Allegheny states that the Commission must settle on a definition of performance, the performance

criterion should be economic reliability, the owner must have an opportunity to recover investment, the Commission should recognize that some aspects of performance will be outside of the control of the RTO, and the particular PBR rate calculation should be considered on a case-by-case basis.

A number of commenters recommend that PBR not be instituted immediately upon the formation of the RTO. California Board, Trans-Elect, and WPSC maintain that time is needed to establish base year benchmarks. PG&E and APPA say that PBR should be set aside until the RTO is up and functioning and Arkansas Consumers and Wyoming Commission argue that the RTO should first demonstrate that it can and will provide reliable and non-discriminatory service before PBR is established.

At least eight commenters were opposed to PBR for RTOs as a Commission policy. Industrial Consumers, Williams, and CMUA do not think that PBR can be effective in promoting efficiency in the operation of RTOs. Salomon Smith Barney and East Texas Cooperatives believe that RTOs will be able to game the system and take advantage of PBR. PJM/NEPOOL Customers, Lincoln, and NASUCA argue that PBR should not be allowed for RTOs because they are unnecessary. NASUCA is also skeptical of PBR for RTOs because some areas where performance is important are not under the RTO's control. NJBUS argues that PBR will not put a stop to transmission discrimination.

NEPCO *et al.* disagree with those commenters who oppose PBR.⁶³⁵ PBR is effective, as shown in the United Kingdom, and they are not "bribes" given freely to transmission owners. Enron/APX/Coral Power does not agree with NASUCA and California Board that there is not enough experience on which to base PBR. According to Enron/APX/Coral Power, there is a large amount of experience in regulating transmission plus a lot of experience with the ramifications of EPAct.

A few additional commenters neither strongly support nor oppose PBR, but offer specific comments about PBR use. Project Groups recommends that the Commission construct a way to decouple revenues from transmission rates so that efficient transmission service rather than total throughput determines revenue. Florida Commission states that questions as to the advisability and particulars of a PBR mechanism should be left to regional solutions that have the endorsement of the state regulatory

⁶³² *Id.*, at 33,755.

⁶³³ See, e.g., EPSA, PJM, Los Angeles, Georgia Transmission, Illinois Commission, Pacific Corp and Desert STAR.

⁶³⁴ See, e.g., Florida Power Corp., MidAmerican, Tri-State, FirstEnergy, Alliance Companies, Duke and PGE.

⁶³⁵ See, e.g., APPA, Minnesota Power and CMUA.

⁶³¹ FERC Stats. & Regs. ¶ 32,541 at 33,759.

bodies. Big Rivers states that PBR is inappropriate for cooperatives and public power utilities. WEPCO believes that RTOs should be not-for-profit and that PBR should be available only to the for-profit transmission owner. Metropolitan is concerned that PBR might cause RTOs to neglect needed expansions and upgrades and jeopardize reliability.

Commission Conclusion. At the outset, we think it is important to emphasize that PBR is far from a new concept. Over the last 10 to 20 years, a significant amount of research, primarily by economists, has been done regarding the conceptual basis of, and efficient designs for, PBR.⁶³⁶ This research addresses its use in the electric utility industry as well as other regulated industries. It is also important to note that the Commission has been receptive to PBR proposals, at least since issuance of the Policy Statement on Incentive Regulation in October 1992. In that Policy Statement, we provided guidance to public utilities as well as natural gas and oil pipelines considering proposing some form of PBR.⁶³⁷ Although the Policy Statement invited public utilities to develop and file incentive regulation proposals, the Commission has not received any proposals from public utilities.⁶³⁸

The Commission's current interest in PBR stems from the proposition that PBR will allow the Commission to rely on market-like forces, to the maximum extent possible, to create incentives for RTOs to efficiently operate and invest in the transmission system. This does not mean that we expect that transmission services will be provided in competitive

markets any time soon, or at all. We recognize that transmission service will retain most or perhaps all of the characteristics of a natural monopoly for the foreseeable future, and that some type of explicit price regulation will therefore be required to prevent monopoly abuse. But we believe that PBR, especially if accompanied by explicit and well-designed incentives, may provide significant benefits over traditional forms of cost-of-service regulation. We believe this view of PBR is entirely consistent with other initiatives taken by the Commission, such as Order Nos. 888 and 889, to promote competitive power markets, and given the impracticality of competitive transmission markets, to rely on market-like forces to the maximum extent possible.

Before providing further specificity on PBR, it is useful to restate the overarching concerns of commenters. A large number of commenters support the use of PBR, and many of them, as discussed above, believe that PBR and other forms of incentive regulation will significantly enhance the incentives RTOs have to make efficient operating and investment decisions. For example, Professor Joskow notes:

It is very important for the Commission to adopt regulatory mechanisms that provide transmission owners and operators with powerful economic incentives to operate transmission networks efficiently and to invest the resources necessary to expand their capabilities efficiently. These incentives should be an integral component of a performance-based regulatory (PBR) framework for the regulation of transmission rates that rewards transmission owners for achieving these objectives and penalizes them for failing to do so.⁶³⁹

On the other hand, a somewhat smaller group of commenters, mostly transmission customers, oppose the use of PBR. They express doubts about whether PBR will provide good incentives for RTOs to operate and invest efficiently. They are also concerned that PBR design is so difficult that RTOs will easily game the system, which will likely result in higher revenues for RTOs and therefore higher prices for transmission services for all transmission customers.

Commenters describe a wide array of PBR mechanisms, including some relatively unsophisticated proposals and others which are analytically complex. For example, a number of commenters have proposed that the Commission entertain transmission rate moratoriums, e.g., where transmission rates are locked into their current levels

for a limited period of years. To the extent the transmission provider can achieve any transmission costs savings, these would be retained by the transmission provider. In this sense, it falls within the concept of PBR.

It is argued that this rate treatment may promote the establishment of independent transmission companies because it provides the certain revenue stream that is needed to obtain financing for the purchase of transmission systems from existing owners. It is also argued that this approach is analogous to a hold harmless commitment for existing customers which may simplify the efforts of those state regulators who value transmission rate certainty during their conversion to retail choice. This approach would also reduce litigation at the Commission during the moratorium.

Finally, if the rate level selected takes into account the existing transmission component of bundled retail power rates, it addresses the concern expressed by many that one deterrent to participation in RTOs is the fear and uncertainty that transferring retail transmission services from state to Commission jurisdiction leads to reduced revenues.

Other commenters suggest that the essence of PBR is to set cost and performance benchmarks and then reward or penalize an RTO based on performance relative to those targets. Clearly, such an approach presents significant analytical challenges. Ideally, an RTO's cost and operating performance can be compared with other, similar entities. One benefit of setting such targets is that it overcomes the asymmetric information problem, i.e., a transmission service provider will usually have better knowledge of the potential efficiency gains than will regulators. Benchmarking performance helps reduce the information imbalance.⁶⁴⁰

We have carefully considered all of the comments about PBR. We conclude that the Commission should encourage RTOs to consider use of PBR, although we recognize the difficult analytical challenges that RTOs will face. To facilitate such consideration, we are providing additional specificity on PBR. We address several threshold procedural issues, and articulate additional design principles that should provide a framework for RTO consideration of PBR.

⁶⁴⁰ We note that there have been some early attempts to compare the relative cost and performance of ISOs in the U.S. See, e.g., California ISO, "A Comparative Analysis of Operating ISOs in the United States" (Oct. 15, 1998).

⁶³⁶ See, e.g., Paul Joskow and Richard Schmalensee, Incentive Regulation for Electric Utilities, *Yale Journal of Regulation*, Vol. 4 at 1-49 (1986); Sanford Berg and Rajiv Sharma, Techniques for Assessing Firm Efficiency, University of Florida Public Utilities Research Center Working Paper (June 1999); Peter Navarro, Seven Basic Rules for the PBR Regulator, *Electricity Journal* at 24-30 (April 1996); G. Alan Connes, Steven Stoft, et al., Six Useful Observations for Designers of PBR Plans, *Electricity Journal* at 16-23 (April 1996); Lorenzo Brown and Ingo Vogelsang, Incentive Regulation: a Research Report, Federal Energy Regulatory Commission, Office of Economic Policy, Technical Report 89-3 (1989); and Jean-Jacques Laffont and Jean Tirole, A Theory of Incentives in Procurement and Regulation, MIT Press (1993).

⁶³⁷ The Policy Statement articulated five regulatory standards: (1) incentive ratemaking must be prospective; (2) participation must be voluntary; (3) incentive mechanisms must be understood by all parties; (4) benefits to consumers must be quantifiable; and (5) quality of service must be maintained.

⁶³⁸ We note that PBR mechanisms have been widely used by state regulators and the FCC as applied to the U.S. telecommunications industry. See, e.g., John Kwoka, Implementing Price Caps in Telecommunications, *Journal of Policy Analysis and Management*, Vol. 12, No. 4 at 726-52 (1993).

⁶³⁹ Professor Joskow at ES-iv.

A first threshold issue is whether the Commission should require that RTOs use PBR or whether it should be voluntary. There is almost no support for making PBR mandatory, and we therefore will not require RTO filings to include PBR proposals, although we encourage such proposals.

A second threshold issue is what types of RTOs are eligible for PBR. As discussed above, some commenters argue that PBR is not appropriate for cooperatively-owned and publicly-owned transmission owning utilities. Similarly, other commenters argue that PBR is appropriate only for profit-making RTOs. We conclude that, although the application of PBR may vary according to the type of RTO, there is no reason to limit the applicability of PBR to certain members or types of RTOs. The Commission welcomes RTO filings with PBR proposals from any source. For example, in the context of an ISO or a tiered ISO/transco that has been described by some commenters, the activities that contribute to performance may be shared between the RTO and the transmission owners. This does not invalidate the use of PBRs; however, the RTO design would simply ensure that the rewards and penalties associated with activities performed by transmission owners flow through to the owners to achieve the desired result.⁶⁴¹ In addition, we see no impediment to the use of PBR to provide incentives for efficient behavior by non-profit RTOs. We note that some existing ISOs have in place performance incentives for some of their managers, and such an incentive scheme may have application for RTOs which do not own the transmission assets they control.

A third threshold issue is how PBR proposals will be formulated and when they will be filed. The Commission recognizes that PBR design involves highly complicated issues, and that there is the possibility that a bad PBR proposal can result in lower quality transmission service, at higher costs, compared with service that might prevail under traditional ratemaking practices. One key element in the process of designing a PBR proposal would be to ensure adequate input from all stakeholders. We believe that the best PBR designs will emerge when all stakeholders have an opportunity for input, even if a filed PBR design does not represent full consensus. We

therefore conclude that RTOs that wish to implement PBR need not necessarily file the PBR proposal at the time the RTO makes its compliance filing if more time is needed to negotiate among stakeholders the details of a well-designed PBR. Some commenters suggest that an additional consideration in allowing delayed filings of PBR is the need to evaluate operating experience of the RTO before appropriate benchmark measures for PBR can be developed.

The Commission also believes it is appropriate to provide additional specificity on what constitutes good PBR design. We continue to endorse the regulatory standards included in the Incentive Regulation Policy Statement, described above. And we note that in some regions, certain types of PBR mechanisms may be better suited than others. For example, where there are already state-imposed rate moratoriums, continuation of such programs after RTO formation may be an appropriate PBR approach. Alternatively, a transmission rate moratorium based on the existing rate level may be appropriate for a transitional period during RTO formation.⁶⁴² Similarly, in an area that has experience with a particular performance-based mechanism, extension and perhaps refinement of such a program after RTO formation may be the most appropriate policy.

We encourage RTOs to file fully documented PBR proposals that are consistent with the amended regulatory text. PBR proposals should include a detailed explanation of how the PBR mechanism will work, as well as all of the information necessary for the Commission and all market participants to evaluate the benefits and costs of implementing the PBR mechanism.

Based on the comments we received in this docket, as well as our understanding of international⁶⁴³ and state experience with incentive regulation, we expand on the considerations for PBR addressed in the amended regulatory text by offering the following additional principles for

RTOs to consider in designing PBR proposals.

PBR should not be applied piecemeal. To the extent possible, PBR programs should focus on the entire operation of the RTO, rather than smaller parts of the operation. Commenters caution that PBR programs that focus narrowly, e.g., only on the cost aspects of RTO operations, may result in inattention by the RTO to the quality of service offered. Similarly, a focus on only one aspect of costs, e.g., short-run costs, may result in reduced costs for that single aspect, but higher total costs for the RTO.

PBR should encompass both rewards and penalties. Although some PBR designs employ either rewards or penalties, but not both, most commenters suggest, and the Commission agrees, that the most effective and most fair designs will likely encompass both. One rationale for this is that it is not always clear what incentives an RTO will respond to, and therefore the prospect of higher revenues as well as the threat of lower revenues may induce an RTO to provide the best possible performance. An additional rationale is that under the FPA, the Commission is required to set rates for transmission service at just and reasonable levels. To the extent that rates may vary within a range—both up and down—as a function of RTO performance, this statutory requirement may be better satisfied.

PBR rewards and penalties should create incentives for an RTO to make efficient operating and investment decisions, and should not compromise system reliability. A significant concern in any PBR application is the possibility that incentives will distort RTO decisionmaking. For example, commenters caution that an RTO may manage congestion through a combination of generation redispatch and investment in transmission infrastructure, and that poorly designed PBR mechanisms could distort RTO decisionmaking toward the most profitable, rather than the least-cost, solution, or toward an approach that inappropriately reduces system reliability. An additional concern is that PBR mechanisms may create bias with respect to the trade-off between investment in generation and transmission, or in siting generation and transmission facilities in the most efficient places on the grid.

The benefits of PBR should be shared between the RTO and its customers. The Commission believes that as a matter of fairness, the efficiency gains occasioned by PBR should be shared. This will involve difficult analytical issues, including identifying efficiency gains,

⁶⁴² As noted *infra*, this is one of the pricing reforms that will be available for a defined transition period during which RTOs are being established.

⁶⁴³ We note that a PBR system that uses a variant of price cap regulation of the National Grid Company has been in use for nine years in England and Wales. More recently, the price cap has been combined with a separate incentive mechanism that focused on reducing congestion on the grid. Since this is the longest-running PBR targeted to grid operations, we encourage any RTO that intends to propose PBR to examine the strengths and weaknesses of the British approach.

⁶⁴¹ For example, PJM states that it can facilitate the application of PBRs to its transmission owners by using the stakeholder process to set the performance parameters and, once the parameters are in place, to independently evaluate the transmission owners' performance and apply the PBR.

measuring them, and determining the effect of sharing such gains on the strength of the incentives faced by the RTO. The Commission does not believe it would be appropriate to specify the exact distribution of such gains, as such a decision is better left to negotiation by all stakeholders.

To the extent possible, the rewards and penalties should be prescribed in advance based on known and measurable benchmarks. PBR designs involve an inevitable trade-off between simplicity and administrative ease on the one hand, and the potential benefits of the program. Although relatively simple designs such as rate freezes provide significant incentives for an RTO to reduce its costs, they produce relatively limited incentives to maintain reliability, promote service quality, or manage congestion. PBR mechanisms that benchmark an RTO's performance, either to its own historical performance, to industry performance indices, to some normative goal, or to a combination of these, may be designed to provide incentives for more efficient operation and investment decisionmaking. The Commission recognizes that designing sophisticated PBR mechanisms will be a significant challenge for RTOs already grappling with other development issues. The Commission, therefore, will make its staff available through our pre-filing process to work with RTOs to help identify and resolve issues on an informal basis prior to their filing a PBR proposal.⁶⁴⁴

7. Other RTO Transmission Ratemaking Reforms

The Commission proposed in the NOPR to consider innovative pricing proposals for transmission owners who turn over control of their transmission facilities to an RTO.⁶⁴⁵ The types of pricing that the Commission proposed to consider include: a higher ROE on transmission plant; allowing the transmission owner to retain the benefits of cost saving attributable to RTO formation; acceleration of transmission cost recovery in rates; non-traditional valuation of transmission assets such as an estimate of replacement costs for assets purchased at higher than net original cost; and liberalized allowance of levelized or non-levelized rate methods. The Commission proposed that transmission owners meet all of the requirements to

become an RTO before an innovative pricing proposal is accepted.⁶⁴⁶

Comments. A large number of commenters addressed the Commission's proposals to consider transmission pricing reforms for RTOs. About 30 commenters expressed support, and about 30 commenters expressed opposition. There were also a number of comments which did not explicitly support or oppose this aspect of the NOPR.

*Supporting Innovative Pricing.*⁶⁴⁷ Of the commenters that support innovative pricing, a common theme is that if RTO formation is to be voluntary, incentives are required to encourage participation.⁶⁴⁸ For example, Justice Department recommends that the positive and negative incentives be designed to secure universal compliance rather than have some utilities not participate because the advantage of continuing outside of the RTO is greater than the incentive to join. EEI supports incentives since RTO formation will probably not generate increased earnings for transmission owners since most of the efficiencies will be a benefit to others. EEI suggests that an application for RTO formation and incentives should include some assessment of the benefits from which the incentives are generated but a precise calculation of benefits should not be required because of the extreme difficulty in making such an estimate. PacifiCorp is in favor of incentives but is concerned that a "case by case" consideration of incentives may jeopardize their realization because customers will call for lower transmission rates in the short term once the RTO has been formed. PacifiCorp argues that a more detailed uniform policy on incentives "up front" is preferred.

On the other hand, several commenters suggest that the Commission should consider incentives only on a case-by-case basis. Desert STAR says that different RTOs may need different sets of incentives as will public power transmission owners. MidAmerican supports case-by-case consideration of incentives to join an RTO, and favors a higher ROE reflecting the fact that transmission is not limited to selling to a captive customer base in

a bundled context but is serving a wholesale marketplace at greater risk. Duke is in favor of incentives for transmission expansion, but cautions that incentives should not bias investment and other decisions, should be considered on a case-by-case basis, and may not be very effective where operation is separated from ownership. Oregon Office is in favor of incentives for meeting all of the RTO characteristics and functions faster than the industry average, but not for average speed in accomplishing RTO formation.

A number of commenters favor offering incentives to public utilities that are already members of an ISO as well as to provide incentives for public utilities to join an RTO. For example, PJM says that incentive rates should be offered to new and existing RTO members to reflect the benefits generated and to prevent inefficient consequences such as transmission owners moving from an existing ISO to a new RTO to receive incentive rates. PSE&G favors a correspondingly higher ROE and faster depreciation of transmission assets for transmission owners who participate in RTOs, including those who have already joined an existing organization. LG&E says that incentive plans can be useful in promoting RTO participation and that existing members of RTOs should be allowed to propose incentive rates as well. LG&E stresses that it is just as important not to enact policies on rates that might jeopardize revenue requirement recovery and thus act as a disincentive. An additional consideration is offered by PP&L Companies which argues that existing participants in RTOs should be allowed the same incentive rates as those which are just forming because the benefits of an existing RTO are greater than those of a start-up RTO not yet in operation.

The proposed incentive addressed most frequently by commenters is allowing a higher rate of return on transmission assets. Georgia Transmission believes that higher ROEs as an incentive to voluntarily join an RTO is appropriate because of the benefits that participation would bring. NSP and others argue that ROE must be sufficient to attract capital and compensate utilities for the risks involved. Conectiv and EEI argue that the current rate of return policy should be modified, arguing that the DCF method gives results that are too low to provide adequate returns to transmission owners causing a reduction in building at a time when more transmission is critically needed. According to Conectiv, the DCF method should be abandoned or its application

⁶⁴⁴ Alternatively, the RTO could seek guidance in a more formal proceeding, e.g., if an RTO files a petition for a declaratory order seeking approval of its PBR proposal.

⁶⁴⁵ FERC Stats. and Regs. ¶ 32,541 at 33,755.

⁶⁴⁶ *Id.* at 33,756.

⁶⁴⁷ While we used the term incentive pricing in the NOPR, this term is an imprecise description of the various transmission pricing reforms that will be addressed in this Rule, and we now describe these pricing reforms as innovative rate proposals. However, the comments sections that follow continue to use the term incentive because the parties used this term in their comments.

⁶⁴⁸ See, e.g., Avista, TEP, Duquesne, APS, NEPCO et al., Florida Power Corp.

should be modified to account for the current industry situation and be more reflective of conditions in the general economy and reflect reasonable transmission asset lives. Cinergy, in reply comments contends that the record in this proceeding is sufficient to establish a presumption of reasonableness for higher ROEs.

SoCal Edison does not believe that pure incentives in the form of ROE "awards" are necessary for encouraging participation in RTO but it does argue that higher returns may be justified on transmission assets controlled by an RTO because the original owner no longer has control over planning and expansion decisions. In addition, distributed generation and bypass may be found to increase risk. SoCal Edison says that it is very important to prevent the move to RTO control from being a financial loss due to Commission rate setting or because of greater risk and higher costs. SoCal Edison does agree with the proposal to allow accelerated depreciation of transmission assets to encourage participation.

TXU Electric is in favor of consideration of higher ROEs for RTO participants and thinks it is more important to take a more global look at transmission ROEs in a new and uncertain industry environment where transmission investment is important. TXU Electric warns that it would be inappropriate to penalize RTO participation with reduced earning potential because unbundled transmission ROEs are lower than ROEs allowed in bundled rates. Conlon suggests that the Commission could allow a higher return on assets of a transco or ISO to serve as an incentive for IOUs to transfer ownership. Southern Company explains that there are major tax consequences to the sale of transmission assets to form a transco and recommends that the Commission find ways to accommodate such a transition. As to rate incentives, Southern Company advocates a change in the Commission's ratemaking policy in order to increase returns to be more commensurate with non-regulated businesses. Southern claims that recent court rulings support higher returns on transmission service.

A number of commenters argue that participation in an RTO increases financial risk, and that incentives are therefore required to encourage RTO participation. For example, Empire District says that turning over control of transmission assets to an RTO increases the risk because someone else will control their operation, justifying higher ROEs for participation. PSE&G argues that a stand-alone transmission

company or an RTO is more risky than an integrated electric utility where transmission was a strategic asset. FirstEnergy justifies higher ROEs by noting a number of sources of risk, including emergence of distributed generation, vulnerability of firms that are less diversified than integrated utilities, and quicker phase out of older generation plants which may result in stranding some transmission plants. Midwest ISO argues that RTO membership may cause a loss in earnings due to reduced transmission revenues, higher costs, and operational risks. United Illuminating believes that risk for transmission investment is higher for assets controlled by an RTO and that accelerated depreciation is warranted because transmission companies can no longer count on captive customers, and industry changes have the possibility to abandon transmission plant before its physical life is over. WPSC is in favor of higher ROEs for transmission owners who join RTOs but not as a pure incentive. WPSC's justification for higher ROEs would be the greater risk due to removal of pancaked rates, new generation options, loss of higher state returns, and new technologies. WPSC supports the other rate incentives as long as the benefits exceed the costs based on careful examination.

Some commenters address the broad range of proposed incentives. For example:

- Trans-Elect argues in favor of incentives to include: acquisition premiums, hypothetical capital structures, higher ROE, accelerated recovery of costs, rate moratoriums, and expedited FPA section 205 and 203 approvals. Trans-Elect would limit incentives to those that do not harm transmission customers. It notes that PBRs would allow transmission owners to share in cost savings but some operating history may be needed before they are put in place. It argues that acquisition premiums may assist in the formation of independent transcos, and suggests that if there is a rate moratorium in place, RTOs should be allowed to recover acquisition premiums after the moratorium.

- FirstEnergy advocates flow through of cost savings to owners, non-traditional valuation of assets, flexibility in the use of levelized rate methodology, retention of hourly non-firm revenues, deference to management in dispute resolution, elimination of codes of conduct where there is structural separation, and simplification of filing requirements. Some of these measures should be offered on a limited basis to RTOs not yet meeting all of the

characteristics and functions. Incentive plans should weigh costs versus benefits. Cal DWR goes further, saying that incentives should not be allowed until benefits are actually proven.

- Los Angeles recommends that the Commission consider several options for the valuation of assets transferred to an RTO in order to reflect the true value of the assets to native load customers. Selected options to explore include: an up-front acquisition premium used to moderate rates to native load customers, provide native load customers a congestion premium, or grant native load customers an exemption to congestion charges.

- NYPP is in favor of sufficient ROE to provide for expansion and accelerated depreciation to compensate for increased risks as opposed to a "bonus" type incentive to join an RTO. Its members contend that this type of incentive should be available to all transmission owners, not just the ones who meet the NOPR's characteristics and functions.

A number of commenters note that incentives are needed to facilitate efficient expansion of transmission assets.⁶⁴⁹ Transmission ISO Participants view the incentive needed to induce new transmission construction as more important than incentives to encourage RTO formation. IPCF suggests that FERC should offer transmission owners incentives to expand their networks without meeting all of the requirements of becoming an RTO in order to reverse the trend against building caused by Order No. 888. Williams says that decisions to expand transmission facilities must be made by for-profit entities, must be driven by economic considerations, and the returns allowed must be commensurate with the greater risks today. Williams cautions that returns for RTO participants certainly should not be at a rate that results in a penalty.

Opposing Innovative Pricing. Many commenters oppose the use of incentives for many different reasons. One common theme is that incentives are inappropriate because RTO participation should be mandatory.⁶⁵⁰ PJM/NEPOOL Customers argues that the Commission should mandate RTO formation because of the transmission owners' duty to operate in an efficient manner, and because transmission customers will likely pay the costs of the incentives. Ohio Commission

⁶⁴⁹ See, e.g., AEP, United Illuminating, PP&L Companies, NU, Otter Tail, NYPP, FirstEnergy, Transmission ISO Participants, Allegheny and Salomon Smith Barney.

⁶⁵⁰ PJM/NEPOOL Customers, Lincoln, TDU Systems, APPA, WEPCO.

prefers mandatory participation and questions whether the proposed incentives will be effective. If incentives are used, Ohio Commission recommends that the Commission consider evaluating which incentives will be effective, balancing incentives with disincentives, and recognize regional differences especially in arriving at a solution for the Midwest.

Another common theme is that the costs of incentives may well outweigh the benefits of RTO participation. Illinois Commission argues that if the Commission finds that there are benefits in RTO creation, they should be mandatory. According to Illinois Commission, the examples of incentives proposed in the NOPR, *i.e.*, ROE enhancement, revaluation of transmission facilities at replacement cost, accelerated depreciation, and flexibility in use of leveled cost, would consist of money transfers to transmission owners without contributing to cost control or efficiency. South Carolina Authority is opposed to incentives or disincentives to promote RTO participation unless a factual determination is made that they are absolutely necessary. Similarly, RECA is generally opposed to incentives but would recommend their consideration if savings to the public are well established. RECA finds the rate freeze proposal the least objectionable.

APPA advocates mandatory participation in RTOs and strongly objects to the use of incentives to achieve participation. It argues incentives would be ineffective because of the small proportion that Commission-regulated transmission makes up of the total utility revenue compared to the value of transmission in maximizing generation and merchant revenue. To be effective, APPA argues that the cost would be so large that it would not be offset by the benefits of the RTO. Also, APPA raises the participation issue of whether to give incentives to existing ISO members. Seattle warns against transmission owners "dumping" transmission facilities into an RTO to receive incentives when those particular facilities are of no benefit to the RTO being formed.

Some commenters argue that it is inappropriate for the Commission to provide incentives for the provision of a monopoly service. Metropolitan argues that incentives should not be offered because many of the customers who pay for the incentives are the same customers who paid for the original transmission facilities. TDU Systems argues that ROEs for transmission service in an RTO is less risky because

of the concentration of monopoly business and the lack of any regulatory gap since all transmission under an RTO will be regulated by the Commission. TDU Systems notes that transmission entities, since they are monopolies, should not earn the same return as firms in other industries. TDU Systems argues that other NOPR proposals, including rate freezes, accelerated recovery of costs and investment, and revaluation of assets, are also an inappropriate enrichment of transmission owners and are unneeded to attract investors. And TDU Systems argues that the proposal for an acquisition premium is troublesome because customers have already been paying for these assets for years. TDU Systems also suggests it will be difficult to calculate what level of incentives would be required to persuade a transmission owner to participate in an RTO and the likelihood of offering a greater incentive than is needed.

Some commenters suggest that providing incentives would violate the Commission's statutory requirement to set rates at just and reasonable levels. NRECA believes that transmission owners should not be rewarded for unjust conduct with incentives and that the Commission should rely on standard cost-of-service based rates. TAPS, which favors mandatory RTO formation, argues that incentives are unnecessary and could nullify the benefits of electric industry restructuring. TAPS argues that incentive rates, including each of the examples suggested in the NOPR, would violate FPA's requirement for just and reasonable rates because they do not reflect the cost of providing transmission service. TAPS does recommend that the Commission remedy unintended disincentives such as utilities' fear of the unknown. UAMPS also favors mandatory participation, and argues that incentives would unfairly raise transmission costs to the benefit of monopoly transmission owners. UAMPS also argues that it is not feasible to divide the benefit of RTO participation before these benefits are even known. In response to the comments of several IOUs, UAMPS argues that the claim that stand-alone transmission companies are more risky is unsubstantiated and should be heard in another proceeding. NASUCA argues that EEI and others are incorrect in saying that the DCF method does not produce reasonable results. According to NASUCA, the DCF method takes explicit account of the transmission owners' risk and the realities of the current regulatory climate.

Some commenters suggest that incentives will not necessarily increase

RTO participation, or will not necessarily produce the benefits which the NOPR describes. For example, ICUA notes that incentives cannot be relied upon to achieve participation by all necessary utilities. WPPI opposes incentives to participate in RTOs citing the RTO activity that has already taken place without incentives and the contention that the Commission should designate boundaries and require participation within one year.

Wyoming Commission does not agree that increasing the ROE will be sufficient to encourage more transmission building. According to Wyoming Commission, low building activity may be attributable to difficulty in meeting siting requirements, uncertainty related to retail access and native load, and competition for more localized generation. Wyoming Commission does not think that the Commission should rush too quickly into some innovative ratemaking before the industry has committed to making RTOs work as planned. And the Wyoming Commission suggests that a higher ROE for transmission investment may discourage a balanced consideration of options.

A number of commenters generally opposed incentives, believing that sanctions or penalties against public utilities which do not join RTOs is superior to providing incentives. NASUCA argues that mandates or disincentives for not joining at the time of merger or market-based rate requests should be used rather than incentives. Incentives would not be cost based and would therefore make rates unjust and unreasonable. As to specific incentive proposals, NASUCA says that using replacement cost for transferred assets would allow higher rates than necessary as an incentive and would charge customers for assets they have already paid for. Such incentives could set off a transmission sell-off in anticipation of an adjustment and some companies may refuse to form transcos until they were granted the same adjustment as any other company. NASUCA is opposed to accelerated depreciation of assets for similar reasons. NASUCA also states that incentive rates could harm electric competition by increasing transmission costs. And Big Rivers states that the incentives proposed in the NOPR are inappropriate for rural electric cooperatives.

Other Comments. A few commenters did not take an explicit position on the use of incentives, but made general comments on the Commission's proposals. For example:

- Cal ISO is more concerned that there not be disincentives to RTO

participation than offering incentives. In particular, Cal ISO points out the disincentive created by the Commission's annual fee policy, from which temporary relief was granted⁶⁵¹ but a permanent solution is needed.

- New Century recommends against the use of "remedial measures" to encourage participation such as the suspension of market-based rate authority, denial of merger authority, and denial of non-pancaked rate access to RTO facilities.

- Entergy says that the NOPR's statements on incentives are vague and would cause too much regulatory uncertainty. Entergy asks the Commission to provide more explicit provisions as to what incentives would be approved.

- Canada DNR is concerned that Canadian transmission owners not be placed at a disadvantage for non-participation in an RTO in terms of incentives and disincentive.

- SRP supports incentives as long as they are applied to both public power entities and investor owned companies equitably.

- Metropolitan contends that it would not receive much benefit from any incentives offered to RTOs because it is a public entity and because its asset base is so heavily depreciated. However, replacement cost methodology could be of use in mitigating cost shifts from rolling in higher costs of other utilities.

Commission Conclusion. As noted earlier, the NOPR and the comments use the term incentive pricing as a label for the transmission pricing reforms that we raised for discussion. Certainly, good pricing affects behavior. But good pricing also achieves a valuable goal, in terms of competition, system expansion, or efficient practices that benefit more than the transmission owners or the RTO. In this section we provide greater specificity with respect to certain transmission pricing mechanisms that may be appropriate for RTOs. These mechanisms were described in the NOPR or otherwise proposed by commenters, and are included in the amended regulatory text.⁶⁵² We emphasize that we do not intend this policy guidance to be interpreted as a Commission regulatory requirement for a specific transmission pricing method, nor should it be interpreted as a guarantee that the Commission will approve any particular innovative pricing proposal. We emphasize that all

innovative pricing proposals filed by RTOs must be fully and adequately supported in accordance with this Final Rule and the regulatory text. We believe that we are providing sufficient guidance for RTOs to make critical decisions with respect to transmission pricing policies. If industry participants believe that further guidance from the Commission is needed to resolve transmission pricing issues, they may request such guidance through requests for declaratory orders or further rulemakings.

As discussed earlier, transmission pricing reform is needed as a result of the rapid restructuring of the industry that is underway, particularly with respect to changes in the ownership and control of transmission assets, and changes in the transmission services being provided in competitive generating markets. As a result of these changes, and consistent with a number of commenters' arguments, we have concluded that the Commission, at a minimum, needs to mitigate various "disincentives" that may prevent transmission owners from efficiently operating their systems. Commenters cite to the potential that transmission owners will earn lower returns for providing unbundled transmission service than they earned for providing bundled service, even though risks associated with transmission ownership have increased. Commenters suggest a number of sources of increased risk. One source is the potential for bypass of transmission assets due to distributed generation and the phasing out of older generators from service. Other sources are directly related to RTO formation. For example, some commenters assert that stand-alone transmission companies (e.g., transcos) are riskier because they have a less-diversified portfolio of assets than a vertically integrated utility. Other commenters argue that participation in an RTO that is an ISO is inherently riskier, suggesting that increased risk comes from ownership of transmission assets that are ceded for purposes of operational control to another, non-affiliated entity.

Other commenters argue that a reevaluation of transmission pricing is needed because it is absolutely critical that the transmission grid support competitive generating markets, and the only way that the Commission can ensure this will happen is to pursue pricing policies that encourage it. Some commenters suggest that because the contribution of transmission to total

costs of energy is relatively small⁶⁵³ overinvestment in transmission will not significantly affect delivered electricity prices. Further, the Commission should be much more concerned about underinvestment, not overinvestment, in the transmission grid.⁶⁵⁴ Stated another way, an efficient transmission grid is a prerequisite to achieving competitive generating markets, and the potential benefits for consumers far exceed any limited overinvestment that may occur on transmission service. A related argument is that efficiency benefits of improved transmission service will be captured by producers and customers of generation, not transmission providers; therefore, greater incentives for RTOs to provide good transmission operations and efficient investments in the grid are warranted.

The NOPR sought comments on several procedural issues related to transmission pricing reform and incentives. One issue was whether these pricing reforms should be available to participants of existing ISOs, or be available only to transmission owners that join RTOs as a result of the Commission's RTO initiative. We have concluded that members of an existing ISO organization that satisfy the minimum RTO requirements in the regulatory text should be allowed to seek transmission pricing reform as newly formed RTOs, so that they can avail themselves of the same incentives for efficient operation of and investment in the transmission grid. Furthermore, we believe that the Commission's approach to evaluating innovative transmission reforms should be neutral with respect to the organizational structure of the Applicant, so that RTOs that own transmission assets as well as RTOs that do not own transmission assets would be equally eligible for such ratemaking treatments.

Another issue is whether the Commission would prescribe which transmission pricing reforms it would accept and which it would not accept, or whether the Commission would consider such proposals on a case-by-case basis. We conclude that a case-by-case evaluation of transmission pricing

⁶⁵³ For example, Salomon Smith Barney, citing to an article by Leonard Hyman notes that the direct, total costs of transmission service represents about six to seven percent of the average customer's bill, and raising transmission prices even as high as 25 percent in order to attract capital adds only two percent to the overall electric bill.

⁶⁵⁴ Professor Joskow points out that the external factors, such as licensing requirements, the need for rights of way, and NIMBY (i.e., "not in my backyard") opposition to transmission expansion already places significant constraints on overinvestment in major new transmission projects.

⁶⁵¹ PJM Interconnection L.L.C., 88 FERC ¶61,109 (1999).

⁶⁵² Note that these mechanisms are discussed below on a thematic basis, although the regulatory text lists them on an individual basis.

reform proposals is appropriate, given that such proposals are not generic in nature, and a proposal may be appropriate in some RTO circumstances but not in others. However, the Commission believes some further specificity on transmission pricing reform is warranted to provide industry participants with the Commission's evolving views, as RTOs consider the appropriateness of various reform measures.

Therefore, we provide greater specificity on three transmission pricing reform measures: (1) ROE; (2) levelized rates; and (3) accelerated depreciation and incremental pricing for new transmission investments. We note that some of these measures may be useful only as transitional devices that may be necessary to spur the prompt creation of RTOs and, therefore, we intend to offer these pricing options only for a defined period of time, as detailed later in this Final Rule. On the other hand, other pricing reforms may be useful as permanent features, and will not be limited only to the period during which RTOs are forming. Finally, while certain of these innovative pricing proposals may be more helpful to one RTO structure than another (e.g., ISO vs transco), we do not believe that any of these pricing proposals would be incompatible with any particular structure adopted by RTOs.

a. Return on Equity (ROE). More commenters focused on ROE-based proposals than any other type of transmission pricing reform. These commenters make two main points. One argument is that higher ROEs will be demanded by the market as a matter of course as the industry restructures and the risk of transmission business increases, and the Commission must allow higher ROE to reflect participation in RTOs. A second argument is that joining an RTO adds another level of risk that warrants a specific adjustment to ROE (e.g., going to the high end in the range of reasonable ROE, or a specific basis point adjustment).⁶⁵⁵

As discussed above, commenters urge the Commission to provide flexibility in allowing ROE-based programs for RTOs. Many of these commenters specifically urge the Commission to ensure that there are sufficient incentives for an RTO to make needed investments in transmission infrastructure. On the other hand, a number of commenters oppose ROE-based programs on the grounds that they constitute a "bribe"

for utilities to provide service that they are statutorily required to provide.

We believe that there are a number of issues surrounding ROE that must be addressed by the Commission. For example, we believe that allowing an RTO to propose a formula rate for determining return on equity is consistent with our view that risks and rewards for transmission owners should reflect market-like forces to the extent possible. Allowing a formula rate of return would decouple a transmission owner's earnings from its own equity valuation, and would tie it more to external standards such as industry-wide performance. Such an approach is also consistent with the benchmarking that may occur under PBR.

We also agree that the risk profile of the transmission business is changing as the industry restructures, and that it may vary as a function of the structure each transmission company elects. For example, the risk associated with owning facilities that are leased for a sum certain to another entity operating an RTO may be different from the risk associated with operating a stand-alone transco that is facing a significant expansion program. We therefore conclude that ROE-based initiatives—as well as other ratemaking reforms discussed below—may be applicable to all types of RTOs, without regard to organizational structure.

We further recognize that historical data typically used to evaluate ROEs may not be reliable since it reflects a different industry structure from the one that exists recently. And we believe that as patterns of transmission ownership and control evolve, new approaches to compensating transmission owners for different capital structure mixes may be warranted, including allowing a transmission owner to seek a return on invested capital, independent of its exact capital mix.⁶⁵⁶ As noted above, we are willing to consider moratoriums tied to the rates the transmission provider earns on transmission assets with respect to bundled retail power sales, and the moratorium option may be tied to the existing transmission rate level, or to the existing return on equity.⁶⁵⁷

Finally, we agree that the uncertainty associated with the transition of the industry, and in particular participation in RTOs, may increase risks in the short-run. Certainly, our goals have not

changed, which are to ensure that customers have access to nondiscriminatory service at just and reasonable rates, and that transmission owners have an opportunity to earn a reasonable rate of return on their investment. We recognize that in this era of rapid change, new approaches to setting ROE may be needed to implement that standard. We therefore invite RTOs to submit proposals for ROE-based programs that are in conformance with these new approaches.

We note that pricing reforms involving ROE would clearly be compatible with all types of RTO structures that involve a determination of return on equity on transmission rate base, e.g., transcos, ISOs, or tiered organizational structures.

b. Levelized Rates. A number of commenters argue that the Commission should allow RTOs to adopt levelized rates. A levelized rate is designed to recover all capital costs through a uniform, nonvarying payment over the life of the asset, just as a traditional home mortgage payment does. The Commission, has held in a number of recent proceedings that both levelized and nonlevelized rates can produce reasonable results, depending on the circumstances.⁶⁵⁸ The Commission stated in these cases that where a utility proposes to switch from a nonlevelized net plant rate design method, "[i]n supporting such a switch, a utility must prove that its proposed method is reasonable in light of its past recovery of capital costs using a different method."⁶⁵⁹

The Commission believes that levelized rates are preferable in an RTO environment because all customers, regardless of when they take service, face the same price. Also, given a depreciated investment base, levelized rates based on existing investments will be higher than non-levelized rates and will address concerns that RTO formation will decrease revenues.

The principal objection to allowing levelized rates for RTOs is that it may raise RTO transmission rates in the short-run. The Commission has been reluctant outside the RTO context to approve switches from or to levelized rates proposed by public utilities under traditional cost-of-service ratemaking because of the opportunities that switching may provide for utilities to

⁶⁵⁵ As noted *infra*, this is one of the pricing reforms that will be available only for a defined transition period during which RTOs are being established.

⁶⁵⁷ As noted *infra*, moratoriums are among the pricing reforms that will be available for a defined transition period during which RTOs are being established.

⁶⁵⁸ See, e.g., American Electric Power Service Corp., Opinion 440, 88 FERC ¶ 61,141 at 61,441-42 (1999) (AEP); Allegheny Power Service Corp., Opinion 433, 85 FERC ¶ 61,275 at 62,117 (1998); Kentucky Utilities Co., Opinion 432, 85 FERC ¶ 61,274 at 62,100-03 (1998) (KU).

⁶⁵⁹ See AEP, 88 FERC at 61,441-42.

⁶⁵⁵ Some commenters recommend abandoning the DCF method of calculating ROE entirely. We are not adopting that recommendation.

over recover transmission costs. However, consistent with our discussion above of how market restructuring may require innovation in transmission pricing, we believe that levelized rates may be appropriate in circumstances, as here, where an RTO reflects a fresh start with respect to the provision of transmission services, and potentially the customers for those services. This is especially true in cases where RTO formation occurs coincident with market restructuring, such that the transmission customers of the RTO may be significantly different than the traditional, captive customers, that formerly took transmission service. We therefore conclude that the Commission should allow increased flexibility for RTO proposals that include ratemaking practices based on levelized rates. Clearly, this pricing reform, which relates to the method used to compute the transmission revenue requirement in the first instance, is compatible with any type of RTO structure, e.g., transco, ISO, or tiered structure.

c. Accelerated Depreciation and Incremental Pricing for New Transmission Investments. While a number of commenters have suggested accelerated depreciation as a transmission pricing reform that should be considered, these arguments are premised on the possibility that transmission costs will be stranded by changes in the industry, such as bypass of portions of the transmission system. We think that these concerns are speculative at this point in the industry's restructuring. For example, we are not convinced that the problem of stranded transmission assets is anywhere near the level of concern that stranded generating assets represents.⁶⁶⁰ In any event, should certain limited transmission facilities become stranded, nothing prevents proposals to recover prudent costs under traditional ratemaking policies.

We will, however, make a distinction between accelerated depreciation for existing transmission assets, and accelerated depreciation for new transmission facilities. While we will not bar proposals of this type for existing assets, we cannot give any encouragement to them in the Final Rule. On the other hand, we believe that it is appropriate for the Commission to provide those willing to make new

transmission investments with the flexibility to propose that such assets follow non-traditional depreciation schedules. The purpose of providing such flexibility is to remove disincentives for the construction of new facilities. We think such flexibility is warranted because the fundamental nature of transmission investment may be changing with respect to the entities that will make investments in the transmission system in the future and who pays for the new transmission facilities. Furthermore, given the rapid changes in market structure and dynamics that have occurred and will likely continue, we are not certain that traditional determinations of the economic life of new transmission facilities remain appropriate.

In addition, we believe it is appropriate for the Commission to provide flexibility for pricing of new facilities, such that proposals for pricing of new facilities that combine elements of incremental prices with embedded-cost access fees will be considered. Although we are concerned that such ratemaking practices have the potential to lead to higher prices for new transmission services, and also potential to lead to overinvestment in transmission facilities, e.g., where generation redispatch could accomplish the same objective at lower cost, we believe that such practices, if carefully constructed, will create appropriate incentives for efficient investment in new transmission facilities. We also believe that this pricing reform will be attractive to all types of RTO structure, e.g., transcos, ISOs, or tiered structures. It may also be used by any RTO that chooses to rely on third parties to construct new facilities.

d. Acquisition Adjustments. A number of commenters suggest that the Commission adopt new policies for acquisition adjustments that would provide assurances to purchasers of transmission facilities that acquisition premiums would be recoverable through transmission rates. We do not adopt this suggestion in this Final Rule.⁶⁶¹

8. Additional Ratemaking Issues

A number of comments on ratemaking issues address topics not specifically enumerated in the NOPR.

⁶⁶⁰ See Order No. 888, wherein the Commission allows recovery of stranded costs (primarily generation related) only when they are unrecoverable from customers that depart the system, and only upon a definitive showing that the utility had a reasonable expectation of continuing to serve the customer after the customer's departure.

⁶⁶¹ See Minnesota Power & Light Company and Northern States Power Company, 43 FERC ¶ 61,104 at 61,342 (1988), for a discussion of the Commission's existing policies with respect to the ratemaking treatment for acquisition premiums. See also Duke Energy Moss Landing LLC, et al. 83 FERC ¶ 61,318 (1998).

Comments

- Williams, CSU, Alliance Companies and WPSC encourage the Commission to consider rate designs based on mileage or network usage.
- Great River, NCPA and IMPA raise the concern that cooperatives and public power entities need assurance that they will receive full customer credit and compensation as was explicitly stated in Order No. 888. SoCal Edison claims that full compensation will be forthcoming and will not be a problem.
- Ohio Commission recommends that a tariff for border transactions (between RTOs) be implemented that makes the market over the combined regions seamless to persuade some regional organizations to combine.
- PPC notes that IndeGO ran into a problem with developing rates for combined systems with very different levels of quality and cost, and that systems at a position of lower quality should be required to meet combined system standards at their own cost.
- Puget argues that RTO rates must provide for the collection of stranded costs.
- PSNM sees a problem with load-side generation customers who do not have to pay their fair share of total system transmission costs.
- Powerex objects to the proposal to segment companies' service areas into sub-zones for pricing purposes.
- Alliance Companies and AEP favor the flexibility in RTO rate filings that would allow companies to make proposals that reflect market forces.
- Alliant Energy is concerned that RTO structures promote workable markets and that transmission rates be permitted to include a fair accounting of RTO start-up costs.
- East Texas Cooperatives recommends that RTO pricing structures adequately compensate small transmission owners who join the RTO, creating an incentive to join and be a more equitable system.
- Georgia Transmission says that ratemaking for RUS borrowers must take into account the requirements of any RUS loans. In addition, Georgia Transmission recommends that the cost of RTO formation be allowed in RTO rates.
- Metropolitan, Cal DWR, and SoCal Cities favor the use of time-of-use pricing or off-peak rates for transmission.
- Oregon Office recommends load-based fees for transmission rather than volume based charges.
- IMEA argues that the RTO start-up and administrative costs should be

allocated to all customers including bundled native retail load. In contrast, LG&E notes that if native load is assigned RTO administrative costs there may be under recovery because of retail rate freezes.

- Industrial Customers argue that assets used for remote generation should be excluded from the RTO.

- Merrill Energy says that the incremental pricing of new transmission upgrades prevents expansion because customers are unwilling to pay.

- NERC is concerned about the recovery of costs related to reliability-related generators.

- NRECA is concerned about compensation by an RTO for low-use transmission facilities owned by cooperatives, because large transmission owners are opposed to revenue sharing. NRECA notes that if a cooperative joins an RTO, transactions for all will increase and there is more to share. Also, there should be protection for joint use agreement income.

- Project Groups says that pricing must facilitate entry and usage by efficient, environmentally benign resources. Grid access barriers to these resources need to be eliminated. NMA/WFA/CEED respond by saying that the policies that Project Group objects to are equitable overall.

- Seattle argues that hub and spoke pricing should be used and discrete inter-regional tariffs are needed.

- NWCC notes that the characteristics of wind-produced power presents problems fitting into an RTO pricing arrangement and says that wind power works best with energy-based pricing systems.

- Detroit Edison advocates a two-part pricing structure similar to that proposed by the Alliance RTO. It includes a local rate and a regional rate. To encourage participation, Detroit Edison proposes that the Commission allow RTOs to develop market-based transmission pricing methodologies.

Commission Conclusion. Commenters raise a number of important ratemaking issues that must be considered in the establishment of RTOs. We clarify that the reasonable costs of developing an RTO may be included in transmission rates. Other issues are at a level of detail and specificity that we do not believe should be resolved in this Final Rule. Therefore, these issues will be considered as they apply to individual RTO proposals on a case-by-case basis.

9. Filing Procedures for Innovative Rate Proposals

We shall evaluate all RTO proposals including any innovative rate treatment based on the applicant's demonstration

of how the proposed rate treatment would help achieve the goals of regional transmission organizations, including efficient use of and investment in the transmission system and reliability benefits. We shall also require applicants to provide a cost-benefit analysis, including rate impacts, and demonstrate that the proposed rate treatment is appropriate for the proposed RTO and that the rate proposal is just, reasonable, and not unduly discriminatory.

In addition, pricing proposals involving moratoriums and returns on equity that do not vary according to capital structure may not be included in RTO rates after January 1, 2005. Thus, if the Commission approves an RTO rate proposal involving, e.g., a rate moratorium, unless otherwise ordered, the moratorium would end on or before January 1, 2005. We are limiting these rate proposals for a defined period during the formative stage of RTOs because, while either may be appropriate as transitional rate mechanisms, they do not promote long-term efficiency through rate design. In addition, the limited duration for these rate treatments will encourage the earliest possible filings, while at the same time giving some flexibility to those filings that may be delayed.

H. Other Issues

1. Public Power and Cooperative Participation in RTOs

In the NOPR, the Commission stated its objective of encouraging all transmission owning entities including transmission owned or controlled by public power entities and cooperatives, including Federal Power Marketing Agencies (PMAs), Tennessee Valley Authority (TVA), and other state and local entities to place their transmission facilities under the control of an RTO.⁶⁶² To this end, we expressed an expectation that public power entities would fully participate in the collaborative process for forming RTOs.⁶⁶³ In addition, we noted that some public power entities filed open access tariffs with the Commission and others are participating in ISOs and other regional institutions. The Commission, however, is aware and concerned that public power entities face several difficult issues regarding RTO formation and participation.⁶⁶⁴

The first issue is the Internal Revenue Service (IRS) Code "private use" restrictions on the transmission facilities of public power entities

financed by tax-exempt bonds. We noted that IRS temporary regulations may allow facilities financed by outstanding tax-exempt bonds to be used to wheel power in accordance with Order No. 888, but that these temporary regulations may not allow the issuance of additional tax-exempt bonds for expanded transmission or permit transfer of operational control of existing transmission facilities financed by tax-exempt bonds to a for-profit transco.⁶⁶⁵ The Commission asked for comments on the extent to which IRS Code restrictions may limit the transfer of operational control or other forms of control, or ownership of public power transmission facilities to a for-profit transco or other forms of an RTO.

The Commission also requested comments on state and local charter limitations, prohibitions on participating in stock-owning entities, the current policies of various local regulatory entities that affect or impede full public power participation in RTOs and legal restrictions or other considerations regarding PMAs that prevent their participation in RTOs. We questioned whether the Commission should consider some forms of associate membership or participation and other special accommodations in order for public power entities to overcome obstacles to RTO participation.⁶⁶⁶

Comments. Most commenters support the Commission's position that a properly formed RTO should include all transmission owners, including cooperatives and public power, in a specific region.⁶⁶⁷ As EEI notes, public power participation will enhance the reliability and economic benefits of an RTO. Furthermore, some commenters argue that in some areas of the country, especially in the Northwest and Southeast, RTO formation may be impractical without public power participation.⁶⁶⁸ Virtually all commenters recognize that regulatory and legal restrictions exist that may impede public power and cooperative participation in RTOs. EEI, SERC and Metropolitan argue that the best way to

⁶⁶⁵ *Id.*

⁶⁶⁶ *See id.*

⁶⁶⁷ *See, e.g.,* Oglethorpe, Allegheny, Montana Power, CREDA, Tallahassee, Arkansas Cities, PPC, California Board, Industrial Customers, Entergy, BC Hydro, Powerex, Aluminum Companies, MEAG, Arizona Commission, Nevada Commission, East Texas Cooperatives, Lincoln, NPPD, Wyoming Commission, Georgia Transmission, WPSC, PGE, Montana Commission, SMUD, Cal ISO, MLGW, Loveland Customers, NASUCA, Duke, LG&E, CP&L, South Carolina Authority, STDUG, NCPA, PP&L Companies, Desert STAR, PG&E and EEI.

⁶⁶⁸ *See, e.g.,* EEI, Snohomish, MLGW, Loveland Customers, Montana Commission, Wyoming Commission, Aluminum Companies, Industrial Customers and Powerex.

⁶⁶² FERC Stats. and Regs. ¶ 32,541 at 33,756-57.

⁶⁶³ *Id.* at 33,757.

⁶⁶⁴ *See id.*

facilitate non-jurisdictional utility participation in RTOs is for the Commission to avoid a "one-size-fits-all approach" and to provide flexible rules in order to accommodate the unique needs of public power entities.

Section 141 of the IRS code imposes limitations on the use of non-governmental entities of public power facilities financed with tax exempt bonds. These private use limitations restrain the form and extent of participation by public power systems in RTOs. The key private use limitation that is material to RTO participation is a bar on the sale of the output of facilities financed with tax exempt debt to non-governmental entities on terms not available to the general public. Commenters note that in January 1998, the IRS issued temporary regulations relating to the application of the private use rules to public power entities that provide some relief for transmission facilities. These temporary regulations permit issuers of outstanding tax exempt bonds to offer open access transmission services and competitive access to distribution systems, and to join RTOs, provided that certain conditions are met, particularly that the facilities continue to be owned by the municipal entity. The temporary regulations, however, do not provide the same relief to issuers of new tax exempt bonds. Many commenters assert that the temporary regulations will expire in January 2001 and that these regulations are incomplete and not permanent.⁶⁶⁹ LPPC notes that the ability of issuers to continue to rely on the temporary regulations after expiration is unclear and therefore, issuers taking actions permitted under the temporary regulations risk having tainted the tax-exempt status of their bonds on the expiration of the regulations.

Commenters offer varying solutions to the "private use" restriction problem. Many commenters urge the Commission to actively attempt to influence the IRS and Congress to remove and/or mitigate the tax impediment.⁶⁷⁰ SRP also recommends that the Commission require all RTOs to demonstrate that they have made a good faith effort to reduce barriers to participation and to accommodate legal restrictions faced by potential participants. Arkansas Cities proposes a transitional grandfathering of existing tax-exempt bonds. Arkansas

Cities notes that such legislation is pending in Congress and is identified as the Bond Fairness and Protection Act (BFPA). Arkansas Cities states "that if enacted, the BFPA would clarify tax laws and regulations governing tax exempt bonds so that publicly owned utilities would be able to participate in the development of competitive electric utility markets."⁶⁷¹ Duke asserts that the leasing of transmission facilities to an RTO is a viable option. Moreover, LPPC states that public power entities have to be allowed to participate in a way that permits them to retain sufficient operational control of their transmission systems to stay within the private use limitations. In addition, LPPC, Snohomish, Arkansas Cities and East Texas Cooperatives argue that public power entities need an opt-out provision if their tax exempt status is threatened. TEP recommends that the final rule contain a template for addressing how transactions can be administered if they involve the use of tax exempt facilities. TEP proposes that (1) an RTO should operate in a manner that either preserves the tax exempt status of such facilities or provides compensation to the facilities' owner to the extent it incurs economic harm; and (2) that an RTO should develop specific rules governing the operation and administration of tax-exempted financed facilities.

NRECA details the obstacles confronting cooperatives including the requirement that in order to maintain tax exempt status under Section 501(c)(12) of the IRS Code, at least 85 percent of a cooperative's income must come from the cooperative's members. If such member-derived revenue does not equal at least 85 percent of total revenue, then a cooperative would lose its tax-exempt status. Georgia Transmission argues that there is a real risk that participation in an RTO could result in a cooperative losing its tax exempt status if the revenue received from the RTO (assuming the RTO is not a member of a cooperative) exceeds 15 percent of the cooperative's total income. The revenue received from the RTO would stem from revenue attributed to use of the cooperative's transmission facilities controlled by the RTO.

One remedy to this problem, suggested by AEPCC and Wolverine Cooperative, is to increase an RTO's compensation to the cooperative to include a gross-up of net margins to cover the income tax expense. Under this approach, the RTO would pay the cooperative the full revenue

requirement for the transmission facilities, including any other taxes. East Kentucky proposes that a conduit or a pass-through relationship between the RTO and the cooperative would satisfy the IRS restrictions and allow a cooperative to maintain its member-derived character. According to East Kentucky, the RTO would act as an agent for the cooperative by collecting the transmission revenues and holding these revenues in a trust on behalf of the cooperative. Furthermore, Georgia Transmission suggests that the Commission allow a cooperative to leave an RTO if it appears that it may lose its tax exempt status because of the level of RTO and other non-member revenue it expects to receive in a given year.

Another impediment to public power participation in RTOs is mortgage restrictions. AEPCC notes that under the terms of a typical RUS mortgage, either transfer of control of transmission assets to an RTO or a sale, unless authorized by RUS, would be an event of default. East Texas Cooperatives argues that the Commission should require all RTOs to accommodate mortgage restrictions by allowing cooperatives to retain control of their facilities until the mortgage restriction is lifted or a creditor or RUS approves the transfer. In its comments, RUS recognizes that development of RTOs may offer considerable benefits to RUS borrowers, and RUS states that it is exploring means to facilitate borrower participation consistent with the Rural Electrification Act and RUS's fiduciary duties to the U.S. Treasury and taxpayers.

According to several commenters,⁶⁷² many public power entities operate under explicit state constitutional restraints with respect to their ability to participate in the ownership of a privately-owned RTO.⁶⁷³ Further, some state constitutions include restrictions on the use of public funds.⁶⁷⁴ Several states, however, expressly authorize public power entities to join with other

⁶⁷² See, e.g., LPPC, NPRB, Snohomish, Clarksdale, MEAG and CAMU.

⁶⁷³ For example, the Nebraska Constitution provides: "No city, county, town, precinct, municipality or other sub-division of the state, shall ever become a subscriber to the capital stock, or owner of such stock, or any portion or interest therein of any * * * private corporation or association."

⁶⁷⁴ For example, the Colorado Constitution states: "Neither the state, nor any county, city, town, or township shall lend or pledge credit or faith thereof, directly or indirectly, in any manner to, or in aid of, any person, company or corporation, public or private, for any amount, or for any purpose whatever; or become responsible for any debt, contract or liability of any person, company or corporation, public or private, in or out of the state."

⁶⁶⁹ E.g., Los Angeles, SoCal Cities, LPPC, APPA, Tacoma, NCPA, SRP, TAPS, EEI, NPPD and East Texas Cooperatives.

⁶⁷⁰ See, e.g., EEI, TAPS, SRP, Georgia Transmission, Arkansas Cities, Nevada Commission, PP&L Companies, TANC, Desert STAR, NCPA, Montana-Dakota Enron/APX/Coral Power and Tallahassee.

⁶⁷¹ See Reply Comments of Arkansas Cities at 6.

public entities in the ownership and operation of electric transmission facilities.⁶⁷⁵ In addition, state and local laws impose additional restrictions on the activities and operations of public power entities that could affect the operations of any RTO in which they hold an ownership interest. For example, some laws prohibit the sale or lease of transmission facilities to a for-profit entity.⁶⁷⁶

In states in which laws allow a public utility district to sell or lease its transmission facilities to an RTO, the laws impose requirements on such sale or lease. For instance, Washington law would require the property to be offered in a competitive bidding process, and no sale could occur without voter approval.⁶⁷⁷ Furthermore, LPPC notes that state and local laws in California, Florida, Nebraska, and Texas would require the approval of the City Council, the public utility commission, the governing board, or other governmental authority before a transfer of facilities could occur. CAMU and NPPD also state that many municipals and power authorities have statutory authority to condemn property and that it is unlikely that this eminent domain authority can be delegated to an RTO.

Enron/APX/Coral Power notes that an unwillingness to participate in an RTO for commercial reasons should render non-jurisdictional transmission owners ineligible for RTO services and savings. Moreover, Duke argues that public power must take the lead in resolving these issues for themselves. Duke notes that investor-owned utilities have overcome numerous obstacles to become RTO participants. Furthermore, Enron/APX/Coral Power argues that public power and other non-jurisdictional transmission owners that elect to share in the benefits of an RTO must be held to the same characteristics and functions as jurisdictional transmission owners. Cinergy suggests that the Commission commence regional technical conferences to address legal obstacles to public power entities' participation in RTOs and to

explore possible alternatives to operational and functional integration of public power systems into RTOs.

Commenters also address issues relating specifically to PMAs. Many commenters support the expansion of the FPA to give the Commission jurisdiction over all transmission owners.⁶⁷⁸ CREDA points out that PMAs are restricted by: (1) enabling statutes; (2) congressional appropriations; (3) the inability to grant indemnification without congressional approval; (4) the sovereign immunity doctrine; and (5) their load serving responsibilities. MLGW notes that other PMA restrictions include the TVA "fence restriction," whereby, TVA's organic statute prohibits TVA from performing any transmission service that would result in the delivery of power generated by TVA outside the specified TVA service area. MLGW further notes that existing long-term contracts between TVA and its distributors are another barrier to RTO participation by PMAs. To remedy these problems, TVA and others⁶⁷⁹ argue that the Final Rule should provide enough flexibility to ensure that public power obstacles can be addressed and mitigated.

On the issue of whether the Commission should consider special accommodation, commenters disagree over whether the Commission should provide incentives to public power entities in order to make RTO membership financially attractive. EEI and APPA urge the Commission to adopt an RTO policy that makes membership attractive to public power entities in terms of efficiency and benefits.

SoCal Edison is strongly opposed to the Commission providing incentives in the form of uniform grid-wide rates or transmission credits. SoCal Edison argues that these incentives are nothing more than inequitable cost shifts to retail ratepayers. Likewise, Duke argues that public power entities should not be provided with competitive advantages in order to encourage voluntary RTO participation.

In contrast, IMPA and SoCal Cities urge the adoption of a final rule that provides proper credits or compensation for facilities contributed to an RTO, including customer-owned facilities. Furthermore, East Kentucky states that return on equity can be mitigated by allowing cooperatives to earn a rate of return similar to investor-owned

utilities. Vernon argues that the entitlement for transmission facilities contributed to the RTO grid and the appropriate level of compensation are matters that should not be determined nationally on a generic basis, but rather, should be decided in the context of each RTO. SRP supports PBRs and other incentives as long as they are applied to both public power entities and investor owned companies equitably. Metropolitan contends that it would not receive much benefit from any ROE incentives offered to RTOs because it is a public entity and because its asset base is so heavily depreciated. However, a replacement cost methodology could be of use in mitigating cost shifts for Metropolitan due to rolling in higher costs of other utilities. Oregon Office recommends that public power entities be eligible for the same incentives as offered others to the extent that the Commission regulates their rates.

A few commenters discuss issues relating to public power and the filing requirements. South Carolina Authority states that any RTO proposal should contain a detailed description of the efforts made by petitioners to accommodate the transmission facilities of publicly owned utilities. Similarly, SRP, APPA and LPPC recommend that the Commission require each RTO proposal to demonstrate: (1) how a good faith effort was made to accommodate public power participants, particularly deciding ownership structure; and (2) where public power entities are not included, why there are no reasonable terms and conditions under which the RTO could accommodate its participation. Lincoln and Cinergy essentially concur.

Commission Conclusion. We reaffirm our preliminary determination that a properly formed RTO should include all transmission owners in a specific region, including municipals, cooperatives, Federal Power Marketing Agencies (PMAs), Tennessee Valley Authority and other state and local entities. As noted by some commenters, public power and cooperative participation in RTOs will enhance the reliability and economic benefits of an RTO. Furthermore, participation by public power entities and cooperatives is vital to ensure that each RTO is appropriate in size and scope.

Virtually all commenters note that public power entities and cooperatives face numerous regulatory and legal obstacles regarding RTO participation. Commenters assert that these obstructions include: (1) IRS "private use" restrictions and the temporary regulations enacted to mitigate the "private use" restrictions; (2) the

⁶⁷⁵ For example, Washington law provides: "Any two or more [Washington] cities or public utility districts or combinations thereof may form an operating agency * * * for the purpose of acquiring, constructing, operating, and owning plants, systems and other facilities and extensions thereof, for the generation and transmission of electric energy and power."

⁶⁷⁶ Nebraska law provides that: "[T]he plant, property, or equipment of a public power district shall never * * * by outright sale, or lease, become the property or come under the control of any private person, firm, or corporation engaged in the business of generating, transmitting, or distributing electricity for profit." Nebraska Rev. Stat. § 70-646.01.

⁶⁷⁷ See LPPC at 17.

⁶⁷⁸ See, e.g., LG&E, Otter Tail, WPSC, Alabama Commission, Montana Commission, and DOE.

⁶⁷⁹ See, e.g., CAMU, CMUA, STDUG, CREDA, NY ISO, Powerex, PP&L Companies, Desert STAR, CP&L, LPPC, MEAG and Tennessee Authority.

requirement that at least 85 percent of a cooperative's income must come from the cooperative's members (IRS Code Section 501(c)(12)); (3) RUS mortgage restrictions; (4) state constitutional restraints; (5) state and local laws; and (6) specific legal restrictions applicable to PMAs. In addition, commenters offer a variety of solutions to mitigate or eliminate these obstacles to public power participation in RTO formation and operation.

We acknowledge that public power entities face several difficult issues regarding RTO participation and we appreciate the potential solutions offered by numerous commenters. At this time, however, we will not analyze each of the specific resolutions proposed by the various commenters. Instead, on an RTO-by-RTO basis, we will examine submitted proposals that provide public power and cooperatives with the flexibility to join an RTO without jeopardizing their tax or mortgage status. We note, however, that the offered solutions must be consistent with the minimum functions and characteristics outlined in the Final Rule.

We are aware that some public power entities and cooperatives have found ways to participate in existing ISOs. For example, we approved the formation of the NY ISO contingent upon a ruling of the Internal Revenue Service that the formation and operation of the NY ISO would not jeopardize the tax-exempt status of the New York Power Authority.⁶⁸⁰ Furthermore, we are encouraged by the recent efforts of the Member Systems of the New York Power Pool (NYPP) to include and accommodate the participation of Long Island Power Authority (LIPA) in the NY ISO. NYPP proposed language in their OATT that provides LIPA will not be required to provide transmission service where the provision of such service would result in the loss of its tax-exempt status for its bonds. NYPP also proposed additional scheduling protocols and procedures to ensure the continued tax-exempt status of LIPA. The Commission accepted the proposed language as described above.⁶⁸¹ We also note that there are two cooperatives Hoosier Energy Rural Electric Cooperative, Inc. and Wabash Valley Power Association that are members of the Midwest ISO.⁶⁸² We are hopeful that similar agreements between RTOs and

public power entities and cooperatives can be reached to provide flexibility and achieve broad regional RTO participation by all entities.

We expect public power entities and cooperatives to participate fully in the collaborative process for forming RTOs. During the collaborative process, the Commission hopes that the parties will explore, in detail, the impediments and various solutions to public power and cooperative participation in RTOs. As discussed below with respect to the collaborative process, we will make staff resources available to assist in facilitating communication between all entities and in designing regional solutions to full RTO formation and participation. Moreover, in all filings under this Rule, we require a description of efforts made to accommodate participation by public power entities and cooperatives in RTOs.

We recognize that there is uncertainty regarding what may happen after the IRS temporary "private use" regulations expire on January 22, 2001.

Accordingly, we intend to continue to support efforts to mitigate the "private use" and other tax restrictions. Furthermore, in its comments, RUS recognizes that the development of RTOs may offer considerable benefits to RUS borrowers. RUS states that it is exploring means to facilitate borrower participation in RTOs. The Commission welcomes the efforts of RUS to facilitate borrower participation in RTOs, and also encourages RTOs to seek ways to accommodate mortgage restrictions. It would be unfortunate if public power entities and cooperatives were not able to participate in RTOs and share in the benefits available in a regional organization because of tax rules and other government restrictions.

2. Participation by Canadian and Mexican Entities

In the NOPR, the Commission noted that currently, electricity trading regions exist across national borders and therefore, Mexican and Canadian involvement in RTO formation would be beneficial to both countries, as well as to the United States.⁶⁸³ The Commission asserted that regional institutions should include all market participants in order to provide direct access to information and the benefits of non-pancaked rates. The NOPR also proposed that in order to prevent wasteful duplication of grid facilities, reliability standards implemented by RTOs must be acceptable to the affected

nations.⁶⁸⁴ The Commission also emphasized that Canadian and Mexican authorities would be responsible for approving prices and other terms and conditions of transmission service provided over any RTO transmission facilities located in their country.⁶⁸⁵

Comments. The U.S. entities that submitted comments on this issue support the efforts by the Commission to encourage participation in RTOs by Canadian and Mexican entities.⁶⁸⁶ For example, PG&E states that given the high degree of operational interconnection between our national grid and components of their systems, participation by these entities is beneficial.

Similarly, some Canadian entities believe that significant benefits can be achieved by trading over "natural" or "appropriate" transmission regions that do not necessarily stop at the border.⁶⁸⁷ Other Canadian entities welcome the opportunity to participate in the RTO proceedings and support the Commission's efforts to encourage international collaboration.⁶⁸⁸

Canadian entities are concerned with sovereignty issues and urge the Commission to adopt flexible RTO rules that allow voluntary participation by Canadian utilities.⁶⁸⁹ According to the Manitoba Board and Ontario IMO, one option in this regard would be to allow members of an RTO the freedom to conduct transactions—through a contractual relationship—at the international border with foreign utilities that do not join a cross-border RTO. Furthermore, Canada DNR asserts that a decision not to participate in an international RTO by a Canadian jurisdiction should not place entities in Canada engaged in trade with United States at a disadvantage. Grand Council *et al.* proposes that the Commission sever the Canadian issues from this proceeding and open a separate docket to examine the international issues raised by the restructuring of electricity markets. Grand Council *et al.* urges the Commission to cooperate with Canada and Mexico to establish a genuine tri-national consultative process in order to resolve international issues based on an adequate record. Alberta notes that each

⁶⁸⁴ *Id.* at 33,758–59.

⁶⁸⁵ *Id.* at 33,759.

⁶⁸⁶ See PG&E, Desert STAR, Michigan Commission and Industrial Consumers.

⁶⁸⁷ See, e.g., Ontario Power, H.Q. Energy Services, BC Hydro and Canada DNR.

⁶⁸⁸ See, e.g., Powerex, CEA, Manitoba Board, British Columbia Ministry, Alberta, Canada DNR, BC Hydro and Ontario IMO.

⁶⁸⁹ E.g., Manitoba Board, British Columbia Ministry, BC Hydro, Canada DNR, CEA and Ontario Power.

⁶⁸⁰ See Central Hudson Gas & Electric Corp., *et al.*, 83 FERC ¶ 61,352 at 62,405 (1998).

⁶⁸¹ See Central Hudson Gas & Electric Corp., *et al.*, 88 FERC ¶ 61,138 at 61,402–03 (1999).

⁶⁸² See Midwest Independent Transmission System Operator, Inc., *et al.*, 84 FERC ¶ 61,231 (1998).

⁶⁸³ FERC Stats. and Regs. ¶ 32,541 at 33,758.

individual Province has jurisdictional responsibility for the development of the electrical industry within each Province and accordingly, only the Province has the jurisdiction to pass legislation to develop a competitive electricity market.

Commission Conclusion. After reviewing the comments, we continue to believe that Canadian and Mexican involvement in RTO formation and operation would be beneficial to both countries, as well as to the United States. As we stated in the NOPR, expansion of electricity trade in the North American bulk power market requires that regional institutions include all market participants so that everyone may enjoy direct access to market information and the benefits of non-pancaked transmission rates. Commenters from the United States and Canada agree that significant benefits can be achieved by trading over "natural" or "appropriate" transmission regions that do not necessarily stop at the border.

We note first that we are pleased with the level of participation in our proceedings by Canadian parties, and we encourage their continued participation as RTO formation progresses. We especially appreciate the RTO Consultation Conference sponsored by Natural Resources Canada in Ottawa in November 1999.

In response to Canadian comments, we point out that the Final Rule makes participation in an RTO voluntary for U.S. transmission owners, and participation is certainly voluntary for Canadian transmission owners. Further, we emphasize that our RTO Rule does not in any way require competition in retail electricity markets, whether they are located in the United States under state regulation or in Canada under provincial regulation. For those Canadian entities that want to join an RTO, the Final Rule is flexible: they may propose a cross-border RTO or a Canadian-only RTO that is compatible with the Rule. The Final Rule is not exclusionary: Canadian entities are not precluded from joining a cross-border RTO.

Several parties were concerned that a cross-border RTO would have its rates, terms, and conditions subject to the rate jurisdiction of at least two regulators. If a cross-border RTO forms, we will be open to proposals for innovative approaches for jointly overseeing a cross-border RTO with domestic and foreign utilities. For example, one approach might be for the cross-border RTO to try to develop a proposal acceptable to both regulators, with the understanding that any regulatory

difficulty would normally be referred back to the RTO for resolution and resubmission to both regulators. Another approach might be to have different but complementary rate designs in the two countries.

In the case of a Canada-only RTO, some Canadian transmission providers believe that having contractual and other agreements for coordination between separate RTOs across the border is better than having a cross-border RTO. However, some Canadian transmission customers are concerned that this would maintain a lack of standardization of market rules across the border. The RTO Rule is intended to permit a U.S. RTO on the Canadian border to develop contractual and other agreements for coordination with its Canadian RTO neighbor. Further, we have added a new minimum RTO function that an RTO must ensure the integration of reliability practices with other regions in the same interconnection and market interface practices with other regions. We clarify here that this provision applies to integration with interconnected regions in Canada and Mexico.

For either a cross-border or a Canada-only RTO, we acknowledge the sovereign authority of Canadian governments over Canadian entities and transactions that take place in Canada. Moreover, we re-emphasize that our Rule does not affect the authorities of Canadian government entities to approve prices and other terms and conditions of transmission service provided over any transmission facilities located in Canada. These conclusions apply equally to Mexico.

We encourage Canadian and Mexican entities to participate in continued RTO consultations and, if appropriate, formation and filings for cross-border RTOs. In particular, we urge Canadian and Mexican entities to attend the appropriate regional workshops to be held in the spring of 2000. These workshops will provide a forum for initial discussion of the issues associated with a cross-border RTOs.

Regarding the suggestion to establish a tri-national consultative process with Canadian and Mexican authorities to resolve international electric industry issues, we note that there are existing institutions and processes for resolving international disputes. The RTO process is just getting underway, and it is not clear that significant international disputes will develop or, if they should develop, that they would require a non-traditional method of resolution. Indeed, the RTO itself through its dispute resolution process may provide

a new and quicker way to resolve some disputes.

3. Existing Transmission Contracts

In the NOPR, the Commission asked for comments addressing what the appropriate treatment should be for existing transmission agreements when an RTO is formed. We noted that in Order Nos. 888 and 888-A, the Commission specifically chose not to abrogate existing requirements contracts and transmission contracts when the utility filed an open access transmission tariff.⁶⁹⁰ We stated, however, that an RTO represents an entirely different context. In the NOPR, the Commission recognized the importance of balancing a uniform approach for transmission pricing with the equities inherent in existing transmission contracts.⁶⁹¹ Furthermore, we noted that the potential financial impact of giving up an advantageous transmission arrangement may serve as a disincentive to joining an RTO. In the NOPR, we proposed to address the issue of existing transmission contracts on an RTO-by-RTO basis, rather than resolve the issue generically.⁶⁹²

Comments. Many commenters argue that the Commission should preserve and protect existing transmission contracts.⁶⁹³ These commenters note that existing contracts represent negotiated rights and obligations achieved through mutual negotiation. SRP believes that the Commission should grandfather existing transmission contracts in order to protect customers from cost shifts and prevent uncertainty in the marketplace. Turlock argues that the preservation of existing contracts, while cumbersome, is the bedrock of predictability and reliability and a key element of contract law. NPRB states that existing contracts should be honored until the contract expires or until the parties come to a new agreement. STDUG asserts that in order to be properly inclusive, an RTO must take members as it finds them, existing contracts, warts, and all. In contrast, CP&L asserts that the elimination of grandfathered agreements to the greatest extent possible ensures the most level playing field for all market participants.

⁶⁹⁰ FERC Stats. & Regs. ¶ 32,541 at 33,757.

⁶⁹¹ See *id.* at 33,757-58.

⁶⁹² *Id.* at 33,758.

⁶⁹³ *E.g.*, TANG, Turlock, UAMPS, Desert STAR, CMUA, Sithe, Georgia Transmission, Lincoln, PG&E, NPRB, NCPA, Great River, NRECA, Loveland Customers, San Francisco, Platte River, Florida Commission, Nevada Commission, DOE, Wolverine Cooperative, Tri-State, CREDA, EPSA, Big Rivers, SPP, SoCal Cities, TEP, PJM/NEPOOL Customers, Metropolitan, STDUG and PacifiCorp.

A few commenters propose a reasonable transition period to allow parties to existing contracts to conform their arrangements to an RTO tariff.⁶⁹⁴ EPSA notes that the transition period should be of sufficient length to reduce the financial and other burdens on the customer and on the original transmission provider. PSNM argues that at a minimum, a transition period of as long as ten years is needed to move the existing transmission contracts to RTO service. Furthermore, TAPS proposes that the Commission provide entities with an open season for transmission customers to choose to terminate or switch service under the terms of an RTO tariff. Alternatively, TAPS suggests that the Commission apply a just and reasonable standard to all transmission customers who seek contract modifications. Regarding contract modification, Southern Company asserts that in order to promote fairness, both parties to a contract must have an equal opportunity to modify the existing agreement. In addition, Entergy argues that the Commission should encourage all entities to re-negotiate existing contracts.

Several commenters support the Commission's preference that issues relating to the continued validity of existing transmission contracts be addressed on an RTO-by-RTO basis.⁶⁹⁵ WPSC argues that treatment of existing transmission contracts within a particular RTO should be consistent. Turlock urges the Commission to proceed with caution when addressing existing contracts. On the other hand, PSE&G asserts that the Commission should not address the treatment of existing contracts on a case-by-case basis because this leads to arbitrary and inconsistent results. Instead, PSE&G and Dalton Utilities argue that the Commission should address the issue of existing transmission contracts on a generic basis consistent with Order No. 888 and the Mobile-Sierra doctrine (recognizing the need to preserve the sanctity of contracts where possible).⁶⁹⁶ Sitch and NRECA concur that a generic policy is appropriate.

Cal ISO argues that the Commission's policies on existing contracts deserve revisiting, at a minimum for the limited purpose of conforming scheduling and

metering rules to those of the RTO/control area operator. Cal ISO states that it has experienced the challenges of workability when the ISO was required to honor existing contracts, but not permitted to interpret them or conform their scheduling rules to those of the regional organization. Cal ISO notes that it has experienced the most significant market inefficiencies associated with existing contracts in the area of scheduling and information gathering.

A few commenters note that not honoring existing contracts would create disincentives for both transmission customers and owners to join an RTO.⁶⁹⁷ For example, CMUA and Georgia Transmission argue that the financial impact of giving up an advantageous transmission arrangement would be a significant disincentive to RTO membership.

Commission Conclusion. At this time, we continue to believe that it is not appropriate to order generic abrogation of existing transmission contracts. We recognize that existing contracts represent negotiated rights and obligations achieved through mutual negotiation. However, in PJM⁶⁹⁸ and the Midwest ISO⁶⁹⁹ we adopted the rationale that it was unreasonable and discriminatory to maintain the pancaked rates in existing contracts for others when transmission-owning utilities had designed a non-pancaked rate approach for their own transactions. In our examination of existing contracts, we intend to balance the preference for preservation of existing contracts with the importance of consistency in transmission pricing and the elimination of pancaked rates.

As the above comments demonstrate, there is no consensus on how the Commission should manage the transition from existing transmission contracts to RTO service. In fact, parties offer diverse and conflicting views as to what the Commission should do regarding existing transmission contracts. Some commenters would have us let all contracts run their course with no opportunity to modify or terminate. Others advocate an elimination of existing agreements to the greatest extent possible. Yet others argue for a transition period ranging in duration for up to ten years to move

existing transmission contracts to RTO service.

Rather than adopting one extreme position or the other, we will take a measured approach with regard to the treatment of existing transmission contracts. We intend to address the issue of existing transmission contracts on an RTO-by-RTO basis, rather than resolve the issue generically. Accordingly, each RTO can propose whatever contract reform is necessary, including the limited changes suggested by the Cal ISO for the limited purpose of conforming scheduling, information gathering, and metering rules to those of the RTO. To this end, we encourage each RTO to address how and when it might convert existing contracts and submit a contract transition plan that contains specific details about the procedures to be utilized involving the conversion from existing contracts to RTO service. Again, our goal in reviewing existing transmission contracts and contract transition plans is to balance the desire to honor existing contractual arrangements with the need for a uniform approach for transmission pricing and the elimination of pancaked rates.

4. Power Exchanges (PXs)

The NOPR described the apparent advantages and disadvantages of having a power exchange coincident with an RTO. As further described in the NOPR, supporters state that PXs can reduce price volatility by providing price transparency, reduce the impact of defaults by spreading transaction risks among all participants through credit standards and reserve fund requirements, facilitate risk hedging by providing a basis for a futures market, and help facilitate retail access programs. Detractors argue that the principal functions of a PX are not natural monopoly functions. They contend that PXs, compared with bilateral markets, force participants to buy and sell electricity using standardized contracts, which may not suit their particular needs. They further argue that competition within the electricity market and its full benefits can only be achieved if there is competition for the PX market.

The NOPR left it to each region to determine whether there is a need for a power exchange and whether the RTO should operate it.⁷⁰⁰ The NOPR said that the Commission will accept any RTO proposal that includes a power exchange in its design as long as its operation of the power exchange does not compromise its independence as a

⁶⁹⁴ See, e.g., Williams, EPSA, First Energy, Duke, PSNM, LG&E, PGE and MidAmerican.

⁶⁹⁵ See, e.g., WPSC, Great River, DOE, ICUA, Entergy, TDU Systems, TEP, South Carolina Authority, MidAmerican, SNWA, UAMPS and TAPS.

⁶⁹⁶ See *United Gas Pipe Line Co. v. Mobile Gas Serv. Corp.*, 350 U.S. 332, 338 (1956); *FPC v. Sierra Pacific Power Co.*, 350 U.S. 348, 353 (1956).

⁶⁹⁷ E.g., CMUA, Desert STAR, Georgia Transmission, Wolverine Cooperative, Cal ISO, Entergy, Tri-State, SNWA, Metropolitan and TEP.

⁶⁹⁸ See *PJM*, 81 FERC ¶ 61,257 at 62,280-81 (1997).

⁶⁹⁹ See *Midwest Independent Transmission System Operator, Inc., et al.*, 84 FERC ¶ 61,231 at 62,169-70, *order on reh'g*, 85 FERC ¶ 61,372 at 62,418-20 (1998).

⁷⁰⁰ FERC Stats. and Regs. ¶ 32,541 at 33,760.

transmission service provider. The Commission sought comments on a number of questions related to power exchanges, including whether regional flexibility is appropriate and how RTOs should deal with an independent power exchange.

Comments. Commenters' views on power exchanges are mixed. The largest group of commenters basically agree with the NOPR.⁷⁰¹ A smaller group of commenters recommend that the Commission require that RTO applications include provisions for a power exchange,⁷⁰² with some recommending that the power exchange be internal to the RTO⁷⁰³ and some recommending that the PX be independent of the RTO.⁷⁰⁴ CalPX argues strongly that a power exchange should be separate from the RTO, given the continuing need to separate market and transmission functions; the need for market transparency to facilitate determination of whether congestion is being exploited; the need to provide a credible reference price for new retail choice market entrants; and the potential need for the RTO and power exchange to serve differing geographic areas. CalPX also submits that there is no concrete evidence that an RTO-operated power exchange will be more efficient and economical than an unrelated power exchange. NYMEX agrees that an RTO should be permitted to operate a power exchange, as long as a proper code of conduct is in place. PJM points to its success with a combined ISO/power exchange.

Another group of commenters argue that power exchanges should not be included in RTOs, but should be allowed to occur naturally as needed.⁷⁰⁵ Elaborating on this point of view, Salomon Smith Barney advises that the power exchange should not be in the RTO because it could throttle innovation and that the Commission should let the market decide. If there are really advantages to be gained, as some claim, from the operation of a single power exchange associated with the RTO, then such a power exchange will naturally develop. Florida Power Corp. argues that, while a region may prefer that its RTO closely coordinate with the power exchange, the two should not be part of the same organization because there is a fundamental difference in the business objectives of the two.

Similarly, EPSA contends that the Commission's vision of an RTO being an entity independent from all generation and power marketing interests is fundamentally incompatible with an RTO-run power exchange. Nevada Commission offers that a power exchange is not necessary to the formation of an RTO. And while PG&E sees every region needing a real-time balancing market regardless of whether it is run in-house by the RTO, PG&E also prefers that markets should otherwise be left to develop on their own accord.

Comments were received on additional aspects of the power exchange concept. PG&E argues that an RTO should not be allowed to use control of a power exchange to alter or cap prices set by the market. LG&E submits that the RTO should be required to be the provider of last resort for ancillary services, although market participants should not be required to purchase from the RTO. NASUCA notes that the NOPR does not cover some important power exchange issues such as exactly which markets would be included. NASUCA recommends that a NOI on power exchanges and related power market issues be initiated soon after the final rule.

Several commenters state that multiple power exchanges in a region should have equal standing before the RTO.⁷⁰⁶ FTC, however, recommends that the Commission assess whether competition is feasible in power exchange services. Similarly, CalPX notes that multiple power exchanges may hurt the market's function because each power exchange would be small, and therefore would not offer high levels of depth, liquidity and efficiency. NYMEX counters that there should be no credence given to the idea that one power exchange should enjoy any form of artificial franchise vis-a-vis others.

Commission Conclusion. The NOPR proposed leaving it to each region to determine whether there is a need for a power exchange and whether the RTO should operate the power exchange. We have decided to adopt the NOPR proposal. As the commenters have pointed out, there are advantages and disadvantages to the inclusion of a PX in the RTO structure. We do not believe that including a PX as part of the RTO structure would necessarily preclude the market benefits associated with bilateral transactions. We believe an RTO can accommodate both a bilateral market and a PX market. As the individual structures of the various RTOs supported by the regions are

likely to be quite varied, we think that it is best to let market preferences dictate the form of any one or more regional power exchanges and whether the RTO should operate a power exchange.

5. Effect on Retail Markets and Retail Access

The NOPR addressed the impact of RTOs and any associated PXs on retail competition and the states' jurisdiction over retail competition. For example, the Commission found that RTOs will enhance the effectiveness of retail competition:

We believe that the likelihood of success for existing and planned retail choice initiatives is significantly enhanced if the Commission can ensure fair and efficient access to a regional market without pancaked transmission access charges, and that we need to take steps beyond Order No. 888 to accomplish this.⁷⁰⁷

In addition, the Commission found that an RTO does nothing to interfere with the state's authority to decide retail access policy, but asked whether a PX is necessary for successful retail competition.

Comments. Several commenters state that RTOs were either essential or of great benefit in the implementation of retail competition.⁷⁰⁸ Mid-Atlantic Commissions notes that PJM has worked closely with the Pennsylvania, New Jersey and Delaware Commissions to assist with the implementation of their retail choice legislation in an organized fashion, while maintaining that the grid will be operated in a reliable fashion without any major economic or operational changes. According to Mid-Atlantic Commissions, this has also further provided those states in the region that have not implemented retail choice with a stable organization that continues to maintain reliability.

A few commenters express concern that the Commission's RTO policy could threaten the states' ability to control the pace of retail access and retail competition.⁷⁰⁹ South Carolina Commission counsels that the Commission should try to avoid affecting retail restructuring through its efforts to establish an RTO process. Central Maine raises the concern that retail choice programs already developed in concert with existing ISOs may be adversely impacted by any changes to such ISOs that are found to be necessary for them to conform to the RTO requirements (e.g., energy service

⁷⁰¹ See, e.g., Entergy, NJBUS, NY ISO, TDU Systems, Wisconsin Commission and UtilitCorp.

⁷⁰² See, e.g., Pennsylvania Commission, Duke and California Board.

⁷⁰³ See, e.g., PJM, ISO-NE and TAPS.

⁷⁰⁴ See, e.g., EPSA and MidAmerican.

⁷⁰⁵ See, e.g., APX, SMUD, Southern Company, Tri-State and Lincoln.

⁷⁰⁶ See, e.g., Duke, Florida Power Corp. and Desert STAR.

⁷⁰⁷ FERC Stats. and Regs. ¶ 32,541 at 33,704.

⁷⁰⁸ See, e.g., TXU Electric, DOE, First Rochdale, Illinois Commission and Williams.

⁷⁰⁹ See, e.g., Iowa Board and Puget.

company and other load serving entity contracts entered into in reliance upon the existing ISO market structures).

Puget views allowing RTOs to make FPA section 205 filings that unilaterally propose changes to the RTO tariff as conflicting with the Commission's commitment to respect the retail access efforts of the individual states. Puget argues that a unilateral decision by an RTO to provide transmission service to a retail customer and make that customer an eligible customer under the *pro forma* tariff would force states without retail access to accept such access as a *fait accompli*. Puget also fears that the term "market participant" as ultimately defined may include any entity that buys or sells electric energy in the RTO's region or in any neighboring region that might be affected by the RTO's actions. If so, since market participants must also have the option of self-supplying or acquiring ancillary services from third parties, this further suggests that retail customers may have the ability to acquire transmission service regardless of whether the affected state has yet decided retail choice and stranded cost recovery issues. Industrial Customers, however, question the legal basis for Puget's apparent suggestion that utilities be allowed to decide which retail customers may access RTO transmission.

EPSA contends that, while states tout each state's rights to protect its retail native load customers, some actions taken under this banner to limit exports of power actually disadvantage adjoining state's retail customers or participants in the bulk power markets. Therefore, the Commission should move forward with a rulemaking to assure full transmission comparability for retail customers of all states, and to prevent individual states from continuing to disadvantage each other and to prevent individual utilities from continuing to disadvantage other market participants. New York Commission also submits that this proceeding is not the place to address the issue of preemption of state jurisdiction over bundled retail electric sales.

TAPS raises the question of jurisdictional conflict as to which facilities need to be regulated at the federal or state level, and whether the policies of the Commission toward open access will be undercut by transmission owners using the seven factor transmission/distribution classification test to place new generation at a disadvantage relative to existing generation owned by the transmission provider. TAPS contends that the Commission must take steps to ensure

that RTOs contain the appropriate facilities and that refunctionalization of transmission to distribution does not interfere with competition by creating RTOs that control little or no transmission.

Another concern expressed is that RTOs may cause cost shifting to retail customers that could interfere with restructuring.⁷¹⁰ As to the impact of the power exchange on retail competition, both CalPX and MidAmerican argue that power exchanges assist in the effectiveness of retail competition programs by providing transparent and credible reference prices.

Commission Conclusion. We continue to be persuaded that RTOs can positively affect each state's implementation of its retail choice program, without interfering with those states that have not yet adopted such programs. As noted by commenters, existing ISOs have already successfully facilitated retail choice programs in areas where only some of the states have adopted such programs, and the ISOs were able to do so without clashing with or frustrating the other states that have not undertaken such programs. We do not believe that an RTO could interfere with a state's decisions on whether or how fast to implement retail choice within its borders, either through the RTO's Section 205 filing authority or otherwise through the RTO's jurisdictional obligation to provide non-discriminatory and non-preferential transmission service.

Commenters pointed to potentially extensive reclassification of transmission facilities to local distribution as part of the unbundling of retail rate schedules to implement retail choice programs, and how this might lead to RTOs that are "empty vessels" with little significant transmission under their control. We agree that RTOs must control all transmission facilities that are necessary to support competitive wholesale power markets. For this reason, we specified the scope, configuration and operational control requirements adopted in this Final Rule. We will judge any proposed reclassification on a case-by-case basis. We note that any reclassification of transmission facilities to local distribution will require Commission approval and will not remove from the Commission's jurisdiction any facilities used to deliver power to wholesale customers. Furthermore, under the principle of open architecture (discussed *supra* in section III.F), the Commission expects RTOs to remain flexible such that, if over time

⁷¹⁰ See, e.g., LG&E and Southern Company.

circumstances should change and certain facilities need to be reclassified as transmission, procedures will be in place to do so.

With regard to RTO pricing causing transmission cost shifting that adversely affects retail choice customers, this issue is discussed in the Transmission Rulemaking section of this Final Rule.⁷¹¹ The Commission will continue to review transmission rate proposals to ensure that they are just and reasonable, and not unduly discriminatory.

Finally, on the matter of whether a power exchange is needed to facilitate states' retail choice programs, it is our view that, to the extent that a region forming an RTO chooses to voluntarily establish an RTO-affiliated power market, we anticipate that any such power exchange would provide retail choice customers with transparent and credible reference prices for power and other information that otherwise might not be available.⁷¹²

6. Effect on States with Low Cost Generation

In the NOPR, we recognized that states with relatively low cost power are concerned that an RTO would result in local utilities selling their low cost power to other states.⁷¹³ However, we noted that a state that is low cost today may not be low cost tomorrow without an RTO in its area.⁷¹⁴ In addition, we stated that utilities that now have low cost generation will help assure access to future low cost generating plants by participating in an RTO and that new low cost generation plants are more likely to be attracted to regions with a well-functioning regional market governed by an RTO. We sought comment from state commissions regarding how an RTO in their state would affect power costs.

Comments.—A number of commenters raise concerns about the effect of RTOs on states with low cost electricity. These concerns center around one issue—that the costs of creating an RTO may outweigh the benefits.

South Carolina Commission argues that customers in South Carolina enjoy very high quality service and pay some of the lowest rates. Duke power concurs, noting that, it is not necessarily true that North Carolina and South Carolina will conclude that sufficient long-term benefits exist for these states to justify costs of RTO membership. Duke argues

⁷¹¹ See *supra* section III.G.

⁷¹² For a further discussion of PXs, see *supra* section III.H.4.

⁷¹³ FERC Stats. and Regs. ¶ 32,541 at 33,722.

⁷¹⁴ See *id.*

that any proposed RTO should be shown to provide tangible benefits to the relevant region.

Alabama Commission believes that RTOs will cause states to lose the efficiency of integrated systems and lead to retail competition, whether it is in the interest of customers or not. Southern Company agrees, noting that due in large part to the low cost status of southeastern states, they are proceeding cautiously with retail competition and restructuring initiatives. This does not mean that these states are ignoring the potential benefits of restructuring. Indeed, Southern Company notes that states in its service territory are actively studying the potential advantages and disadvantages of retail competition but have not yet concluded that the potential benefits outweigh the costs and risks associated with changing the current industry structure.

SMUD points out that it has not joined the Cal ISO over similar concerns. It indicates that its customers already enjoy low cost electricity and that participation in the Cal ISO could not ensure that SMUD's retail rates would be any lower, and on the contrary, the cost of participation would cause rate increases.

Kentucky Commission indicates that inefficiencies may occur for a variety of reasons and examples of inefficiencies include: multiple RTOs in a small region; several layers of governance within one RTO; and too many tasks shifted from the RTO members to the RTO itself. Kentucky Commission argues that if the proposed transmission organizations are not operated at levels of maximum efficiencies and minimum reasonable costs, the Commission will have failed to promote one of its primary objectives, the growth and success of the wholesale power market. Kentucky Commission further argues that the Commission must be mindful of these costs in developing rules for the establishment of RTOs.

Commission Conclusion. We are mindful of the potential costs of setting up and running an RTO, but we anticipate that the collaborative process will result in an RTO proposal that incorporates a design that, overall, increases the existing level of transmission system and market efficiency for each region. As we discuss more fully in the Scope, Implementation and Benefits sections of this Final Rule, we are taking a results-oriented, practical approach to establishment, organization, implementation and operation of RTOs. We do not expect that regions with no existing institutions will necessarily invest in new, high-cost RTO infrastructure. Instead, such a

region may propose an RTO that relies on existing infrastructure to accomplish its mission. However, we expect the RTO to satisfy the minimum characteristics and functions and to improve the efficiency of regional transmission service.

In response to the concern of low cost states that RTOs could result in exports of their low cost power to other states, we do not believe that an RTO will cause utilities to sell their lowest cost power out of state. While retail choice arguably might lead to low cost power being sold out of state because incumbent utilities no longer have an obligation to serve local in-state loads, this would occur with or without an RTO in the region. Where there is no retail choice, our Final Rule does not affect a state commission's authority to require a utility to sell its lowest cost power to native load, as it always has. We point out that, if the utility's transmission is operated by an RTO and its higher cost power can be sold more readily to new, more distant customers, this will lead to recovery of more capital costs and lower retail rates. In the long term, low cost states may benefit from an RTO that facilitates expanded access to wholesale electricity markets, increasing the choice of low cost resources available to utilities as they acquire new power resources.

7. States' Roles with Regard to RTOs

In the NOPR, we noted that states want a role in the governance of any RTOs for their states, and we proposed to be flexible in accommodating the states' needs.⁷¹⁵ The NOPR encouraged RTO design to accommodate appropriate state oversight, especially with regard to planning and siting new multi-state transmission facilities. We sought comments on the appropriate state role in RTOs on these and other RTO matters.

Comments. Comments on the states' roles in RTO development and governance were fairly extensive, with by far the greater percentage of comments supporting a strong and clearly defined state role. Comments can be grouped into four primary categories: (1) governance; (2) formation; (3) siting and planning authority; (4) regional regulation.

Governance. Almost all commenters on this issue expressed support for a clear state role in governance; however, there were differences as to exactly what that role should be. Some commenters believe that states should be allowed to determine their own role in governance, either as members of advisory panels to

the board of directors, as voting members of the board, as non-voting members of the board, or having authority to appoint board members. Some commenters, however, feel strongly that states should not be permitted to be voting members of boards.

Commenters argue that the appropriate state role in an RTO is a matter of local control. For example, Northwest Council states that the Commission should not set restrictive rules on the type of state participation in RTO governance, but should allow the states to propose to the Commission the kind of roles they view as appropriate, e.g., voting members of a stakeholder board, *ex officio* status on an independent board, and so forth.

The California Board suggested that state officials should be allowed as either voting or non-voting members. Los Angeles has no objection to state board membership, either voting or non-voting, if a state has determined that a government official can best represent that state's interests. The Washington Commission agrees that states should be able to define their own role. Mid-Atlantic Commissions note that they have a Memorandum of Understanding with the PJM ISO Board of Managers to facilitate communication and promote a cooperative relationship.

Some commenters, however, think that state officials should not have voting membership on boards of directors since that could raise conflict of interest problems where the state official would have to approve decisions of the board while sitting as a regulator. For example, Minnesota Power believes that state cooperation will be enhanced if state officials participate as members of an RTO advisory board, but they should not participate as voting members of an RTO because the RTO process could be compromised by parochial state politics. ISO-NE agrees, pointing out that some states' conflict of interest laws may expressly prohibit such service, and that it might be difficult for an official from one state to make decisions as a board member that are good for residents of all states encompassed by the RTO.⁷¹⁶ WEPCO believes the appropriate role of the states in RTO governance includes active participation in regional planning efforts and continued oversight of siting of new transmission facilities. In addition, many commenters supported

⁷¹⁵ FERC Stats. and Regs. ¶ 32,541 at 33,724.

⁷¹⁶ See also MidAmerican, Montana-Dakota, PSNM, East Kentucky and NPRB.

an advisory role for state officials, through advisory boards.⁷¹⁷

Formation. Numerous commenters supported a role for states in the formation of RTOs. ISO-NE points out that the states in its region had a significant role in the development of the ISO. In addition, the California Board argues that states should have a role in determining the structure of the RTO and any other market institutions that are formed to serve the citizens of their respective states. California Board further notes that mechanisms to ensure that states' interests are protected might include statutory or regulatory reliability criteria; independent market monitoring by the states or requiring market monitoring reports to be provided to the state; and accountability to the states to ensure adequacy of transmission and generation planning.

The Michigan Commission notes that most states have little direct authority to order the development of an RTO, especially when the RTO encompasses several states. According to the Michigan Commission, at best state commissions should serve in an advisory role as the utilities develop the structure and guidelines of the RTO proposal. The Michigan Commission, however, joins a few other states in urging the Commission to defer to state recommendations once the basic RTO characteristic and functional guidelines have been met.

NARUC comments extensively on the potential collaborative process and the importance of state participation in this process and other steps in the formation of RTOs. To achieve the public policy goal of assuring reliable service at an affordable cost, NARUC argues that states should fully participate in RTO development and formation, particularly in matters for end-use native load customers. NARUC notes that based on some states' retail choice or ISO experiences, state oversight can play a significant role in assuring a well-functioning ISO and competitive wholesale and retail markets.

NARUC further suggests that once RTOs are formed, continuing interaction is necessary, and market development and evolution will be continuous. NARUC believes that RTO formation must continue to be a dynamic process requiring continuing dialogue between FERC and the states. NARUC further believes that once organizations are formed and approved, some type of formal reporting to FERC and the states

by the organizations on an annual basis would be appropriate.

Nine Commissions suggests that state commissions are well positioned to balance the competitive motivations of utilities in the RTO formation process with the interests of all other stakeholders in defining markets in their respective regions and conforming the RTO boundaries to those markets. According to Nine Commissions, the state commissions' continued cooperation with FERC will ensure that the mutual public interests of providing reliable electric service will be met, and that market participants in every region of the country will be treated comparably.

Siting, Planning and Reliability. A number of commenters, many state commissions, and quite a few other parties, argue strongly that the Commission should be careful not to preempt traditional state regulatory authority in promulgating its rule. In particular, commenters suggest that the Commission should not usurp state authorities over siting, planning, and reliability of the transmission system. Some commenters proposed solutions to state/Federal jurisdiction issues in the RTO context, such as joint state/Federal review bodies. The Alabama Commission suggests that FERC should not take any action that would infringe on state jurisdiction.

South Carolina Commission asserts that transmission siting should remain in the hands of the states and local governments. South Carolina Commission further asserts that states must continue to have a significant role with regard to matters of reliability for end-use native load customers. The Iowa Board concurs and suggests that the Commission's RTO policies cannot alter states' continued interest in local matters such as transmission and generation siting, local transmission and distribution interface issues, adequacy of generation and transmission, service quality, and retail rates.

The Montana Commission notes that in roughly half the states with siting laws the function is not vested in the regulatory commission, but rather in a separate energy policy, environmental or commerce agency. They recommend that the Commission amend the language in the Final Rule to make it clear that the Commission does not intend to preempt state siting authority as part of this NOPR.

UAMPS warns that RTOs may create a separation between generation planning and transmission planning that endangers reliability. UAMPS argues that states must be left with authority to assure reliability and that

retail competition issues should also be left to the states. UAMPS suggests that because state cooperation and participation will be so critical to an RTO's effectiveness, in addition to the four minimum characteristics the Commission has proposed, RTOs should be required to provide specifically for significant state involvement in their development and operation. Allegheny, on the contrary, states that system operations in an RTO will be pursued for the good of the RTO service area, not of any one state. Allegheny notes that if that fact yields a dilution of state authority it must be the price paid for RTO benefits.

Regional Regulation. A number of commenters propose or support regional regulatory cooperation or joint state/Federal sharing of jurisdiction. The Kentucky Commission proposes the creation of a Federal/state "joint board," that is styled similarly to the Universal Service Joint Board currently used by the Federal Communications Commission, state utility commissions, and other parties. The Kentucky Commission suggests creating this voluntary Board to develop and review standards for transmission expansion. The Joint Board would include participation from FERC, state commissions, RTOs, and other interested parties. The Joint Board would also convene ad hoc committees to review specific transmission expansion proposals. These committees would include the participants described above, and would include representatives from regulatory commissions in states where the expansion is proposed. The RTO would present the *ad hoc* committee with a plan for transmission expansion with appropriate documentation for need, cost effectiveness, and alternatives. The committee would in turn pass on its recommendation or refusal of support for the plan to the specific state commissions for their official approval. The Kentucky Commission believes that such an arrangement could avoid Federal/state conflict while allowing both levels of government to exercise appropriate jurisdiction. In addition, ISO-NE points to existing regional regulatory groups such as NECPUC that could continue to provide valuable assistance to the Commission in the collaborative process to encourage RTO formation envisioned in the NOPR.

Nine Commission argues that an appropriate regional oversight venue will lead to more consistent treatment of issues and parties between state and Federal regulatory forums. With appropriate deference by both FERC and the states, such a regional venue could

⁷¹⁷ E.g., ISO-NE, PJM, Midwest ISO, MidAmerican, Project Groups, PSNM, Iowa Board, Arizona Commission and UAMPS.

obviate the need for many parties to expend redundant resources to participate in multiple state and Federal regulatory processes for matters relating to transmission and RTOs.

Nine Commissions notes that one possible mechanism to effectuate such a regional venue is interstate compacts, which are provided for in the Administration's proposed electric industry restructuring legislation. Nine Commissions argues that regional regulatory organizations have the advantage of being able to coordinate state interests for providing regional recommendations to FERC. State oversight functions (e.g. siting, local outages, customer complaints) would not change. According to Nine Commissions, such regional regulatory organizations would provide greater coordination among states within the region, allowing for ADR processes that could satisfy multiple state jurisdictional requirements, and such organizations would monitor markets that have evolved beyond state borders and facilitate joint FERC and multi-state facilities siting.

Pennsylvania Commission prefers a joint Federal/state approach toward regulating RTO siting approvals, expansion, innovation and customer service. Pennsylvania Commission notes that a joint approach would resolve the vexing problem of Federal/state jurisdictional uncertainty and a joint Federal/state approach would avoid the potential for creative forum shopping by individual stakeholders, who will always seek to cast a dispute in jurisdictional terms so as to dictate a jurisdictional resolution to the perceived favorable outcome. A joint Federal/state approach has been used with success in other areas, such as the Susquehanna River Basin Commission, the Delaware River Basin Commission and the Joint Pipeline Office for the Trans-Alaska Pipeline System. Likewise, the Virginia Commission believes that there is no conflict between state goals and Commission goals and that the two levels of government should be able to work together and avoid conflict as long as both parties recognize that the common goal is the public interest.

Commission Conclusion. We continue to believe that states have important roles to play in RTO matters. For example, most states must approve a utility joining an RTO, and several states have required their utilities to turn over their transmission facilities to an independent transmission operator. Also, states must approve the siting of transmission facilities that are called for in an RTO expansion plan.

We believe, however, that it is not appropriate to try to set out a full set of states' roles in this Rule. It is difficult, and not necessary, to reach generic conclusions about states' roles given the diversity of possible RTO forms and state authorities. For example, a state's role may be different for an ISO, transco, and other organizational form, and it may be different for a multistate RTO and a single-state RTO, if any. States differ regarding the authorities they have vested in their regulatory and siting agencies. Further, states differ regarding their jurisdiction over municipal and cooperative utility owners of transmission facilities.

Regional interests forming an RTO should consult with the states about what state roles best fit the agencies' authorities and preferences and the organizational form of the RTO. This role could vary from state to state within an RTO. Therefore, this Rule takes a flexible approach that allows states to play appropriate roles in RTO matters, consistent with this Commission's exclusive responsibilities and authorities under the FPA.

We note that we have discussed the role of states for particular RTO functions elsewhere in this Final Rule. Regarding RTO formation, the Background discussion above discusses the role that several states played in creating many of the existing ISOs. It also describes our initial consultations with state regulators on RTO formation and our roles in FPA section 202(a) implementation; in those consultations we offered to continue the RTO dialogue with states in the future. The form of consultation to be used should be decided based on the issues and the region so we will not endorse or reject here any particular form of collaboration. However, in the Collaborative Process discussion below, we set out our plans to invite states and others to work with us to foster RTO formation beginning early next year.

In our discussion above of the Independence characteristic, we discuss the role of state agencies in governance, making the point that states will play a key role in RTO formation and development but declining to specify generically a state's role in governance. Also, in our discussion above of the RTO Planning and Expansion function we recognize the exclusive authority of state and local governments and regulatory agencies over the siting of transmission facilities, and we include in our regulations the standard that an RTO must accommodate efforts by state regulatory commissions to create multi-state agreements to review and approve new transmission facilities.

8. Accounting Issues

Although not discussed in the NOPR, EEI commented on some accounting aspects of RTOs. It urges the Commission to address two primary accounting issues for RTOs: (1) The need to revise the Uniform System of Accounts (USofA) and related reports to reflect new RTO and other unbundled rate structures; and (2) the ability of RTOs to use regulatory accounting.

a. Revision of the Uniform System of Accounts

Comments. EEI contends that because the Commission's USofA was developed when utilities' products were bundled and fully regulated, it needs to be revised to support the Commission's adopted policies and this proposed rule. EEI believes that with unbundling of rates, the USofA will need to be revised to reflect, among other things,⁷¹⁸ cost functionalization (e.g., by generation, transmission, distribution, etc.). EEI also believes that the Commission should specifically address the accounting to be used for RTO reporting purposes, as the current USofA was not designed for use by RTOs. EEI states that it is very willing to work with the Commission's staff to address the specific changes that should be made to the USofA.

Commission Conclusion. The Final Rule permits the various regions to select different organizational forms for RTOs. Our open architecture structure for RTOs permits applicants to select the business organization best suited to the needs of its members and RTO participants. It would therefore be difficult to prescribe in this proceeding specific changes to our existing USofA that would accommodate the needs of all RTOs.

We believe a better course at this juncture would be to require RTOs to conform their accounting to our USofA (as have ISOs) and to submit questions of doubtful interpretation to the Commission for individual or generic rulings on particular transactions, events and circumstances.

However, we agree with EEI's observation that unbundling of utility services, and other changes in the industry require the Commission to re-examine its existing accounting and related reporting requirements. This is true not only for the new types of utilities that have emerged in the industry such as ISOs, PXs and RTOs,

⁷¹⁸ Another significant area cited is whether the Commission should modify its original cost accounting requirements for property acquisitions to conform with the evolving fair value requirements of the Financial Accounting Standards Board (FASB). See Appendix I to EEI Comments at 11.

but also for traditional public utilities. The Commission staff has been and will continue to meet with EEI and others, and will continue its efforts to address the specific changes that may be needed as the industry restructures.

b. Ability to Use Special Accounting

Comments. EEI asks the Commission to consider the impact of its actions on the ability of RTOs to use the special accounting rules applicable to cost-based rate-regulated entities.⁷¹⁹ EEI believes that the ability to use regulated accounting would be advantageous to RTOs and viewed favorably by the investment community.⁷²⁰ EEI urges the Commission to structure alternative ratemaking methods (e.g., price and revenue caps, incentive-based rates and price indexing) to allow RTOs to continue to use the special accounting of SFAS 71. In this regard, EEI believes that if the Commission decides it is advantageous to stimulate the establishment of RTOs by ensuring that all start-up costs are ultimately recovered through FERC jurisdictional rates, it could issue ratemaking orders that defer expense recognition of these costs, and allow for future ratemaking recovery. Similarly, EEI urges the Commission to address the time frame over which software development costs could be recovered through rates and to allow utilities to defer expense recognition of such costs. To enhance cash flows from operations, EEI suggests that the Commission accelerate the amortization of all capitalized software costs. These actions, according to EEI, would likely be viewed favorably by the investment community.

Commission Conclusion. RTOs may propose and we are willing to consider alternative ratemaking methods including proposals to delay rate recovery of certain expenses. We will not prescribe any specific requirements at this time but allow RTOs to propose those methods which are appropriate for each RTO's facts and circumstances. In

this regard, we intend to take a flexible regulatory approach toward approving RTO rate design proposals and strive to include adequate information in our rate orders on the appropriate accounting treatments.

9. Market Design Lessons

We expect that bid-based markets will be a central feature in many RTO proposals. To date, the Commission has analyzed and approved, with various modifications, bid-based market designs for four ISOs. The purpose of this section is to summarize the lessons learned from these real-world market experiments. The summary provided below is not intended to favor one market design over another, but is intended to assist RTOs in evaluating existing market designs and meeting the deadlines set forth in this rule.⁷²¹

Cal ISO, PJM and ISO-NE have had operational experience with their respective market designs. For the most part the markets operated by these ISOs have functioned well, and they have not experienced many of the problems encountered in the bilateral markets in the Midwest and the Southeast.⁷²² However, each of the operational ISOs has encountered some market design problems that have resulted in unexpected or undesirable market outcomes.⁷²³ These outcomes have led some ISOs to file many market design changes and requests for temporary remedies or protections until permanent design changes can be implemented.⁷²⁴

a. Multiple Product Markets

The bid-based markets that we have approved to date are premised on the assumption that acceptance of voluntary supply and demand bids which maximize overall net benefits will also maximize efficiency. Each approved ISO design employs some bid-based mechanism to ramp resources up and down to balance the system, manage congestion, and to supply some ancillary services. Employing bids that

indicate a generator's willingness to be ramped down, ramped up, or placed in reserve is an economic way to balance the system, manage congestion and maintain appropriate reserves, both in real time and in any day-ahead markets. However, if more than one product is being sold in the same temporal market,⁷²⁵ efficiency is maximized when arbitrage opportunities reflected in the bids are exhausted (i.e., after the RTO's markets have cleared, no technically qualified market participant would have preferred to be in another of the RTO's markets). In addition, efficient bid-based markets elicit prices that are consistent with technical and cost requirements.⁷²⁶ For example, a situation where generating units are paid more for not generating than for generating as has happened in ISO-NE and the Cal ISO may be an indication of an inefficient market.⁷²⁷

b. Physical Feasibility

Proper design of the market clearing procedures ensures that prices balance the supply and demand for energy, and all transactions, in the aggregate, are physically feasible with appropriate levels of reserves. Some market designs have allowed ISOs to accept schedules that have not been physically feasible (e.g., Cal ISO), while other ISO market designs include mechanisms to ensure the physical feasibility of transactions (e.g., the NY ISO and PJM). Some ISOs have encountered instances where transmission constraints have prevented the use of needed reserves,⁷²⁸ and this is inconsistent with the operator's obligation to make certain that reserve requirements are met and that reserves, along with necessary transmission, are available to respond appropriately to contingencies.

⁷²⁵ For example, energy and operating reserve products may be offered in real-time.

⁷²⁶ One would expect that services with more stringent technical requirements ordinarily have higher costs for providing those services. The prices of these services should reflect the costs. For example, spinning reserves have more stringent requirements and would be expected to command a higher price than non-spinning reserves.

⁷²⁷ See Report of the Market Surveillance Committee of the California Independent System Operator, October 18, 1999 (MSC October Report). Both ISOs have seen prices for services such as non-spinning reserve products, which do not require a unit to be running, higher than the energy price. Also, according to the Market Surveillance Committee (MSC) of the Cal ISO, market participants have an incentive to submit schedules that will cause congestion so that their units can be called upon to relieve the congestion and receive payments for not generating that are greater than payments received for generating.

⁷²⁸ See MSC October Report, at 67, 74-75.

⁷¹⁹ The special accounting rules are primarily contained in Statement of Financial Accounting Standards No. 71, *Accounting for the Effects of Certain Types of Regulation* (SFAS 71). One of the primary accounting differences is the ability to defer expense recognition of an incurred cost if it is probable that the utility will recover that cost in future cost-based regulated rates.

⁷²⁰ Conversely, according to EEI, the inability of an entity to use SFAS 71 accounting could have an adverse effect on earnings, which may be viewed unfavorably by investors. According to EEI, one example would be where the Commission approves a rate levelization plan (e.g., under capital lease transactions) under which rate recovery of certain costs would be deferred until future years. If a utility could not defer expense recognition of such costs, earnings would be depressed in the early years of the levelization plan.

⁷²¹ The Commission has already given considerable guidance on numerous market design issues in a number of orders. See Pennsylvania-New Jersey-Maryland Interconnection, L.L.C., 81 FERC ¶ 61,257 (1997); Central Hudson Gas & Electric Corp., et al. 86 FERC ¶ 61,062 (1999); New England Power Pool, et al. 87 FERC ¶ 61,045 (1999); AES Redondo Beach, et al., 87 FERC ¶ 61,208 (1999).

⁷²² See Staff Report to the Federal Energy Regulatory Commission on the Causes of Wholesale Electric Pricing Abnormalities in the Midwest During June 1998 (September 28, 1998).

⁷²³ The NY ISO has had little operational experience with the particulars of its markets design.

⁷²⁴ See New England Power Pool, et al., 87 FERC ¶ 61,055 (1999); AES Redondo Beach, et al., 87 FERC ¶ 61,208 (1999); New York Independent System Operator, Inc. et al., 88 FERC ¶ 61,228 (1999).

c. Access to Real-Time Balancing Market

Real-time balancing refers to the moment-to-moment matching of loads and generation on a system-wide basis. Real-time balancing is usually achieved through the direct control of select generators (and, in some cases, loads) that increase or decrease their output (or consumption in the case of loads) in response to instructions from the system operator. Over the last several years, the Commission has seen an increasing use by system operators of market mechanisms that rely on bids from generators to achieve, overall, real-time balancing. In order to maintain system balance, the operator also manages congestion while maintaining the appropriate level of reserves. It is expected that any RTO balancing markets will be available to all grid users, *i.e.*, including individual grid users that engage in bilateral transactions. The fact that the overall system must be in balance moment-to-moment does not mean that there must be a moment-to-moment balance between the specific load and resources involved in individual bilateral transactions. Making a real-time balancing market available to all grid users ensures that all users are treated equally for purposes of settling their individual imbalances. The four operating ISOs approved by the Commission already operate such markets.

d. Market Participation

Markets are most efficient when generators and loads, whether internal or external to the RTO, are allowed full and flexible participation in the markets. While generators and loads have the option to choose between participating in any RTO-facilitated markets or other markets, the RTO must have generation and ancillary service quantity information, and any necessary technical information, from self-schedulers in order to balance the system and ensure reliability. This allows bilateral and forward financial markets and independent PX markets to co-exist and complement RTO physical markets. Participants that self-schedule would be expected to pay for the costs that they impose on the physical system at market prices and be paid for the benefits that they supply to the physical system at market prices.⁷²⁹

Unnecessary constraints on the imports of services can lead to increases

⁷²⁹ Costs and benefits associated with self-schedules are congestion costs created by the transaction or congestion relief that the transaction makes possible.

in price volatility due to thin markets.⁷³⁰ Allowing exports will give generators flexibility to take advantage of opportunities outside of the RTO boundaries, while allowing load serving entities external to the RTO a chance to purchase services. Broadening market participation deepens the market and enhances overall efficiency.

e. Demand-Side Bidding

Existing ISO markets offer generators flexible participation, but they often do not offer customers demand-side bidding options. Demand-side bidding is desirable to the extent it is technically feasible, because without it, demand response decreases and market power is easier to exercise.⁷³¹ The availability of price responsive demand also reduces price volatility in the markets.

f. Bidding Rules

A market that provides the flexibility for all generators to bid a reasonable approximation of the costs they incur including start-up, minimum load, energy, and ramping costs will be efficient. Whether it is cost-effective to start up a generator and make it available for dispatch depends on the prices and scheduled quantities over the multiple hours and services for which the generator is committed, not on the prices in any single hour or for any single service. Allowing participants to bid these costs helps provide for a more efficient dispatch of generating units to meet load and other services, because it allows the start-up decisions underlying the dispatch schedules to be based on prices and quantities for a period greater than a single hour. Not permitting start-up and minimum load bids can reduce efficiency because the decision to start up and dispatch generators is made separately for each hour, resulting in start up decisions that can cause losses for generators. Also, when the start-up and minimum load bids are submitted along with minimum run and down times, generators are ensured that they will not be dispatched in a way that is physically damaging to the unit.

g. Transaction Costs and Risk

Transaction costs associated with participation in well functioning RTO markets should be low, and market participation should involve no unnecessary risks. For example, in sequentially clearing markets, bidders

⁷³⁰ Thin markets refers to a situation in which the amount bid into the market is either not enough to match demand, or just enough to match demand.

⁷³¹ The flexibility of demand-side bidding may be limited unless real-time meters are installed. Otherwise, demand-side bidding can simply take the form of interruptible load.

are exposed to the risk that they may be chosen in one of the markets that clears first, yet would have preferred to have been chosen in a market that cleared later. In order to hedge against such risks, bidders may undertake expensive and time consuming bid preparation strategies to decrease the likelihood that such profitable opportunities would be missed.

h. Price Recalculations

In some instances, it may be necessary to post prices on a preliminary basis while the final price calculations are verified. For example, in ISO-NE, the computer algorithms generate new dispatch points every five minutes, and preliminary market clearing prices are based on these dispatch algorithms. However, the actual dispatch instructions are issued manually. In circumstances where time does not permit all changes in dispatch to be communicated and effected through manual processes in a timely manner, the market clearing price resulting from the computer algorithm must be adjusted to reflect the actual dispatch in the hour.⁷³² While an RTO must ensure that the final market clearing prices are correct, market clearing procedures should minimize price recalculations. Also, any price recalculation should be done quickly. Otherwise, market participants could incur large transaction costs in attempts to hedge against such risk. Risk exposure can be further reduced if market participants can engage in bilateral transactions, or participate in other markets, to lock in prices prior to participating in the RTO-facilitated markets.

i. Multi-Settlement Markets

Multi-settlement markets may involve a day-ahead and real-time market. For real-time markets, prices are determined by real-time dispatch quantities, and deviations from day-ahead schedules are priced at the real-time price. When day-ahead schedules are financially binding, they are financial commitments subject to payments for deviations at the real-time price. If market participants adhere to day-ahead schedules, they need not participate in the real-time markets. If needed for reliability, bids need to be physically binding and may be subject to Commission-approved penalties for failure to adhere to the bid. Without financially binding commitments in the day-ahead market, the riskiness of market participation

⁷³² See ISO New England, Internal Review of Operations, June 7-8, 1999, Report issued August 20, 1999. Electronic dispatch is under consideration in ISO-NE.

increases since the day-ahead bids could be changed before real-time dispatch. If bids for ancillary services are accepted, the accepted capacity must be physically ready to meet reliability commitments when called upon. The lack of a physical capacity commitment has been a problem in some ISOs.

j. Preventing Abusive Market Power

An efficient market design does not favor market participants that have the potential to exercise market power and minimizes the incentives for market participants to engage in abuse of market power. For example, since large players are more likely to cause market power problems, a market design that favors large players (e.g., portfolio bidding⁷³³) may create an incentive for consolidation and resulting market power problems. Fewer restrictions on imports of services will help guard against thin markets, which in turn will help mitigate market power. ISO's have experienced problems with thin markets, and easing restrictions on imports should help.⁷³⁴ Also, artificially segmenting a product market into separate geographic markets for the same product can also create additional price volatility and opportunities for the exercise of market power.⁷³⁵

If market participants are allowed to submit bids which can then be changed before financial settlements are completed, these non-binding bids can be used as a signaling device to facilitate collusive behavior.

k. Market Information and Market Monitoring

One property of an efficient market has market clearing prices and quantities being made available immediately. This information enables market participants and potential future market participants to assess the market and plan their businesses efficiently. It will also allow market participants to spot errors in the market clearing process and get them corrected.

Disclosure of individual bids could be made eventually, but not immediately. Such disclosures will allow detection of market design and implementation

⁷³³ Portfolio bidding refers to bids that aggregate all generating units under the same ownership. This is in contrast to generation owners bidding in each unit separately.

⁷³⁴ Report of the Market Surveillance Committee of the California Independent System Operator, August 19, 1998 at 35-36 (MSC August Report).

⁷³⁵ The Cal ISO at one time segmented their product markets into separate geographic markets that corresponded to the defined congestion zones even when no congestion existed. It has since reformed this practice. See MSC August Report, at 32-33.

flaws, and allow study of the market by independent analysts and market participants. It may lead to the exposure of the exercise of market power. To detect the withholding of capacity, a simple screen is to provide the output, reserve quantities, and maximum capacity of each generator. Immediate disclosure of individual bids is undesirable because it might facilitate collusion by the market participants. It also might affect the bids of market participants who wish to keep their costs confidential. However, after six months or a year, the information on individual bids has essentially no value for collusion and discloses little new information about any bidder's current costs. Nonetheless, the information's value for market monitoring remains high.⁷³⁶

l. Prices and Cost Averaging

Market designs that base prices on the averaging or socialization of costs,⁷³⁷ may distort consumption, production, and investment decisions and ultimately lead to economically inefficient outcomes. Where possible and cost effective, cost causality principles can be used to price services and eliminate averaging.⁷³⁸

For example, in some congestion management mechanisms, the cost of alleviating congestion is spread over all loads. This scheme could have some generators creating monetary benefits for other generators. In addition, it could lead to over-consumption of power by some loads and under-consumption by other loads. Moreover, such averaging mechanisms for congestion management do not send the correct price signals for the location of new generation, thus leading to problems with long-term implications.⁷³⁹

Moreover, if pass-throughs or uplift charges are paid by all load to ensure bid-cost recovery, as in some approved ISO market designs, it may be appropriate to couple these pricing mechanisms with incentive mechanisms for the RTO to control them.

⁷³⁶ The Commission approved the disclosure of bid information in the following orders. See PJM Interconnection, L.L.C., 86 FERC ¶ 61,247 at 61,890, order on reh'g, 88 FERC ¶ 61,274 (1999); Central Hudson Gas & Electric Corp. et al. 86 FERC ¶ 61,062 at 61,204, order on reh'g, 88 FERC ¶ 61,138 (1999).

⁷³⁷ Socialization of costs means that costs that could be assigned to a particular market participant(s) are instead spread over all participants regardless of whether or not they caused the costs.

⁷³⁸ While it is desirable from an efficiency standpoint to eliminate the averaging of costs, the costs associated with calculating cost causation in some instances could be shown to outweigh the benefits of eliminating averaging.

⁷³⁹ MSC October Report, at 112.

I. Collaborative Process

The Commission proposed a regional collaborative process to facilitate the creation of RTOs. State commissions had encouraged the Commission to sponsor activities in each region of the country that will bring together representatives of public and private electric utilities, state regulators, consumer groups, representatives from Canada or Mexico, as appropriate, and any other interested parties that need to be part of such a process. The Commission proposed that regional workshops be held after the Final Rule is issued to determine what, if any, impediments exist to the formation of RTOs in a particular region and how the Commission staff could help to overcome those impediments. Staff resources that will be available for the collaborative process include technical staff, dispute resolution staff, and any other staff assistance that would be beneficial.

Comments. Almost all commenters support the Commission's collaborative proposal. Of the 49 comments that addressed this issue, 47 are generally supportive. These commenters include a number of state commissions.⁷⁴⁰ In addition, NARUC supports the continuation of a "dynamic process requiring continuing dialogue between FERC and the states." A number of public power entities also support the process.⁷⁴¹ Numerous Canadian entities also filed comments regarding the usefulness of a collaborative process for the international aspects of RTO formation.⁷⁴²

Only Florida Commission and CP&L are not fully supportive. Florida Commission suggests that FERC collaboration will not work in Florida but may work in other regions of the country. CP&L is not supportive because the collaborative process could be used by the Commission "as a means of forcing utilities to develop RTO proposals on the Commission's timetable" which results in the Commission "being disingenuous when it describes its RTO policy as 'voluntary'." Otherwise, CP&L believes the conferences will only serve as an opportunity for participants to "posture" and that limited Commission resources should not be used for

⁷⁴⁰ See, e.g., Nine Commissions, Illinois Commission, Indiana Commission, Michigan Commission, Montana Commission, Nevada Commission, South Carolina Commission, Wisconsin Commission and Wyoming Commission.

⁷⁴¹ See, e.g., APPA, NRECA, CMUA, SRP, Snohomish, Seattle, RUS, East Texas Cooperatives, IMEA, and Arkansas Cities.

⁷⁴² See, e.g., Powerex, BC Hydro and Canada DNR.

meetings that "are not likely to produce positive results."

Specific comments about the collaborative process address three basic issues: inclusiveness, process and procedures, and outcomes.

Inclusiveness. The NOPR stated that "the Commission expects public utilities and non-public utilities, in coordination with appropriate state officials, and affected interest groups in a region to fully participate in working to develop an RTO." It further stated that the regional public workshops will be convened in cooperation with the affected state officials and that transmission owners and operators will be invited.

Many commenters advocate an open collaborative process that would include a full complement of participants. They suggest that the regional meetings include representatives of all stakeholders, for-profit transmission companies, not-for-profit transmission entities, state regulators, state legislators, state Governors, state energy officials, state and non-state consumer advocates, state economic and environmental regulators, environmental action interests and public power/municipals. Some commenters indicate that in certain regional efforts to form an RTO, the deliberations have excluded key interests and, as a result, the outcomes were not widely supported. For example, PJM/NEPOOL Customers note with respect to the PJM formation process that "[O]nly after all stakeholders were included in organizational discussions was true progress made toward implementing an ISO that adequately addresses all parties' needs." PNGC states that "[I]f other users do not have a seat at the table while merchant functions do, obviously a level playing field is not created." New Orleans cites Entergy's "failure to even attempt to build a regional consensus concerning its transco as a reason that inclusive regional conferences are needed."

Process and Procedures. Commenters raise a number of questions regarding the collaborative process and specifically with respect to the regional public workshops. Many commenters support the use/availability of the Commission's Dispute Resolution Service (DRS) staff or the use of outside facilitators. Some commenters request that the Commission clarify that the meetings will be open meetings that can be attended by any person. Several commenters urge the Commission to take the cost and travel time to attend meetings into account in planning the regional public workshops. Some

specific locations are suggested for sites for the regional workshops: New Orleans, Minneapolis/St. Paul, and Seattle or Portland.

Several commenters suggest that the collaborative process begin prior to spring 2000 in at least one region of the country—the Upper Midwest. Commenters suggest that there is no need to wait and that the region would benefit by immediate assistance from Commission staff as described in the NOPR.

Some commenters ask the Commission to be mindful that the number of regional meetings scheduled may not only be costly but unproductive as well. Two commenters specifically say that we must not allow the "death by meetings" syndrome to be realized. Some interests may want to stall RTO formation by promoting an "endless" series of meetings that are not productive but are designed to "preserve the status quo." A few commenters suggest that the role of Commission staff at the regional events should not be that of meeting referee but primarily to provide policy guidance on key RTO issues and proposals. NRECA proposes the creation of several Commission staff teams to "facilitate and informally monitor each RTO formation process" and provide "neutral guidance" in the regions. Some commenters ask that the Commission establish procedural rules in writing in advance of the regional workshops so that all parties will know and understand the rules prior to the meetings. Some commenters also request that all reports, information and data produced for the meetings be readily available to all participants.

Outcomes. The Project Groups suggest that the Commission should "clearly delineate the substantive results expected" from the collaborative process. They suggest that collaboration progress reports be filed with the Commission and that "work products" be required, including: (1) Identification of RTO boundaries; (2) a list of all transmission owners and facilities in the region; (3) a draft operating agreement; (4) a draft governance structure and bylaws; (5) proposed operating protocols; (6) a proposed budget/financial structure; (7) a draft tariff; and (8) how the proposals meet the Commission's guidelines, including a timetable.

Commission Conclusion. A key element of this Final Rule is our commitment to the use of the collaborative process to assist in the voluntary formation of RTOs. By collaborative process, we mean a process whereby transmission owners,

market participants, interest groups, and governmental officials can attempt to reach mutual agreement on how best to establish RTOs in their respective regions. We reiterate our commitment of Commission staff resources, to the extent possible, to assist parties in developing RTO proposals.

We are encouraged that state Commissions, public utilities, public power entities and cooperative utilities, power marketing interests, and consumer and environmental groups support the use of a collaborative process. We are further encouraged that efforts to develop RTOs continue in the West and Midwest, and that other areas are reviewing the potential benefits of RTOs in their respective areas. We believe that this represents a growing recognition throughout the nation that RTOs will improve competition in electric markets and enhance the reliability of the nation's electric grid.

We welcome participation in the RTO collaborative process by our sovereign neighbors, Canada and Mexico. We believe that it is in our mutual best interest to have electricity flow efficiently and economically across our international boundaries. We pledge to continue to work cooperatively with officials from Canada and Mexico to encourage the operation and improvement of an international electric system that benefits all consumers.

The Commission believes that the collaborative process must accommodate the fact that different regions of the country are in different stages of RTO formation and must be flexible enough to allow for these differences. Therefore, we will initiate the collaborative process with a series of five workshops in the Spring of 2000. The primary objective of each workshop will be to develop a consensus agreement by regional participants establishing a strategic process and a schedule for any further collaboration. The appropriate collaboration process will depend on whether the region is considering formation of an ISO, transco, or other form of RTO. To achieve this objective, participants will share information about the status of RTOs or RTO proposals in the region, identify impediments to RTO formation in the area, explore which process(es) could most expeditiously advance agreements on RTO formation, and determine what role(s), if any, Commission staff should play in advancing discussions in each region. One result of these discussions may be regional decisions that more than one RTO would be appropriate in the area encompassed by participants at the workshop. Therefore, the collaborative

processes that follow the various workshops may differ significantly. This includes possible variations in the role that will be played by Commission staff in each RTO formation effort.

The Commission believes that regional workshops in the Spring of 2000 will expedite the RTO formation process. In selecting locations for the initial Spring 2000 workshops, we recognize trends in the broader regionalization of the nation's electric system. We also consider the evolving electric markets as well as the configuration of the regional grid. We emphasize that the selection of locations for initial workshops is not to indicate a preference for specific RTO boundaries, but to provide convenient workshop locations. With these considerations in mind, we designate the following workshop locations. Parties may attend more than one regional workshop. We expect all transmission owners to attend at least one workshop.

Workshops will be held in the following cities in February, March or April, 2000:

1. Philadelphia, Pennsylvania
2. Cincinnati, Ohio
3. Atlanta, Georgia
4. Kansas City, Missouri
5. Las Vegas, Nevada

Workshops are expected to last for two days. Additional information about the regional workshops will be provided in January 2000.

At the request of parties, the Commission staff may play a role in the formation of RTOs. Commission staff will convene the regional RTO workshops and provide policy and technical guidance consistent with this rule. The Commission will supply meeting space for the five initial Spring 2000 workshops. Regional participants are expected to bear the costs of collaborative meetings after the initial five workshops. Commission staff time and staff travel expenses will be provided as resources allow.

We believe that it is critical to make the Spring 2000 Workshop phase of the collaborative process open to all interested parties. In order to promote an open process, we will provide public notice of Spring 2000 Workshop events to allow all interested parties to attend. We shall also make available agendas and procedural rules to all parties in advance of the regional workshops. Agendas may vary from one workshop to another.

The Spring 2000 Workshops represent the initial step of the collaborative process. We expect that other meetings will be convened following the

workshops by parties in each region to bring the parties together to form an RTO in each region. Commission staff may also convene additional meetings if this would help RTO formation. The post-workshop meetings of parties in regions may be held with or without Commission staff participation. We will make available the Commission's Alternative Dispute Resolution staff upon the request of an RTO group in formation. At the request of such a group, independent private professional facilitation services may be arranged by Commission staff and must be sponsored by the parties within the region. As needed and requested by parties forming an RTO in a region, Commission staff members will be available to act as settlement judges, mediators, facilitators or observers.

We believe that the best interests of the nation's electric consumers will be served by the formation of RTOs. Therefore, we encourage parties to establish strategic schedules at the Spring 2000 Workshops and to convene subsequent meetings with the goal of forming an RTO expeditiously. Commission staff will monitor progress with respect to the results or outcomes in each region.

We expect that, following the initial Commission-sponsored workshops, parties in each region will work collaboratively to identify the appropriate RTO regions, identify all transmission owners and facilities in each region, and develop a timely application in accordance with the Final Rule.

We have designated James Apperson of the Commission Staff to serve as the collaborative process contact. He may be contacted at (202) 219-2962 with any questions or comments about the RTO collaborative process.

J. Implementation Issues

1. Filing Requirements

In the NPR, the Commission proposed that all public utilities that own, operate or control interstate transmission facilities (except those already participating in a regional transmission entity in conformance with the eleven ISO principles enumerated in Order No. 888) must file with the Commission by October 15, 2000 either (1) a proposal to participate in an RTO that will be operational no later than December 15, 2001, or (2) an alternative filing describing efforts to participate in an RTO, obstacles to RTO participation, and any plans and timetable for future efforts.⁷⁴³ For those public utilities that

file an RTO proposal on or before October 15, 2000, we proposed to permit them to file a petition for a declaratory order asking whether a proposed transmission entity that would be operational by December 15, 2001, would qualify as an RTO, with a description of the organization and operational structure, a list of the intended participants of the institution, an explanation of how the institution would satisfy each of the RTO minimum characteristics and functions, and a commitment to submit necessary FPA section 203, 205 and 206 filings promptly after receiving the Commission's determination on the declaratory order petition. Finally, we proposed that the requirements not apply to a public utility that owns, operates or controls transmission that also is a member of an existing transmission entity that the Commission has found to be in conformance with the Order No. 888 eleven ISO principles; instead, each such public utility would be required to make a filing no later than January 15, 2001, that (1) explains the extent to which the transmission entity in which it participates meets the minimum characteristics and functions of an RTO; (2) proposes to modify the existing institution to become an RTO; or (3) explain efforts, obstacles and plans with respect to conforming to these characteristics and functions.

Comments. Most commenters responding on this issue oppose one or more aspects of the proposed filing requirements. For example, a number of public utilities and two state commissions argue that the October 15, 2000, filing requirement does not provide enough time. Southern Company contends that the proposed filing deadline requirement is likely to be counterproductive because it imposes an artificial deadline that may interfere with regional discussions. Moreover, once established, a prematurely formed RTO may itself prove to be an obstacle to more effective transmission organizations. Southern Company also claims that the proposed mandatory filing requirements are inconsistent with a truly voluntary approach. If the requirement is retained, Southern Company suggests that the Commission clarify that the alternative filings will be treated as status reports and not be subject to deficiency orders or otherwise lead to proceedings in which punitive measures might be taken, because any consideration or use of penalties seriously undermines the Commission commitment to the voluntary nature of RTOs.

Wyoming Commission recommends that the deadlines not be made

⁷⁴³ FERC Stats. & Regs. ¶ 32,541 at 33,761-63.

mandatory in any way in the Final Rule because RTO formation is supposed to be voluntary. Since it is unclear as to what happens to those entities who file an explanation as to why they did not join an RTO, Wyoming Commission urges the Commission to defer to each region's process and timetable in developing an RTO and acknowledge that not all regions are processing at the same pace. It recommends that the Commission convert the October 15, 2000, deadline into a milestone for reporting RTO development.

CP&L submits that the time frame is unrealistic because it contemplates that new RTOs can be developed, approved by the Commission, set up, and begin operation in less than two years. Experience has shown that almost every RTO to date has taken at least four years to go through that process. Therefore, the Commission should modify the filing requirements to simply require informational filings on the status of RTO development.

Sierra Pacific is concerned about insufficient time being allowed for transcos to form. It points out that the precedent regarding ISOs is much more well-developed than that regarding transcos. The certainty surrounding ISOs makes them more attractive particularly when a decision to form the entity must be made relatively quickly to meet the proposed October 15, 2000, filing date. To lessen the incentive to rush to join an ISO, Sierra Pacific suggests that: (1) The date for filing an RTO proposal should be extended to June 15, 2002; (2) the Commission permit transition mechanisms that will allow transmission owners to eventually join transcos; and (3) the Commission not require participation in an ISO to become a trap from which a transmission owner cannot extricate itself. ComEd provides supporting arguments, noting that where divestiture of transmission assets is involved to form transcos, the necessary transition period will largely be dictated by the sheer complexity—legal, financial (bonds and mortgage), real estate (titles/easements), taxation—of separating a designated portion of any electric utility that has historically been a vertically integrated utility.

Based on its experience with the Midwest ISO formation process, Kentucky Commission also argues that the proposed date to join an RTO or respond with reasons for not joining is too short. It points out that, if the Commission completes the Final Rule by the end of 1999, transmission owners will have less than one year to make a final decision on participation. Kentucky Commission urges the

Commission to give transmission owning utilities additional time to look into joining an RTO, so that RTOs are not pushed so quickly that the best model fails to materialize as a result of market evolution that remains underway. South Carolina Commission and Big Rivers share the concern that the proposed timeframe is too ambitious, given the complexity of RTO related matters and the need to reach some level of consensus among those with vested interests.

Several commenters noted that meeting the October 15, 2000, filing requirement will depend on the Commission's standard of review of those filings. For example, TDU Systems observes that the proposed filing requirements have no teeth. TDU Systems contends that a public utility that decides not to participate in an RTO can make an alternative filing setting out the reasons why it is not doing so and what plans it has to work towards participation. In TDU Systems' view, while the proposed regulations are consistent with voluntary participation, they are inconsistent with full and effective participation in RTOs. TDU Systems counsels that the Commission should resist calls to water down the RTO regulations even more, so as to treat alternative filings as mere status reports that allow transmission monopolists to hold on to their monopolies.

Duke submits that if the Commission is willing to accept valid, well-justified explanations as to why a utility has not become an RTO member, the October 15, 2000, filing requirement is reasonable, noting that until state commission review of restructuring and RTOs is completed, it may be premature for a utility to commit resources to RTO membership. Similarly, Iowa Board suggests that, where transmission providers are making legitimate progress, a report to that effect should not be received with automatic disfavor. Alternative filings and legitimate progress reports should be given equal validity with definitive proposal filings.

A few commenters explicitly support the October 15, 2000, filing requirements. For example, SRP believes it to be an acceptable balance between mandated participation and the status quo. PJM/NEPOOL Customers also support the filing by a date certain because this would expedite the collaborative process and ensure that no entity can effectively block RTO formation by engaging in inappropriate negotiation tactics. And Oglethorpe views the October 15, 2000, time frame as necessary to assure the timely development of RTOs and help develop

fully competitive efficient wholesale markets. Cinergy, noting that only after the Commission has had opportunity to review the October 15, 2000, filings will it be able to determine whether it should order participation in or reconfiguration of particular RTOs, suggests that by April 15, 2000, all public utilities be required to file a statement of position in which each utility identifies each state in which it owns transmission, and the RTO in which it is considering membership and its potential scope and configuration to the best of its knowledge.

A number of commenters address issues and treatments relating to existing ISOs. Virtually all of the existing ISOs assert that the Commission should allow the previously Approved ISOs to continue to develop without undue interference in order to foster experimentation and testing of proposals.⁷⁴⁴ Cal ISO argues that the Commission should find that existing regional entities generally meet the RTO criteria and that the Commission should confirm its determination not to require substantial changes in approved ISOs that would undermine difficult to reach consensus on critical issues. Similarly, the Pennsylvania and New York Commissions recommend that FERC grandfather the existing ISOs that meet the RTO characteristics and functions. The Pennsylvania Commission states that it does not want to tinker with the inner workings of PJM, nor constantly revisit and revise operations and functions. The New York Commission is concerned that the New York ISO tariff may have to incorporate the "ordinary negligence" liability and indemnification provisions set forth in the pro forma tariff if the ISO becomes qualified as an RTO, and that this will increase the ISO's exposure to litigation. The South Carolina Commission supports NARUC's position urging the Commission to grandfather existing ISO boundaries that are satisfactory to the states. Similarly American Forest, CalPX and Mid-Atlantic Commissions want the Commission to respect existing ISOs.

Furthermore, PJM/NEPOOL Customers contend that their ISOs are in basic conformance with the minimum functions and characteristics. To the extent that any deficiencies are found, the ISOs should be allowed to engage in continued experimentation without interference from the Commission. The Wyoming Commission also fails to see why existing ISOs, already having gone through a rigorous approval process, should have to re-certify as RTOs.

⁷⁴⁴ See, e.g., NY ISO, Cal ISO, NYPP and ISO-NE.

Moreover, EEI notes that the Commission should weigh the incremental gains achieved through economies of scale, efficiency, and additional savings against the potential incremental costs of reorganization, new computer programming, infrastructure changes, and changes required to achieve effective communication and coordination. NYPP proposes that ISOs be allowed to evaluate the costs and benefits of forming an RTO after some years of market experience; hence, they oppose putting members of existing ISOs on the same time frame for compliance as non-members of ISOs/RTOs. United Illuminating recommends that the Commission continue to honor and not abrogate pricing arrangements of existing ISOs. United Illuminating also contends that, since existing ISO members have no opportunity to discriminate because they have turned control of their transmission over to their respective ISO, the Commission cannot generically abrogate existing ISO pricing arrangements pursuant to its FPA section 206 authority in this rulemaking. Central Maine offers that consolidating the PJM, New England and New York ISOs into a super-ISO will require costly expansion of telemetry, communication, and computer equipment, that it could result in a decrease in reliability, and that simple interregional coordination could accomplish the Commission's goals without consolidation.

A few non-ISO entities oppose any grandfathering of existing regional transmission organizations.⁷⁴⁵ For example, New Orleans argues that the Commission should not exempt existing regional transmission entities from requirements of RTO formation because only through universal application will all regions of the country receive the benefits of open and competitive electric markets. H.Q. Energy Services suggests that a larger territory, such as the combined territory served by the existing New York, PJM and New England ISOs, would be more effective than the NY ISO standing alone. PG&E counsels that freezing the existing ISO structures in place would not serve reliability or the marketplace and would be inconsistent with the open architecture requirement. It believes that the Commission has struck an appropriate balance imposing a reporting requirement on existing ISOs.

Most commenters agree that existing operational transmission entities should gradually evolve toward RTOs during a transition period, rather than making

immediate and drastic changes.⁷⁴⁶ According to SMUD, a transition period will enable customers to avoid bearing unnecessary costs.

A few commenters address the specific filing requirements outlined in the NOPR. The New York Commission asserts that the NY ISO should not have to make a filing because it possesses the requirements of an RTO. In addition, the Cal ISO argues that existing entities, rather than individual public utilities, should be responsible for the RTO filing requirements. Likewise, PJM suggests that existing ISOs report to the Commission prior to any report by its public utility members, as the existing ISO is in a better position to provide the Commission with the most accurate information by which to evaluate whether the ISO satisfies the minimum characteristics and functions for RTOs. PJM suggests that existing ISOs and existing transmission entities file reports no later than December 31, 2000, explaining whether they satisfy the Commission's requirements for RTOs and identifying any additional authority they may require for this purpose. On the other hand, EPSA welcomes the proposal requiring a showing of how the existing transmission institutions meet the minimum characteristics and functions by January 15, 2001, as a way to help address and solve continuing discrimination within current ISOs and address whether these institutions should be combined into larger groupings. Similarly, NYC wants the NY ISO's January 15, 2001, filing to demonstrate how its efforts to improve regional cooperation will overcome the institutional impediments that have contributed to the city's load pocket condition.

Finally, commenters raise a number of miscellaneous issues: Puget questions whether there will be negative implications for any entity that choose to cease participation in an RTO; DOE points out that RTOs may need to fund pensions for transferred employees, and existing transmission providers may need to fund early retirements or other compensation for displaced employees; UMPA recommends that recourse to the Commission in a *de novo* capacity must be part of all RTO dispute resolution procedures; and Indiana Commission, Snohomish and Midwest ISO express concern about how the Commission intends to handle multiple RTO proposals covering approximately the same region.

Commission Conclusion. The Commission will adopt the NOPR proposal requiring that all public utilities that own, operate or control interstate transmission facilities (except those already participating in an approved regional transmission entity) file by October 15, 2000, either a proposal to participate in an RTO or an alternative filing describing efforts and plans to participate in an RTO. As proposed initially, we will consider a petition for declaratory order setting forth the items listed in section 35.34(d)(3) as a proposal to participate in an RTO.

We believe that the October 15, 2000, date for filing proposals is realistic. It is not overly aggressive, given the amount of guidance we have provided in this Rule and the amount of flexibility we are permitting in how to satisfy the minimum characteristics and functions. In addition, the collaborative process that we are promoting in this Rule will provide an opportunity for all interested parties with their varied interests to resolve many of their differences, in advance, and reach consensus on the RTO solution that best fits the overall needs of their respective region. The October 15, 2000, filing date should help keep the parties focused and accelerate their efforts toward selecting an appropriate RTO model.

The October 15, 2000, date for filing is also reasonable because, even if a public utility is unable to file an RTO proposal at that time, we are permitting the public utility to make an alternative filing reporting on the status of pertinent RTO formation and development, the obstacles that have prevented the filing of an appropriate RTO proposal, and any of the public utility's plans and timetable for future efforts directed toward RTO formation and participation.⁷⁴⁷ Given the importance that the Commission places on RTO development, it is important for us to understand no later than October 15, 2000 just how much progress the industry is making on forming RTOs. If the October 15, 2000, filings reveal obstacles that prevent serious progress toward RTO formation are reported for a given region, we will be able to act early enough to provide guidance on what steps we think are appropriate to help address the obstacles (e.g., further collaborative efforts). And where serious regional progress is reported, but more time is requested in connection with meeting a particular RTO requirement, we will be able to act early enough to try to accommodate the local needs,

⁷⁴⁵ E.g., Illinois Commission, New Orleans, SMUD and Turlock.

⁷⁴⁶ See, e.g., SMUD, PJM/NEPOOL Customers, NYPP, Cal DWR, MEAG, American Forest and Central Maine.

⁷⁴⁷ Of course, these reports may be filed prior to October 15, 2000.

complications and complexities that the particular region faces.

Some concern has been expressed that the October 15, 2000, filing date is too short to allow transcos to form because of the inherent legal, financial, real estate and taxation complexities associated with the transfer of ownership of the affected transmission assets. We are not proposing that the restructuring be completed by October 15, only that a proposal be filed, or an alternative filing as described in this Rule. Moreover, we take note of the fact that other forms of major corporate restructuring, including mergers, have proceeded from initial idea to formal proposal in a shorter time when the motivation is sufficient. Therefore, we do not think the time allowed is too short for transco proposals.

We also reaffirm the proposed January 15, 2001, filing date for transmitting public utility members of an existing approved transmission entity to address the extent to which that entity conforms to the minimum characteristics and functions of an RTO, any plans to make it conform, and any obstacles to full conformance with our Final Rule. We note that RTOs will not be "starting from scratch." There is significant information available about both the good and bad experiences with ISOs, and this information should help RTOs meet this filing deadline.

While we are allowing a later filing date for existing transmission institutions to file (January 15, 2001, versus October 15, 2000), we do this because, in general, the transmission owners in those regions have already made substantial progress in establishing regional entities. Nonetheless, the Commission needs to know, for all regions, including those covered by existing approved transmission institutions, the extent of progress toward formation of fully functional RTOs. To the extent that an existing ISO, for example, is less than adequate with regard to one of the necessary characteristics or functions, we would expect the existing institution to be working on a plan of action to make the remedial improvements that are required to bring it into conformance with the Final Rule.

In sum, we continue to believe that the October 15, 2000, and January 15, 2001, filing dates represent an acceptable balance between the need to move toward RTOs as soon as possible and the need for sufficient time for transmission owners and market participants to develop proposals.

2. Deadline for RTO Operation

The Commission proposed that all public utilities participate in an RTO that will be operational by December 15, 2001. In addition, we contemplated implementation of the congestion management function within one year after startup (by December 15, 2002), and implementation of inter-regional parallel path flow coordination and transmission planning and expansion functions within three years after startup (by December 15, 2004).⁷

Comments. Most commenters suggest the December 15, 2001, deadline should be changed to a later date or that the Commission provide greater flexibility in meeting the deadline. On the other hand, Oregon Commission explicitly favors the December 15, 2001, deadline, arguing that the time line is designed in stages so that the easiest requirements come earliest. EPSCA fears that further delay of any of the operational deadlines for any of the required RTO functions (*i.e.*, for initial startup, congestion management, parallel path flow coordination, or transmission planning and expansion) will only encourage further debate and dialogue without driving the industry towards acceptable resolutions, and prolong the problems of residual discrimination and remaining market inefficiencies.

Two commenters propose an earlier deadline. PG&E contends that the transition period for RTOs to meet all requirements must be as short as possible—no more than one or two years to fully operational RTOs may be reasonable. Sithe similarly argues that, while the negotiations and proceedings associated with voluntarily RTOs can take years to complete, the California experience suggests that an RTO can be established quickly if a deadline exists. Sithe recommends that the Commission reconsider its time frame and do everything it can to hasten the process of putting in place RTOs with all minimum characteristics and functions. It observes that, as proposed in the NOPR, an RTO could defer for up to three years the filing of a plan for transmission planning and grid expansion. The details may not be finally approved by the Commission for at least another year such that a delay of over five years could result.

SRP and American Forest express concern about who will be responsible for building and paying for new transmission facilities until the RTO takes on this responsibility. In particular, SRP suggests that the Commission require each RTO filing to describe who will be responsible for

financing and building transmission expansions during the interim.

Most commenters, however, view the proposed deadline as too aggressive, and recommend that it be eliminated or extended. CP&L views the operating deadline as arbitrary and capricious, and argues that the deadline will impose higher implementation costs and inefficiency that will not benefit the public or the industry. South Carolina Authority believes that to assume that a large group of stakeholders with diverse interests can somehow come together and agree on a particular RTO model and configuration by October 15, 2000 that is up and running by December 31, 2001, is unrealistic. East Kentucky suggests that the timetable be extended approximately two years. Montana Power encourages extension by one year because areas like the Pacific Northwest will probably need significant infrastructure to be developed or re-deployed and the 14 month time frame contemplated after RTO proposals are due on October 15, 2000, is not sufficient time.

A number of commenters favor a flexible approach and allowing provisional RTO status. Cinergy offers that, to overcome obstacles such as legal impediments to public power participation, alternative means of RTO participation be considered such as joint operations without the functional integration of public systems' facilities to allow them to control the private use of their systems. SERC generally concurs. Williams contends that not all RTOs will be able to develop at the same pace, and supports provisional RTO status with dates certain respecting those functions not able to be performed at startup.⁷⁴⁸ SNWA recommends that, if necessary, a phase-in approach should be used in the implementation of an RTO to smooth the implementation process. Project Groups contends that, given the California experience, the cost of attempting to do everything at once is significant. Transmission ISO Participants urges flexibility for transmission owning members of exiting ISOs since the current structure represents an imperfect and probably unfinished agenda. EEI contends that the Commission should allow flexible timetables to establish RTOs that are transcos, contending that a vertically integrated utility that selects the option of moving transmission assets to a transco faces complex financial and tax issues. Nevada Commission urges the

⁷⁴⁸ Note that a number of comments opposing deadlines are based on the difficulty of attaining specific RTO functions. These comments are also addressed in the sections regarding the specific functions.

Commission to clarify that there is no prohibition against forming interim organizations such as an independent system administrator until such time as a viable RTO for the region is formed. South Carolina Commission claims that each RTO proposal should be reviewed on a case-by-case basis for general adherence to the Commission's overall policy goals.

Indiana Commission cautions, however, that careful consideration should be given to what will be lost by the acceptance of an RTO "lite." It argues that existing transmission entities may see little value in maintaining relatively high standards and could view the Commission acceptance of lower standards as an incentive to gravitate to lower standards. PG&E recommends the Commission grant waivers from its requirements only in limited cases and only for short durations. AEPSCO, contends that there should be a reasonable basis for granting waivers, particularly for non-jurisdictional entities. In particular, a request for waiver should consider: (1) How much additional RTO transmission would result from inclusion of the facilities in an RTO; and (2) whether the RTO would be functional without inclusion of the entity's facilities. Sithe argues that care should be taken when considering whether to permit RTOs to go into effect without meeting functions and in granting waivers, and suggests that the Commission establish clear requirements for RTO approval, strictly scrutinize proposals, and not hesitate to reject inadequate proposals.

Commission Conclusion. We have decided to retain the originally proposed startup and other functional implementation deadlines (RTO startup by December 15, 2001, implementation of congestion management by December 15, 2002, and implementation of the parallel path flow coordination and transmission planning and expansion functions by December 15, 2004).

As a general proposition, we believe that, given the urgent needs of electricity markets as discussed elsewhere in our Final Rule, we have an obligation to promote RTO operation at the earliest feasible date. Even where a market may already be served by an ISO or other approved transmission entity, we are concerned that such market may remain hampered to the extent that the approved entity has yet to fully conform with our Final Rule.

In response to those who contend that December 15, 2001, is too ambitious for RTO start-up, we note several points. First, we, and the industry, now have had the benefit of the experience of the

formation of five ISOs under Commission jurisdiction, an ISO in ERCOT, some international experience with regional transmission entities, and substantial discussion of the subject of regional transmission entities within the industry. While the timeframe we are suggesting for RTO formation may have been unrealistic several years ago, much has been learned since then which should facilitate more rapid formation.

Second, our Final Rule is providing substantial flexibility that should permit an RTO to satisfy the minimum characteristics and functions in a cost efficient manner. For example, we are not requiring control area consolidation; we are not requiring the establishment of a PX; we are allowing an RTO to meet its operational control obligation through indirect or hierarchical control arrangements via contractual agreements with the existing infrastructure such as transmission owners and control area operators; and we are allowing an RTO to satisfy its security coordinator functions through contractual arrangements with an external security coordinator, as long as it is independent. An acceptable RTO structure need not be a monolithic organization that requires an extended period of time to become fully set up so that it can directly "push all of the buttons." Moreover, we are allowing a longer phase-in period for functions that may be more difficult to establish, such as congestion management, parallel path flow measures, and transmission planning and expansion.

With respect to the comments that question the December 15, 2002, deadline for implementing the congestion management function, we believe that lack of effective and market-oriented congestion management is a critical issue in the industry, and that it needs attention soon. We acknowledge that developing a sophisticated congestion management program can be an extremely complex and time consuming matter. However, implementation of economic approaches to congestion management by some of the approved ISOs shows the feasibility of these concepts where there is an institution to undertake the organization of this function over a large area.

Some say that transmission congestion is not a serious problem in their regions, and that they therefore should not be required to develop a complex congestion management plan within a short time-frame. We agree that an RTO should not have to expend large resources to address a problem that does not exist. However, we are concerned that an RTO fully analyze the extent to

which transmission congestion does or could interfere with electricity sales in its region, and that it be prepared to address congestion if it becomes a more serious problem through changing markets. As markets become more competitive and the volume of discrete transaction increases, transmission congestion may become serious unless action is undertaken beforehand. Where transmission congestion is infrequent, this Rule does not preclude the establishment of relatively less complex forms of market-compatible congestion management such as generation redispatch protocols.

In sum, we think that the phased startup and other functional implementation deadlines are reasonable.

3. Commission Processing Procedures

The Commission recognized that RTO formation would be complicated by the requirements for Commission approval of transfer of control of jurisdictional facilities under FPA section 203 and Commission approval of RTO transmission rates, terms and conditions under FPA section 205. In the NOPR, the Commission requested comments on whether the Commission should provide expedited or streamlined processing procedures for RTO filings and asked for suggestions regarding how the Commission can further expedite and streamline procedures.⁷⁴⁹

Comments. Views on streamlined and expedited processing of RTO filings are mixed. Commenters that generally favor streamlining include Desert STAR and TEP, which suggests that filing requirements be kept simple and flexible.

A number of commenters offer specific suggestions for streamlining and expediting the process, including:

- Florida Commission believes that once an RTO or other structure has been agreed upon by a group of entities, the Commission should expedite all required processes in order to allow the participants to start implementing the agreed upon changes.

- Tallahassee recommends that the Commission should clarify that it is not revisiting the functional test for distinguishing transmission and distribution facilities addressed in Order No. 888.

- Entergy asserts that significant delay in obtaining Commission approvals will make it difficult for Entergy to institute a transco within the time-lines established by state restructuring laws in Arkansas and Texas. Providing clear rules on the

⁷⁴⁹FERC Stats. and Regs. ¶ 32,541 at 33,759.

required and permissible features of RTOs as the Commission did in its July 30, 1999 Declaratory Order for Entergy and providing clear standards on pricing policies will help. Entergy argues that the Commission should make explicit its willingness to consider requests for expedited approval when a showing is made that expedition is necessary, as it has done for California ISO.

- Trans-Elect notes that if a transfer of facilities cannot close under Section 203 until the related FPA section 205 proceeding is concluded, an expedited Section 205 filing must also take place. One way to do this is to waive an Initial Decision and set a date certain for the Commission's section 205 decision.

- PJM/NEPOOL Customers recommend that a standard RTO governance structure be adopted that allows participation by all stakeholder groups. It would expedite processing by requiring that any RTO filing demonstrate that all stakeholders were included in the formation process.

- SMUD recommends that the Final Rule require that RTOs be designed, developed and implemented in a manner that does not require numerous tariff amendments to remedy market ills that could be addressed prospectively or at a speed that does not dramatically increase RTO development costs.

On the other hand, some commenters urge the Commission to exercise caution regarding streamlining and expediting:

- East Texas Cooperatives observes that a poorly configured RTO can potentially be more harmful to the industry than the status quo, by allowing large transmission owners to dominate regional grid management, maintain pancaked rates and discriminate in allocating transmission revenue.

- Indiana Commission recommends that state commissions and other interested parties have full opportunity to thoroughly review, comment, and have an impact on the RTO proposals once they are filed with the Commission.

- Puget indicates that a negative implication of allowing streamlined filing and approval procedures for RTO participants is that regulatory burdens will be leveled against nonparticipants while those who join an RTO will be freed from what the Commission implicitly recognizes are unnecessary requirements. A truly voluntary system would not continue to impose unnecessary regulatory requirements on nonparticipants and there is no reason for the Commission to delay implementing these regulatory reforms

now before a final decision is made regarding the wisdom or efficacy of RTOs, or to condition the implementation of such reforms on an entity's participation in an RTO.

- Duke contends that, given the size and complexity of the typical section 203 and 205 of the FPA filings, it is not clear that reducing the time that parties are granted to review such filings and provide initial comments may be appropriate. Nonetheless, the Commission should work to dismiss irrelevant issues used as leverage to extract concessions unrelated to RTO formation, it should consider use of less formal hearing procedures for issues that do not require discovery, and the Commission should limit the time period allowed for evidentiary hearings. Duke acknowledges that the effect of streamlined filing and approval procedures could be to reduce costs that would otherwise be born by market participants.

Commission Conclusion. While there is broad-based consensus for simplifying the Commission's RTO filing process and responding to RTO proposals expeditiously, we must maintain an appropriate balance between streamlining and expediting the filing and processing of RTO proposals and ensuring due process and the development of an adequate record. Given the amount of flexibility we have built into the Rule as to organizational structure, it is difficult to predict what issues will be raised by the RTO proposals and the degree of complexity raised by such issues. Accordingly, while the Commission has the goal of ensuring the rapid formation of RTOs, and will attempt to process each RTO proposal as expeditiously as possible, certain RTO proposals will take longer to analyze and review depending upon the complexity of the issues and the level of support among the affected parties. Therefore, in addition to the specific guidance provided elsewhere in this Rule, we provide further guidance and note the following factors which are intended to assist public utilities in streamlining their required filings and help expedite the processing of the RTO proposals.

One factor that should facilitate faster processing is that the Final Rule permits delayed implementation dates for various highly complex FPA section 205 related RTO provisions (congestion management by December 15, 2002, and parallel path flow coordination and transmission planning and expansion each by December 15, 2003). Therefore, initial RTO proposals need not contain the details for these provisions, but need only contain a commitment to complete

the provision and a timetable for submitting appropriate future filings. Likewise, we need not act on those matters initially in our RTO orders.

Expeditious processing of an RTO submittal is more likely to occur if the RTO proposal is the result of a comprehensive and open collaborative process with widespread support from transmission owners, market participants, and affected state commissions. While we cannot pre-approve unopposed proposals, many of our potential concerns could be minimized to the extent the proposal has broad support.

Another potential streamlining measure is that public utilities are permitted to file RTO proposals jointly with other entities. For example, in the case of existing ISOs and other approved regional transmission entities, the regional entity may file on behalf of the individual public utilities. This will reduce the volume of submittals that must be developed by public utilities and be reviewed by the Commission.

We note that, with the exception of governance, experience gained from past ISO proceedings, will be directly transferable whether the form of RTO is an ISO or a transco. For transcos, as discussed elsewhere in the Final Rule, restrictions on ownership of transcos that we have adopted are designed to work in tandem with restrictions on governance in order to ensure adequate levels of independence.

We believe that RTO proposals that reflect the above factors, should allow the Commission to minimize the amount of time necessary to analyze and process the submittal. While the Commission cannot guarantee that we will be able to respond to every proposal within a pre-set period of time, we will make every reasonable effort to issue an initial order on an RTO proposal within 60 days,⁷⁵⁰ after the comment period closes.⁷⁵¹ With respect to RTO proposals that present contested issues or problematic RTO provisions, we will make every effort to expedite

⁷⁵⁰ We recognize that, while there is no statutory deadline to act on section 203 filings, there is a 60-day statutory clock requiring action on section 205 related filings within 60 days from the date of filing, in the absence of a proposed effective date extending beyond the 60-day time frame. However, in most instances, we expect that the RTO submittals will typically propose FPA section 205 effective dates that will be beyond the 60-day nominal clock.

⁷⁵¹ This proposed time frame refers to applications that are consistent with the guidance provided in this Rule and that provide all the necessary information. We further note that the Commission's review process will restart in the event that applicants modify their proposal or supplement the supporting information in their application.

consideration of the proposed RTO and we will continue to consider alternatives to formal procedures (e.g., *ADR procedures*), where warranted, to avoid initiating a hearing.

What the Commission has approved for ISO forms of governance can be used as models for governance of RTOs that are ISOs. Nothing in this Rule prohibits the types of independent governance structures we have approved to date. All of the ISOs approved to date, except one, have a two-tier form of governance wherein a non-stakeholder board at the top generally has final decision-making authority on most issues. Below this board are advisory groups or committees comprised of stakeholders that provide advice and may share some decision-making authority. With regard to the second-tier, the Commission has required that no one constituency in any group or committee be allowed to dominate the recommendation or decision-making process over the objection of the other classes, and that no one class holds veto power over the will of the remaining classes. The California ISO's governance structure is different. It has a single-tier hybrid decision-making board comprised of both stakeholders and non-stakeholders. No two classes can push through a decision over the objection of other classes, and no one class has veto power over the will of the remaining classes.

4. Other Implementation Issues

Commission Conclusion. An additional issue some commenters raised in connection with implementation concerns how the Commission intends to handle multiple RTO proposals that pertain to the same or overlapping regions. We expect that proper adherence to the collaborative process and the RTO scope and configuration factors we have identified, in the first instance, will bring order to the formation of RTOs such that the Commission will not need to step in and decide the matter of competing RTOs at the filing stage.

Several miscellaneous RTO implementation issues that were raised by some commenters concern the terms of withdrawal for members from an RTO, the RTO's funding of staff compensation in connection with transfers of personnel from other entities, and the Commission serving as a backstop for RTO's ADR processes. These matters, however, are best left to case-specific determinations in response to particular RTO proposals.

In response to those who argue for or against rejection or waiver in connection with less-than-fully-conforming RTO submittals, we believe

the concepts of rejection and waiver are not appropriate. We have provided a significant degree of flexibility in the minimum characteristics and functions, and in many instances specifically allow for alternative ways to satisfy those characteristics and functions. Proposals that do not satisfy the minimum characteristics and functions will not be approved as RTOs. That does not mean that such a proposal would be summarily rejected; in fact, it may still be an improvement over the status quo as long as it is consistent with the FPA requirements. However, it may be questioned the extent to which entities that are not participating in RTOs have acted to eliminate the impediments to competition we have identified in this Final Rule.

IV. Environmental Statement

This section reviews and adopts the Environmental Assessment (EA) prepared by the Commission staff in connection with this Final Rule. It identifies the alternatives considered by the agency in reaching its decision; analyzes and considers whether and to what extent, if any, the chosen alternative—adoption of this Final Rule—affects the quality of the human environment; and states the Commission's decision.

Summary

The analysis compares generation and emission trends under the Final Rule to baseline trends without the Final Rule. The analysis indicates that the Final Rule will result in little generation change on a net national basis, but there may be shifts in regional generation. Economic benefits of the Final Rule can be realized with no significant, adverse environmental impacts. Further, the potential exists for environmental benefits to be realized, through the encouragement of newer, cleaner resources.

Discussion

A. Background

To further the policies and goals of the National Environmental Policy Act of 1969 (NEPA), Commission staff prepared an EA in order to examine potential impacts that could result from implementing the Commission's Rule, and to serve as the basis for considering whether the Final Rule will have significant impacts on the quality of the human environment. On May 14, 1999, the Commission issued a notice of intent to prepare an EA, and a request for comments on the scope of the issues that should be addressed in the EA. On July 8, 1999, a public scoping meeting

was held at the Commission. On October 22, 1999, the Commission issued an EA, and invited interested parties to comment on the EA. Comments were due on November 22, 1999.

The Commission received two filed comments on the EA (NMA/WFA/CEED and Project Groups on behalf of multiple public interest groups). Specific comments are addressed in the relevant sections below.⁷⁵²

B. Scope of the Analysis

The EA examines potential environmental impacts that could result from implementing the Commission's Final Rule. The impacts are necessarily uncertain because they would be the product of changes in economic regulation that may alter the future behavior and perhaps the future structure of electricity supply markets. In turn, these behavioral and structural changes could lead to a different set of environmental conditions than would otherwise be the case. The analysis recognizes the uncertainty of the Rule's potential effects on future markets. It presents a systematic view of possible future market changes and assesses a range of possible responses to market changes, but should not be seen as predictive of specific market or environmental outcomes.

The EA addresses a broad range of potential economic changes that could result from the Rule. These impacts include changes in the mix of electric generating plants built in the future, shifts in the utilization of existing plants, and increases in interregional transmission. The analysis, therefore, includes major air pollutants: sulfur dioxide (SO₂), nitrogen oxides (NO_x), mercury, and carbon dioxide associated with various types of generating plants and fuels. The EA addresses potential environmental impacts at national and regional levels.

Project Groups expressed concern that the EA does not retrospectively analyze the impacts of open access policies to date. As stated in 1.3.2 of the EA, we believe it is neither possible nor desirable to analyze such changes. Data collection lags, and the short period of time that has elapsed since the issuance of Order No. 888, would preclude us from drawing meaningful conclusions.

Project Groups also stated that economic impacts are not specifically reported in the EA, making it more difficult to evaluate the impacts of the

⁷⁵² As noted in the EA, a number of comments filed during scoping relate to matters outside the scope of the EA, and for the most part deal with policy issues that are addressed in the Rule.

Rule. We note, however, that the modeling and analysis conducted for the EA are the basis for the economic discussion contained in the Final Rule. These economic results do not provide a complete analysis of the potential economic impacts because the analysis considers only economic effects which may relate to operating decisions or new capacity, and thus may lead to environmental consequences. However, there are other economic benefits from competitive wholesale electric power markets which have little or no effect on the environment.

C. Analytic Approach

Because the impacts that could result from the rulemaking are uncertain, an analytic approach known as scenario analysis was used. In this approach, alternative views of the future are postulated and analyzed with and without the Final Rule. Potential environmental impacts are evaluated by comparing the analytic results of the scenarios. First, an analytic base case was developed. This base case relies on the assumption that the Commission would pursue current policy with respect to wholesale electric competition using existing rules and procedures, including case-by-case implementation of regional market arrangements.

Having established an appropriate base case, the EA analyzed future impacts assuming that the Rule is in effect. Staff adopted the assumption that the Final Rule, although voluntary, would result in the establishment of RTOs throughout the study area with the characteristics and functions set forth in the Final Rule. Three scenarios were developed to reflect a range of possible economic and environmental outcomes: Transmission Efficiency Scenario; Transmission/Generation Efficiency Scenario; New Entry Scenario.

D. Alternatives to the Rule

The primary alternative to the Final Rule is for the Commission to maintain the status quo, that is, to continue its existing open access policies. The result of this no-action alternative, without implementing the Final Rule, is that the Commission would effectuate an open transmission grid, but not address changes in the industry that have occurred since Order No. 888 was adopted. However, the no-action alternative describes what is likely to happen if the Commission takes no action over and beyond implementation of existing policies. Once this baseline is established to portray what is likely to happen in the electric industry

during the study period, the projected impacts of the Final Rule can then be determined against this backdrop.

In addition to the Final Rule and the no-action alternative, several alternative approaches were considered and ultimately rejected. The alternative of analyzing mandatory RTOs, as compared with voluntary RTOs as set forth in the Final Rule, was rejected as moot, since the EA assumes that voluntary RTO formation proceeds with little delay and is successful in creating RTOs with the functions and characteristics contained in the Rule. Hence, assumptions for voluntary RTOs and mandatory RTOs are analytically indistinguishable in terms of their effects on the transmission grid and on the electric sector generally.

The other major alternative considered was the analysis of alternative fuel price assumptions. Project for Sustainable FERC Energy Policy suggested that we prepare such an analysis. However, as we noted in the EA, this alternative was ultimately rejected for two reasons. First, as reflected in scenarios analyzed in the EIS for Order No. 888, plausible variation in gas prices relative to coal prices is unlikely to have a major impact on the environmental effects of the Final Rule. Therefore, a gas price scenario was selected that had the general characteristics of other forecasts, namely, that gas prices will rise relative to coal prices. The selection of this gas price scenario does not represent an endorsement of this particular gas price path. Although we believe it to be a reasonable projection, it is a merely a representative projection of gas prices for purposes of the EA. Second, there is no need to consider an alternative where competition favors gas over coal because such a scenario would have little adverse impact, especially when compared with scenarios that tend to favor increased coal use relative to gas use. In the rule scenario we selected, we included, therefore, a number of improvements in coal technology as a result of the RTO Rule, to ensure that the potential impacts of any increased coal use relative to the base case would be considered in assessing the environmental consequences of the rule.

E. Analytic Framework and Assumptions

It is expected that the impacts of the Final Rule will result primarily from changes in the types and locations of power plants and transmission facilities constructed in the future and changes in the operating patterns of existing power plants, including changes in the fuel mix. To examine the impacts

thoroughly, the modeling approach chosen includes detailed representations of electric power plants and the electric transmission grid, and allows for an economic (least-cost) compliance with existing and future environmental regulatory requirements.

Computer modeling capable of simulating regional electric utility dispatch and capacity expansion over time was used to characterize electric power markets in the base case and rule scenarios. We used a large supply optimization model of the U.S. electricity supply sector, which emphasizes pollution estimation and pollution control. It has been used for Environmental Protection Agency (EPA) regulatory analysis in publicly accessible proceedings since 1996.

Analytic assumptions are a critical part of the modeling. Because the model cannot tell us directly what the RTO-related changes will be, it must assess how a set of assumed changes in the cost and/or physical properties of the electricity system could lead to changes in the use of the system, and hence to changes in emissions.

A series of specific assumptions were developed to model the base case and scenarios. Assumptions common to all modeled cases include current and future prices of fossil fuels, particularly coal and natural gas, and current and future requirements imposed on the electric sector by environmental laws and regulations. These requirements include: for SO₂, continuation of the Title IV Acid Rain Program, with Phase II coverage and levels of permitted emissions; for NO_x, Title IV requirements on coal-fired boilers (Phase I and Phase II); emissions cap restrictions in the Ozone Transport Region starting in 1999, and implementation of the Final Rule governing ozone transport issued by the EPA in 1997, modeled in accordance with the EPA's guidance. This EPA Rule imposes a cap on NO_x on large utility boilers in 22 states in the eastern United States and limiting summer NO_x emissions to 543,800 tons; no regulatory restrictions are assumed for mercury or CO₂.

Project Groups commented that, since assumptions made in the EA about future environmental regulations are critical in determining the outcome of the analysis, changes in future environmental regulations (particularly due to legal challenges) from those assumed in the EA could result in different environmental impacts. Accordingly, the comment states that the EA should reflect possible changes. We note that there are many important analytic assumptions embodied in the

modeling for the EA. Environmental regulations are directly represented in the analysis, and changes in these assumed regulations do have a large effect on the results of the modeling. In particular, the presence or absence of SO₂ and NO_x caps is a key assumption. Nevertheless, these assumptions are based on regulations which are final, as opposed to proposed regulations or speculative regulatory actions. These rules and associated regulatory analyses from EPA were used as the basis for the EA assumptions. Accordingly, it would be premature and speculative to consider changes, if any, from pending legal challenges or speculative future regulatory changes.

In a broader sense, it is clear that successful competitive energy markets will be complemented by cost-effective environmental regulation, because the incentives for efficient behavior on the part of market participants can be decentralized and the need for intrusive regulatory action is lessened. Emissions trading programs such as those for SO₂ and NO_x are an important example of such cost-effective regulation.

Other invariant assumptions include: net electric demand growth (with the exception of New Entry Scenario); load shape (how demand varies with season and time of day within each model region); costs and performance of new power plants; and capacity and generation of nuclear, hydroelectric, pumped storage, and import supply.

Because of the importance of the transmission system in the Rule, assumptions were made about potential changes that may come about either because of the Rule's requirements or because of its increased incentives for better grid operation and investment. In addition, the Final Rule is expected to develop more competitive bulk electric power markets. Competition is expected to increase the incentives for efficient behavior among market participants. To assess the potential effects of such increased efficiencies on the environment, some assumptions affecting new and existing power plants were changed. Finally, to respond to concerns expressed by parties in the scoping process regarding the role of new entrants in developing competitive power markets, particularly the RTOs, a model scenario was developed that specifically addresses new entry and enhanced consumer choice.

F. Impacts

The EA analyzes the electric power capacity and generation projections on a national and regional level for the base case, and presents the corresponding environmental impacts. Projected trends

in generating capacity, including economic additions, retirements and modifications, and generation by plant type for the base case, are analyzed for the years 2005, 2010, and 2015. The data indicate that virtually all future capacity additions are expected to be gas-fired combined cycle or combustion turbine units; coal will nevertheless remain the dominant fuel for generation. Growth in natural gas, however, will be rapid, with the share of generation increasing from 13 percent in 1997 to 32 percent in 2015; total generating capacity is expected to grow at a slower rate than demand, resulting in plants that will generally be operated at higher capacity factors; regional patterns of generation reflect regional demand growth as well as changes in interregional trade in electricity. In most regions, growth in demand is met by gas-fired (or oil/gas switching) plants, although in the Midwest existing coal-fired capacity meets part of the growth in the early years of the forecast.

The EA projects national emissions in the base case for SO₂, NO_x, mercury, and CO₂. There are also regional emissions projections for NO_x. The analysis indicates the following:

1. SO₂ emissions will decline gradually to 9.5 million tons in 2015. Variations in such emissions during the forecast period primarily reflect economic use of the Title IV emissions banking program, under which emitting parties may elect to over-control SO₂ in any year and bank the extra reductions as emission credits for later use;

2. Regional SO₂ emissions generally will follow the same pattern as the national emissions total. However, emissions reductions and shifts are not expected to occur uniformly across regions because the SO₂ emissions trading program allows emitting parties with higher costs of pollution control to purchase allowances from emitting parties with lower control costs. This can lead to increases in emissions from certain regions;

3. NO_x emissions are projected to decline to 4.1 million tons in 2015. These reductions are due to the development of NO_x regulations under the Clean Air Act. Furthermore, summer or "ozone season" (May to September) NO_x emissions are projected to decrease to 1.3 million tons in 2015;

4. Regional NO_x emissions are projected to follow a pattern similar to the national trend; however, the implementation of NO_x controls is assumed to take the form of an emission cap and permit trading program similar to the Title IV SO₂ program.

Consequently, certain regions may experience different NO_x emissions

trends because of the relative costs of controlling NO_x and the possibility of trading between emitting parties;

5. CO₂ is projected to increase throughout the analysis period by 27 percent. Because CO₂ is an unregulated pollutant at the present time, and because both coal and natural gas emit CO₂, the rise in both coal and gas-fired generation leads to a substantial increase in CO₂ emissions during the analysis period; and

6. Mercury emissions range between 50.6 and 53.2 tons during the forecast period with no clear trend distinguishable. Mercury is also uncontrolled at the present time, but emissions are closely linked to coal use (with considerable variation of mercury content in coal from specific seams). The relative stability of coal-fired generation in later years of the analysis period leads to the observed pattern of mercury emissions.

The analysis indicates that the Midwest is expected to produce slightly more power, the East Coast to produce slightly less power. These changes are likely to be greatest in the near-term, and to decline toward baseline levels over time. The Final Rule would result in the slight shifting of the baseline fuel mix projections toward coal and away from fuel oil and, to some extent, natural gas; these changes are small relative to the overall trend in the fuel mix, in which natural gas remains the most rapidly growing fuel. This is consistent with the change in regional levels of generation.

The analysis shows that the overall emissions of SO_x, NO_x, mercury, and CO₂, are directionally consistent with the observed changes in power generation and fuel mix. That is, emissions tend to increase early in the forecast period and then decline over time, with several instances of emissions reductions. The greatest change in any regulated pollutant (a rise of 3.6 percent or 381,000 tons of SO₂ in one scenario) occurs as a result of changing patterns of emissions banking and trading, which is consistent with the design of the SO₂ cap and trade regulatory program. Regional variations in annual and summer NO_x are also possible and are also consistent with regulatory program design. Emissions budgets are met at all times. Other emission changes are relatively small because coal-fired plants, which contribute a disproportionate share of these emissions, are already heavily utilized and so are unable to increase their output significantly in the rulemaking scenarios. In one scenario designed to examine increased new entry and demand flexibility,

substantial emissions reductions occur as a result of lower demand for electricity combined with cleaner new supply options.

V. Regulatory Flexibility Act Certification

The Commission received no comments on its certification, in the NOPR, that the proposed rule would not have a significant economic impact on a substantial number of small entities and that an initial regulatory flexibility analysis is not required by 5 U.S.C. § 603. The Commission adheres to its earlier reasoning and thus concludes that a final regulatory flexibility analysis also is not required.⁷⁵³ In making this determination, the Commission is required to examine only the direct compliance costs that a rulemaking imposes upon small businesses. It is not required to consider indirect economic consequences, nor is it required to consider costs that an entity incurs

voluntarily.⁷⁵⁴ This rulemaking does not impose significant compliance costs upon small entities. Instead, it leaves them with the choice of whether to join an RTO. The only costs that are mandated are the minimal costs associated with filing a statement, in the event a public utility does not make an RTO filing, explaining its efforts to join an RTO, any barriers it encountered, and any future plans to join an RTO. Thus, this rulemaking will not have a significant economic impact upon any small entities.

VI. Public Reporting Burden and Information Collection Statement

The OMB regulations require OMB to approve certain reporting and recordkeeping (collections of information) imposed by agency rule.⁷⁵⁵ The NOPR was submitted to OMB at the time of issuance. OMB did not comment nor did it take any action on the proposed rule. FERC identifies the

information provided under Part 35 as FERC-516⁷⁵⁶ and under Part 33 as FERC-519.⁷⁵⁷

No comments from the public on the burden estimate were received. The filing requirements remain essentially the same as those in the NOPR so, therefore, the estimated annual filing burden remains the same. The burden estimates for complying with this proposed rule are set out in Table 1. The total annual hours for collection (reporting + recordkeeping (if appropriate)) is 7,600.

Information Collection Costs: The Commission has projected the average annualized cost for all respondents to be: Annualized Costs (Operations & Maintenance): \$401,518 (7,600 hours + 2080 hours per year × \$109,889=\$401,518). The cost per respondent is \$7,722 (participants and non-participants).

TABLE 1.—ESTIMATED ANNUAL BURDEN

Data Collection	Number of Respondents	Number of Responses	Hours Per Response	Total Annual Hours
FERC-516 ¹	12	1	300	3,600
FERC-516 ²	40	1	40	1,600
FERC-519 ¹	12	1	200	2,400
Totals				7,600

¹ Filings to propose participation in an RTO under § 35.34(d).

² Alternative filings under § 35.34(g).

Comments were solicited on the Commission's need for this information, whether the information will have practical utility, the accuracy of the provided burden estimates, ways to enhance the quality, utility, and clarity of the information to be collected, and any suggested methods for minimizing respondents' burden, including the use of automated information techniques.

Title: FERC-516, Electric Rate Schedule Filings; FERC-519 Application for Sale, Lease, or Other Disposition, Merger or Consolidation of Facilities or for the Purchase or Acquisition of Securities of a Public Utility.

Action: Proposed Data Collections.

OMB Control No.: 1902-0096 and 1902-0082.

The applicant shall not be penalized for failure to respond to this collection of information unless the collection of

information displays a valid OMB control number.

Respondents: Business or other for profit, including small businesses.

Frequency of Responses: One time.

Necessity of Information: The Final Rule revises the requirements contained in 18 CFR part 35. The Commission is promoting the voluntary establishment of RTOs nationwide by December 2001. In particular, the Commission will establish in this rule characteristics and functions which applicants must meet to become Commission-approved RTOs. The Commission will engage in a collaborative process with state officials and others to facilitate RTO development. The rule will require that each public utility that owns, operates or controls transmission facilities participate in one-time filings proposing an RTO or make a filing explaining why they are not participating in an RTO proposal.

(10th Cir. 1991) (Regulatory Flexibility Act not implicated where regulation simply added an option for affected entities and did not impose any costs).

⁷⁵⁵ 5 CFR 1320.11, 44 U.S.C. 3507(d).

Internal Review: The Commission has assured itself, by means of internal review, that there is specific, objective support for the burden estimates associated with the information requirements. The Commission's Office of Markets, Tariffs and Rates will use the data included in filings under 18 CFR 35.34 to evaluate efforts for the interconnection and coordination of the U.S. electric transmission system and to ensure the orderly formation of RTOs as well as for general industry oversight. These information requirements conform to the Commission's plan for efficient information collection, communication, and management within the electric power industry.

The Commission received approximately 334 comments and reply comments on its NOPR but none on its reporting burden. The Commission's responses to the comments are addressed in the preamble of this Final

⁷⁵⁶ Electric Rate Schedule Filings.

⁷⁵⁷ Application for Sale, Lease, or Other Disposition, Merger or Consolidation of Facilities or for the Purchase or Acquisition of Securities of a Public Utility.

⁷⁵³ See 5 U.S.C. 604.

⁷⁵⁴ *Mid-Tex Elec. Coop. v. FERC*, 773 F.2d 327 (D.C. Cir. 1985) (Commission need only consider small entities "that would be directly regulated"); *Colorado State Banking Bd. v. RTC*, 926 F.2d 931

Rule. The Commission is submitting a copy of the Final Rule along with information collection submissions for the data collections identified above to OMB for its review and approval.

Interested persons may obtain information on the reporting requirements by contacting the following: Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426 [Attention: Michael Miller, Office of the Chief Information Officer, Phone: (202) 208-1415, fax: (202) 208-2425, E-mail: mike.miller@ferc.fed.us] or send your comments to the Office of Management and Budget, Office of Information and Regulatory Affairs, Washington, DC 20503, [Attention: Desk Officer for the Federal Energy Regulatory Commission, phone: (202) 395-3087, fax: (202) 395-7285].

VII. Effective Date and Congressional Notification

This rule will take effect March 6, 2000. The Commission has determined, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget, that this Rule is a "major rule" within the meaning of section 351 of the Small Business Regulatory Enforcement Act of 1996.⁷⁵⁸ The Rule will be submitted to both Houses of Congress and the Comptroller General prior to its publication in the **Federal Register**.

VIII. Document Availability

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through FERC's Home Page (<http://www.ferc.fed.us>) and in FERC's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street, N.E., Room 2A, Washington, D.C. 20426.

From FERC's Home Page on the Internet, this information is available in both the Commission Issuance Posting System (CIPS) and the Records and Information Management System (RIMS).

• CIPS provides access to the texts of formal documents issued by the Commission since November 14, 1994. CIPS can be accessed using the CIPS link or the Energy Information Online icon. The full text of this document will be available on CIPS in ASCII and WordPerfect 8.0 format for viewing, printing, and/or downloading.

• RIMS contains images of documents submitted to and issues by the Commission after November 16, 1981. Documents from November 1995 to the present can be viewed and printed from FERC's Home Page using the RIMS link or the Energy Information Online icon. Descriptions of documents back to November 16, 1981, are also available from RIMS-on-the-Web; requests for copies of these and other older documents should be submitted to the Public Reference Room.

User assistance is available for RIMS, CIPS, and the Website during normal business hours from our Help line at (202) 208-2222 (e-mail to WebMaster@ferc.fed.us) of the Public Reference Room at (202) 208-1371 (e-mail to public.referenceroom@ferc.fed.us).

During normal business hours, documents can also be viewed and/or printed in FERC's Public Reference Room, where RIMS, CIPS, and the FERC Website are available. User assistance is also available.

List of Subjects in 18 CFR Part 35

Electric power rates, Electric utilities, Reporting and recordkeeping requirements

By the Commission.

David P. Boergers,
Secretary.

In consideration of the foregoing, the Commission amends Part 35, Chapter I, Title 18 of the *Code of Federal Regulations*, as follows:

PART 35—FILING OF RATE SCHEDULES

1. The authority citation for Part 35 continues to read as follows:

Authority: 16 U.S.C. 791a-825r, 2601-2645; 31 U.S.C. 9701; 42 U.S.C. 7101-7352.

2. Part 35 is amended by adding a new Subpart F and a new § 35.34 to read as follows:

Subpart F—Procedures and Requirements Regarding Regional Transmission Organizations

§ 35.34 Regional Transmission Organizations.

(a) *Purpose.* This section establishes required characteristics and functions for Regional Transmission Organizations for the purpose of promoting efficiency and reliability in the operation and planning of the electric transmission grid and ensuring non-discrimination in the provision of electric transmission services. This section further directs each public utility that owns, operates, or controls

facilities used for the transmission of electric energy in interstate commerce to make certain filings with respect to forming and participating in a Regional Transmission Organization.

(b) *Definitions.*

(1) *Regional Transmission Organization* means an entity that satisfies the minimum characteristics set forth in paragraph (j) of this section, performs the functions set forth in paragraph (k) of this section, and accommodates the open architecture condition set forth in paragraph (l) of this section.

(2) *Market participant* means:

(i) Any entity that, either directly or through an affiliate, sells or brokers electric energy, or provides transmission or ancillary services to the Regional Transmission Organization, unless the Commission finds that the entity does not have economic or commercial interests that would be significantly affected by the Regional Transmission Organization's actions or decisions; and

(ii) Any other entity that the Commission finds has economic or commercial interests that would be significantly affected by the Regional Transmission Organization's actions or decisions.

(3) *Affiliate* means the definition given in section 2(a)(11) of the Public Utility Holding Company Act (15 U.S.C. 79b(a)(11)).

(4) *Class of market participants* means two or more market participants with common economic or commercial interests.

(c) *General rule.* Except for those public utilities subject to the requirements of paragraph (h) of this section, every public utility that owns, operates or controls facilities used for the transmission of electric energy in interstate commerce as of March 6, 2000 must file with the Commission, no later than October 15, 2000, one of the following:

(1) A proposal to participate in a Regional Transmission Organization consisting of one of the types of submittals set forth in paragraph (d) of this section; or

(2) An alternative filing consistent with paragraph (g) of this section.

(d) *Proposal to participate in a Regional Transmission Organization.* For purposes of this section, a proposal to participate in a Regional Transmission Organization means:

(1) Such filings, made individually or jointly with other entities, pursuant to sections 203, 205 and 206 of the Federal Power Act (16 U.S.C. 824b, 824d, and 824e), as are necessary to create a new Regional Transmission Organization;

⁷⁵⁸ 5 U.S.C. 804(2).

(2) Such filings, made individually or jointly with other entities, pursuant to sections 203, 205 and 206 of the Federal Power Act (16 U.S.C. 824b, 824d, and 824e), as are necessary to join a Regional Transmission Organization approved by the Commission on or before the date of the filing; or

(3) A petition for declaratory order, filed individually or jointly with other entities, asking whether a proposed transmission entity would qualify as a Regional Transmission Organization and containing at least the following:

(i) A detailed description of the proposed transmission entity, including a description of the organizational and operational structure and the intended participants;

(ii) A discussion of how the transmission entity would satisfy each of the characteristics and functions of a Regional Transmission Organization specified in paragraphs (j), (k) and (l) of this section;

(iii) A detailed description of the Federal Power Act section 205 rates that will be filed for the Regional Transmission Organization; and

(iv) A commitment to make filings pursuant to sections 203, 205 and 206 of the Federal Power Act (16 U.S.C. 824b, 824d, and 824e), as necessary, promptly after the Commission issues an order in response to the petition.

(4) Any proposal filed under this paragraph (d) must include an explanation of efforts made to include public power entities in the proposed Regional Transmission Organization.

(e) *Innovative transmission rate treatments for Regional Transmission Organizations.*

(1) The Commission will consider authorizing any innovative transmission rate treatment, as discussed in this paragraph (e), for an approved Regional Transmission Organization. An applicant's request must include:

(i) A detailed explanation of how any proposed rate treatment would help achieve the goals of Regional Transmission Organizations, including efficient use of and investment in the transmission system and reliability benefits to consumers;

(ii) A cost-benefit analysis, including rate impacts; and

(iii) A detailed explanation of why the proposed rate treatment is appropriate for the Regional Transmission Organization.

The applicant must support any rate proposal under this paragraph (e) as just, reasonable, and not unduly discriminatory or preferential.

(2) For purposes of this paragraph (e), innovative transmission rate treatment means any of the following:

(i) A transmission rate moratorium, which may include proposals based on formerly bundled retail transmission rates;

(ii) Rates of return that:

(A) Are formulary;

(B) Consider risk premiums and account for demonstrated adjustments in risk; or

(C) Do not vary with capital structure;

(iii) Non-traditional depreciation schedules for new transmission investment;

(iv) Transmission rates based on levelized recovery of capital costs;

(v) Transmission rates that combine elements of incremental cost pricing for new transmission facilities with an embedded-cost access fee for existing transmission facilities; or

(vi) Performance-based transmission rates.

(3) A request for performance-based transmission rates under this paragraph (e) may include factors such as:

(i) A method for calculating initial transmission rates (including price caps and any provisions for discounting);

(ii) A mechanism for adjusting initial rates, which may be derived from or based upon external factors or indices or a specific performance measure;

(iii) Time periods for redetermining initial rates; and

(iv) Costs to be excluded from performance-based rates.

(4) An innovative transmission rate treatment or any other rate proposal made for an approved Regional Transmission Organization may be requested as part of any filing that is made under paragraph (d) of this section or in any subsequent rate change proposal under section 205 of the Federal Power Act (16 U.S.C. 824d). Unless otherwise ordered by the Commission, an approved Regional Transmission Organization may not include in rates any innovative transmission rate treatment under paragraphs (e)(2)(i) and (e)(2)(ii)(C) of this section after January 1, 2005.

(f) *Transfer of operational control.*

The public utility's proposal to participate in a Regional Transmission Organization filed pursuant to paragraph (c)(1) of this section must propose that operational control of that public utility's transmission facilities will be transferred to the Regional Transmission Organization on a schedule that will allow the Regional Transmission Organization to commence operating the facilities no later than December 15, 2001.

Note to paragraph (f): The requirement in paragraph (f) of this section may be satisfied by proposing to transfer to the Regional Transmission Organization ownership of the facilities in addition to operational control.

(g) *Alternative filing.* Any filing made pursuant to paragraph (c)(2) of this section must contain:

(1) A description of any efforts made by that public utility to participate in a Regional Transmission Organization;

(2) A detailed explanation of the economic, operational, commercial, regulatory, or other reasons the public utility has not made a filing to participate in a Regional Transmission Organization, including identification of any existing obstacles to participation in a Regional Transmission Organization; and

(3) The specific plans, if any, the public utility has for further work toward participation in a Regional Transmission Organization, a proposed timetable for such activity, an explanation of efforts made to include public power entities in the proposed Regional Transmission Organization, and any factors (including any law, rule or regulation) that may affect the public utility's ability or decision to participate in a Regional Transmission Organization.

(h) *Public utilities participating in approved transmission entities.* Every public utility that owns, operates or controls facilities used for the transmission of electric energy in interstate commerce as of March 6, 2000, and that has filed with the Commission on or before March 6, 2000 to transfer operational control of its facilities to a transmission entity that has been approved or conditionally approved by the Commission on or before March 6, 2000 as being in conformance with the eleven ISO principles set forth in Order No. 888, FERC Statutes and Regulations, Regulations Preamble January 1991–June 1996 ¶ 31,036 (Final Rule on Open Access and Stranded Costs), must, individually or jointly with other entities, file with the Commission, no later than January 15, 2001:

(1) A statement that it is participating in a transmission entity that has been so approved;

(2) A detailed explanation of the extent to which the transmission entity in which it participates has the characteristics and performs the functions of a Regional Transmission Organization specified in paragraphs (j) and (k) of this section and accommodates the open architecture conditions in paragraph (l) of this section; and

(3) To the extent the transmission entity in which the public utility participates does not meet all the requirements of a Regional Transmission Organization specified in paragraphs (j), (k), and (l) of this section,

(i) A proposal to participate in a Regional Transmission Organization that meets such requirements in accordance with paragraph (d) of this section,

(ii) A proposal to modify the existing transmission entity so that it conforms to the requirements of a Regional Transmission Organization, or

(iii) A filing containing the information specified in paragraph (g) of this section addressing any efforts, obstacles, and plans with respect to conformance with those requirements.

(i) *Entities that become public utilities with transmission facilities.* An entity that is not a public utility that owns, operates or controls facilities used for the transmission of electric energy in interstate commerce as of March 6, 2000, but later becomes such a public utility, must file a proposal to participate in a Regional Transmission Organization in accordance with paragraph (d) of this section, or an alternative filing in accordance with paragraph (g) of this section, by October 15, 2000 or 60 days prior to the date on which the public utility engages in any transmission of electric energy in interstate commerce, whichever comes later. If a proposal to participate in accordance with paragraph (d) of this section is filed, it must propose that operational control of the applicant's transmission system will be transferred to the Regional Transmission Organization within six months of filing the proposal.

(j) *Required characteristics for a Regional Transmission Organization.* A Regional Transmission Organization must satisfy the following characteristics when it commences operation:

(1) *Independence.* The Regional Transmission Organization must be independent of any market participant. The Regional Transmission Organization must include, as part of its demonstration of independence, a demonstration that it meets the following:

(i) The Regional Transmission Organization, its employees, and any non-stakeholder directors must not have financial interests in any market participant.

(ii) The Regional Transmission Organization must have a decision making process that is independent of control by any market participant or class of participants.

(iii) The Regional Transmission Organization must have exclusive and independent authority under section 205 of the Federal Power Act (16 U.S.C. 824d), to propose rates, terms and conditions of transmission service

provided over the facilities it operates.

Note to paragraph (j)(1)(iii): Transmission owners retain authority under section 205 of the Federal Power Act (16 U.S.C. 824d) to seek recovery from the Regional Transmission Organization of the revenue requirements associated with the transmission facilities that they own.

(2) *Scope and regional configuration.* The Regional Transmission Organization must serve an appropriate region. The region must be of sufficient scope and configuration to permit the Regional Transmission Organization to maintain reliability, effectively perform its required functions, and support efficient and non-discriminatory power markets.

(3) *Operational authority.* The Regional Transmission Organization must have operational authority for all transmission facilities under its control. The Regional Transmission Organization must include, as part of its demonstration of operational authority, a demonstration that it meets the following:

(i) If any operational functions are delegated to, or shared with, entities other than the Regional Transmission Organization, the Regional Transmission Organization must ensure that this sharing of operational authority will not adversely affect reliability or provide any market participant with an unfair competitive advantage. Within two years after initial operation as a Regional Transmission Organization, the Regional Transmission Organization must prepare a public report that assesses whether any division of operational authority hinders the Regional Transmission Organization in providing reliable, non-discriminatory and efficiently priced transmission service.

(ii) The Regional Transmission Organization must be the security coordinator for the facilities that it controls.

(4) *Short-term reliability.* The Regional Transmission Organization must have exclusive authority for maintaining the short-term reliability of the grid that it operates. The Regional Transmission Organization must include, as part of its demonstration with respect to reliability, a demonstration that it meets the following:

(i) The Regional Transmission Organization must have exclusive authority for receiving, confirming and implementing all interchange schedules.

(ii) The Regional Transmission Organization must have the right to order redispatch of any generator connected to transmission facilities it

operates if necessary for the reliable operation of these facilities.

(iii) When the Regional Transmission Organization operates transmission facilities owned by other entities, the Regional Transmission Organization must have authority to approve or disapprove all requests for scheduled outages of transmission facilities to ensure that the outages can be accommodated within established reliability standards.

(iv) If the Regional Transmission Organization operates under reliability standards established by another entity (e.g., a regional reliability council), the Regional Transmission Organization must report to the Commission if these standards hinder it from providing reliable, non-discriminatory and efficiently priced transmission service.

(k) *Required functions of a Regional Transmission Organization.* The Regional Transmission Organization must perform the following functions. Unless otherwise noted, the Regional Transmission Organization must satisfy these obligations when it commences operations.

(1) *Tariff administration and design.* The Regional Transmission Organization must administer its own transmission tariff and employ a transmission pricing system that will promote efficient use and expansion of transmission and generation facilities. As part of its demonstration with respect to tariff administration and design, the Regional Transmission Organization must satisfy the standards listed in paragraphs (k)(1) (i) and (ii) of this section, or demonstrate that an alternative proposal is consistent with, or superior to satisfying such standards.

(i) The Regional Transmission Organization must be the only provider of transmission service over the facilities under its control, and must be the sole administrator of its own Commission-approved open access transmission tariff. The Regional Transmission Organization must have the sole authority to receive, evaluate, and approve or deny all requests for transmission service. The Regional Transmission Organization must have the authority to review and approve requests for new interconnections.

(ii) Customers under the Regional Transmission Organization tariff must not be charged multiple access fees for the recovery of capital costs for transmission service over facilities that the Regional Transmission Organization controls.

(2) *Congestion management.* The Regional Transmission Organization must ensure the development and operation of market mechanisms to

manage transmission congestion. As part of its demonstration with respect to congestion management, the Regional Transmission Organization must satisfy the standards listed in paragraph (k)(2)(i) of this section, or demonstrate that an alternative proposal is consistent with or superior to satisfying such standards.

(i) The market mechanisms must accommodate broad participation by all market participants, and must provide all transmission customers with efficient price signals that show the consequences of their transmission usage decisions. The Regional Transmission Organization must either operate such markets itself or ensure that the task is performed by another entity that is not affiliated with any market participant.

(ii) The Regional Transmission Organization must satisfy the market mechanism requirement no later than one year after it commences initial operation. However, it must have in place at the time of initial operation an effective protocol for managing congestion.

(3) *Parallel path flow.* The Regional Transmission Organization must develop and implement procedures to address parallel path flow issues within its region and with other regions. The Regional Transmission Organization must satisfy this requirement with respect to coordination with other regions no later than three years after it commences initial operation.

(4) *Ancillary services.* The Regional Transmission Organization must serve as a provider of last resort of all ancillary services required by Order No. 888, FERC Statutes and Regulations, Regulations Preamble January 1991–June 1996 ¶ 31,036 (Final Rule on Open Access and Stranded Costs), and subsequent orders. As part of its demonstration with respect to ancillary services, the Regional Transmission Organization must satisfy the standards listed in paragraphs (k)(4)(i)–(iii) of this section, or demonstrate that an alternative proposal is consistent with or superior to satisfying such standards.

(i) All market participants must have the option of self-supplying or acquiring ancillary services from third parties subject to any restrictions imposed by the Commission in Order No. 888, FERC Statutes and Regulations, Regulations Preamble January 1991–June 1996 ¶ 31,036 (Final Rule on Open Access and Stranded Costs), and subsequent orders.

(ii) The Regional Transmission Organization must have the authority to decide the minimum required amounts of each ancillary service and, if

necessary, the locations at which these services must be provided. All ancillary service providers must be subject to direct or indirect operational control by the Regional Transmission Organization. The Regional Transmission Organization must promote the development of competitive markets for ancillary services whenever feasible.

(iii) The Regional Transmission Organization must ensure that its transmission customers have access to a real-time balancing market. The Regional Transmission Organization must either develop and operate this market itself or ensure that this task is performed by another entity that is not affiliated with any market participant.

(5) *OASIS and Total Transmission Capability (TTC) and Available Transmission Capability (ATC).* The Regional Transmission Organization must be the single OASIS site administrator for all transmission facilities under its control and independently calculate TTC and ATC.

(6) *Market monitoring.* To ensure that the Regional Transmission Organization provides reliable, efficient and not unduly discriminatory transmission service, the Regional Transmission Organization must provide for objective monitoring of markets it operates or administers to identify market design flaws, market power abuses and opportunities for efficiency improvements, and propose appropriate actions. As part of its demonstration with respect to market monitoring, the Regional Transmission Organization must satisfy the standards listed in paragraphs (k)(6)(i) through (k)(6)(iii) of this section, or demonstrate that an alternative proposal is consistent with or superior to satisfying such standards.

(i) Market monitoring must include monitoring the behavior of market participants in the region, including transmission owners other than the Regional Transmission Organization, if any, to determine if their actions hinder the Regional Transmission Organization in providing reliable, efficient and not unduly discriminatory transmission service.

(ii) With respect to markets the Regional Transmission Organization operates or administers, there must be a periodic assessment of how behavior in markets operated by others (e.g., bilateral power sales markets and power markets operated by unaffiliated power exchanges) affects Regional Transmission Organization operations and how Regional Transmission Organization operations affect the efficiency of power markets operated by others.

(iii) Reports on opportunities for efficiency improvement, market power abuses and market design flaws must be filed with the Commission and affected regulatory authorities.

(7) *Planning and expansion.* The Regional Transmission Organization must be responsible for planning, and for directing or arranging, necessary transmission expansions, additions, and upgrades that will enable it to provide efficient, reliable and non-discriminatory transmission service and coordinate such efforts with the appropriate state authorities. As part of its demonstration with respect to planning and expansion, the Regional Transmission Organization must satisfy the standards listed in paragraphs (k)(7)(i) and (ii) of this section, or demonstrate that an alternative proposal is consistent with or superior to satisfying such standards.

(i) The Regional Transmission Organization planning and expansion process must encourage market-driven operating and investment actions for preventing and relieving congestion.

(ii) The Regional Transmission Organization's planning and expansion process must accommodate efforts by state regulatory commissions to create multi-state agreements to review and approve new transmission facilities. The Regional Transmission Organization's planning and expansion process must be coordinated with programs of existing Regional Transmission Groups (See § 2.21 of this chapter) where appropriate.

(iii) If the Regional Transmission Organization is unable to satisfy this requirement when it commences operation, it must file with the Commission a plan with specified milestones that will ensure that it meets this requirement no later than three years after initial operation.

(8) *Interregional coordination.* The Regional Transmission Organization must ensure the integration of reliability practices within an interconnection and market interface practices among regions.

(1) *Open architecture.*

(1) Any proposal to participate in a Regional Transmission Organization must not contain any provision that would limit the capability of the Regional Transmission Organization to evolve in ways that would improve its efficiency, consistent with the requirements in paragraphs (j) and (k) of this section.

(2) Nothing in this regulation precludes an approved Regional Transmission Organization from seeking to evolve with respect to its organizational design, market design,

geographic scope, ownership arrangements, or methods of operational control, or in other appropriate ways if the change is consistent with the requirements of this section. Any future filing seeking approval of such changes must demonstrate that the proposed changes will meet the requirements of paragraphs (j), (k) and (l) of this section.

Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix to Preamble—List of Commenters

Abbreviation—Commenter

1. Advisory Committee ISO—NE—Advisory Committee to the Board of Directors of ISO New England.
2. AEP—American Electric Power Service Corporation and its public utility operating company subsidiaries: Appalachian Power Company, Columbus Southern Power Company, Indiana Michigan Power Company, Kentucky Power Company, Kingsport Power Company, Ohio Power Company, and Wheeling Power Company.
3. AEPCO—Arizona Electric Power Cooperative, Inc.
4. Alabama Commission—Alabama Public Service Commission.
5. Alberta—Province of Alberta, Electricity Branch.
6. Allegheny—Allegheny Energy, Inc.
7. Alliance Companies—American Electric Power Service Corporation, Consumers Energy Company, Detroit Edison Company, FirstEnergy Corp. and Virginia Electric and Power Company.
8. Alliant Energy—Alliant Energy Corporation.
9. Aluminum Companies—Alcoa Inc., Columbia Falls Aluminum Company, Kaiser Aluminum & Chemical Corporation and Vanalco, Inc.
10. American Forest—American Forest & Paper Association.
11. AMP—Ohio—American Municipal Power—Ohio, Inc.
12. APPA—American Public Power Association.
13. APPA *et al.* (WP)—Legal White Paper prepared on behalf of and sponsored jointly by the American Public Power Association, the Electric Consumers Resource Council, the Transmission Access Policy Study Group and the Transmission Dependent Utility Systems.
14. APS—Arizona Public Service Company.
15. APX—Automated Power Exchange, Inc.
16. Arizona Authority—Arizona Power Authority.
17. Arizona Commission—Arizona Corporation Commission.
18. Arizona ISA—Arizona Independent Scheduling Administrator Association.
19. Arkansas Cities—Cities of Benton, Bentonville, North Little Rock, Osceola, Piggott, Prescott and Siloam Springs, Arkansas; the Clarksville Light and Water Company; Conway Corporation; Hope Water and Light Commission; City Water and Light Plant of the City of Jonesboro, Arkansas; Paragould Light and Water Commission; and the West Memphis, Arkansas Utilities Commission.
20. Arkansas Consumers—Arkansas Electric Energy Consumers.
21. Avista—Avista Corporation, Inc.
22. Bangor Hydro—Bangor Hydro-Electric Company.
23. BC Hydro—British Columbia Hydro & Power Authority.
24. Big Rivers—Big Rivers Electric Corporation.
25. Blue Ridge—Blue Ridge Power Agency.
26. Brattle Group—The Brattle Group (Peter Fox-Penner and Philip Hanser).
27. British Columbia Ministry—British Columbia, Canada, Ministry of Employment and Investment, Electricity Development Branch.
28. Cal DWR—California Department of Water Resources.
29. Cal ISO—California Independent System Operator Corporation.
30. California Board—California Electricity Oversight Board.
31. California Commission—Public Utilities Commission of the State of California.
32. CalPX—California Power Exchange Corporation.
33. CAMU—Colorado Association of Municipal Utilities.
34. Canada DNR—Canada Department of Natural Resources.
35. CCEM/ELCON—Coalition for a Competitive Electricity Market and the Electricity Consumers Resources Council.
36. CEA—Canadian Electricity Association.
37. Consumers Energy—Consumers Energy Company.
38. Central Maine—Central Maine Power Company and Maine Electric Power Company.
39. Champion—Champion International Corporation.
40. Chelan—Public Utility District No. 1 of Chelan County.
41. Cinergy—Cinergy Services, Inc.
42. Clarksdale—Clarksdale Public Utilities Commission.
43. Cleco—Cleco Corporation.
44. Cleveland—City of Cleveland, Ohio.
45. CMUA—California Municipal Utilities Association.
46. Coalition of Alliance Users—Coalition of Municipal and Cooperative Users of Alliance Companies' Transmission.
47. ComEd—Commonwealth Edison Company.
48. Conectiv—Conectiv (Atlantic City Electric Company and Delmarva Power & Light Company).
49. Conlon—Mr. P. Gregory Conlon.
50. Consumer Groups—Industrial Consumers, American Public Power Association, National Rural Electric Cooperative Association, Transmission Access Policy Study Group, Transmission Dependent Utility Systems, Consumer Federation of America and International Mass Retail Association.
51. CP&L—Carolina Power & Light Company.
52. CRC—Colorado River Commission of the State of Nevada.
53. CREDA—Colorado River Energy Distributors Association.
54. CSU—Colorado Springs Utilities.
55. CTA—Competitive Transmission Association, Inc.
56. Dalton Utilities—Board of Water, Light and Sinking Fund Commissioners of the City of Dalton, Georgia.
57. Dairyland—Dairyland Power Cooperative.
58. Desert STAR—Desert STAR.
59. Detroit Edison—Detroit Edison Company.
60. Distributed Power—Distributed Power Coalition of America.
61. DOE—United States Department of Energy.
62. Dr. Illic—Dr. Marija Illic and Yong Yoon.
63. Duke—Duke Energy Corporation.
64. Duquesne—Duquesne Light Company.
65. Dynegy—Dynegy Inc.
66. EAL—ESBI Alberta Ltd.
67. East Kentucky—East Kentucky Power Cooperative, Inc.
68. East Texas Cooperatives—East Texas Electric Cooperative, Inc., Northeast Texas Electric Cooperative, Inc., Sam Rayburn G&T Electric Cooperative, Inc., Tex-La Electric Cooperative of Texas, Inc.
69. ECAR—East Central Area Reliability Council.
70. EEI—Edison Electric Institute.
71. EME—Edison Mission Energy.
72. Empire District—Empire District Electric Company.
73. Enron/APX/Coral Power—Enron Power Marketing, Inc., Automated Power Exchange and Coral Power, L.L.C.
74. Entergy—Entergy Services Inc.
75. EPA—United States Environmental Protection Agency.
76. EPRI—Electric Power Research Institute.
77. EPSA—Electric Power Supply Association.
78. Eric Hirst—Mr. Eric Hirst.
79. Fertilizer Institute—The Fertilizer Institute.
80. First Rochdale—1st Rochdale Cooperative Group, Ltd.
81. FirstEnergy—FirstEnergy Corp.
82. Florida Commission—Florida Public Service Commission.
83. Florida Power Corp.—Florida Power Corporation.
84. FMPA—Florida Municipal Power Agency.
85. FP&L—Florida Power & Light Company.
86. FTC—Staff of the Bureau of Economics of the Federal Trade Commission.
87. Gainesville—Gainesville Regional Utilities.
88. Georgia Transmission—Georgia Transmission Corporation.
89. GPU Energy—GPU Energy.
90. Grand Council *et al.*—Grand Council of the Crees, Greenpeace Canada, the Sierra Club of Canada, Mouvement Au Courant, the Centre D'Analyses de Politiques Energetiques and New England Coalition for Energy Efficiency and the Environment.
91. Great River—Great River Energy.
92. H.Q. Energy Services—Energy Services Group of Hydro-Quebec and H.Q. Energy Services (U.S.) Inc.
93. How Group—OASIS How Working Group.
94. ICUA—Idaho Consumer-Owned Utilities Association.

95. Idaho Commission—Idaho Public Utilities Commission.
96. Idaho Power—Idaho Power Company.
97. Illinois Commission—Illinois Commerce Commission.
98. IMEA—Illinois Municipal Electric Agency.
99. IMPA—Indiana Municipal Power Agency.
100. Indiana Commission—Indiana Utility Regulatory Commission.
101. Indianapolis P&L—Indianapolis Power & Light Company.
102. Industrial Consumers—Electricity Consumers Resource Council, the American Iron & Steel Institute and the Chemical Manufacturers Association.
103. Industrial Customers—Industrial Customers of Northwest Utilities.
104. INGAA—Interstate Natural Gas Association of America.
105. Iowa Board—Iowa Utilities Board.
106. IPCF—International Powerline Communications Forum.
107. ISO-NE—ISO New England Inc.
108. JEA—JEA.
109. Justice Department—United States Department of Justice.
110. Kentucky Commission—Kentucky Public Service Commission.
111. Konolige/Ford/Fleishman—Kit Konolige, Daniel F. Ford and Steven I. Fleishman.
112. Lenard—Mr. Thomas M. Lenard.
113. LEPA—Louisiana Energy & Power Authority.
114. LG&E—LG&E Energy Corp.
115. Lincoln—Lincoln, Nebraska Electric System.
116. LIPA—Long Island Power Authority.
117. Los Angeles—Los Angeles Department of Water and Power.
118. Loveland Customers—Loveland Area Customers Association.
119. LPPC—Large Public Power Council.
120. Manitoba Board—Manitoba Hydro-Electric Board.
121. MAPP—Mid-Continent Area Power Pool.
122. Mass Companies—Boston Edison Company, Cambridge Electric Light Company and Commonwealth Electric Company.
123. Massachusetts Division—Massachusetts Division of Energy Resources.
124. MEAG—Municipal Electric Authority of Georgia.
125. Merrill Energy—Merrill Energy LLC.
126. Metropolitan—Metropolitan Water District of Southern California.
127. Michigan Commission—Michigan Public Service Commission.
128. MidAmerican—MidAmerican Energy Company.
129. Mid-Atlantic Commissions—Delaware Public Service Commission, District of Columbia Public Service Commission, Maryland Public Service Commission, New Jersey Board of Public Utilities and Pennsylvania Public Utility Commission.
130. Midwest Energy—Midwest Energy, Inc.
131. Midwest ISO—Midwest Independent Transmission System Operator, Inc.
132. Midwest ISO Participants—Allegheny Energy, Ameren, Central Illinois Light Company, Cinergy Corp., Commonwealth Edison Company, Hoosier Energy Rural Electric Cooperative, Inc., Illinois Power Company, Kentucky Utilities Company, Louisville Gas & Electric Company, Southern Indiana Gas & Electric Company, Southern Illinois Power Cooperative, Wabash Valley Power Association, Inc. and Wisconsin Electric Power Company.
133. Midwest Municipals—Missouri River Energy Services, Iowa Association of Municipal Utilities and Minnesota Municipal Utilities Association.
134. Minnesota Commission—Minnesota Public Utilities Commission.
135. Minnesota Power—Minnesota Power.
136. Missouri Commission—Missouri Public Service Commission.
137. MLGW—Memphis Light, Gas and Water Division.
138. Montana Commission—Montana Public Service Commission and Montana Department of Environmental Quality.
139. Montana Power—Montana Power Company.
140. Montana-Dakota—Montana-Dakota Utilities Co.
141. NARUC—National Association of Regulatory Utility Commissioners.
142. NASUCA—National Association of State Utility Consumer Advocates.
143. NCPA—Northern California Power Agency.
144. NEMA—National Energy Marketers Association.
145. NECPUC—New England Conference of Public Utilities Commissioners, Inc.
146. NEPCO et al.—New England Power Company, National Grid Group, plc and Montaup Electric Company.
147. NERA—National Economic Research Associates, Inc.
148. NERC—North American Electric Reliability Council.
149. Nevada Commission—Public Utilities Commission of Nevada
150. New Century—New Century Energies, Inc. and its operating utility companies: Public Service Company of Colorado, Southwestern Public Service Company and Cheyenne Light, Fuel and Power Company.
151. New Orleans—Council of the City of New Orleans.
152. New Smyrna Beach—Utilities Commission, City of New Smyrna Beach, Florida.
153. New York Commission—New York State Public Service Commission
154. Nine Commissions—Pennsylvania Public Utility Commission, Virginia State Corporation Commission, Public Utilities Commission of Ohio, Indiana Utility Regulatory Commission, Illinois Commerce Commission, Michigan Public Service Commission, Missouri Public Service Commission, Arkansas Public Service Commission and Oklahoma Corporation Commission.
155. NiSource—NiSource Incorporated.
156. NJBUS—New Jersey Business Users.
157. NMA/WFA/CEED—National Mining Association, Western Fuels Association, Inc. and Center for Energy and Economic Development.
158. NU—Northeast Utilities System.
159. Northwest Council—Northwest Power Planning Council.
160. NPCC—Northeast Power Coordinating Council.
161. NPPD—Nebraska Public Power District.
162. NPRB—Nebraska Power Review Board.
163. NRECA—National Rural Electric Cooperative Association.
164. NSP—Northern States Power Company.
165. NU—Northeast Utilities System.
166. NWCC—National Wind Coordinating Committee.
167. NY ISO—New York Independent System Operator, Inc.
168. NYC—City of New York.
169. NYEBF—New York Energy Buyers Forum.
170. NYMEX—New York Mercantile Exchange.
171. NYPP—Member Systems of the New York Power Pool (Central Hudson Gas & Electric Corporation, Consolidated Edison Company of New York, Inc., Long Island Power Authority, New York State Electric & Gas Corporation, Niagara Mohawk Power Corporation, Orange and Rockland Utilities, Inc., Rochester Gas and Electric Corp. and Power Authority of the State of New York).
172. Oglethorpe—Oglethorpe Power Corporation.
173. Ohio Commission—Public Utilities Commission of Ohio.
174. Oneok—Oneok Power Marketing.
175. Ontario IMO—Ontario Independent Electricity Market Operator.
176. Ontario Power—Ontario Power Generation Inc.
177. Oregon Office—Oregon Office of Energy.
178. Otter Tail—Otter Tail Power Company.
179. PacifiCorp—PacifiCorp.
180. PECO—PECO Energy Company and Horizon Energy.
181. Pennsylvania Commission—Pennsylvania Public Utility Commission.
182. PG&E—PG&E Corporation.
183. PGE—Portland General Electric Company.
184. PGP—Public Generating Pool.
185. PJM—PJM Interconnection, L.L.C.
186. PJM/NEPOOL Customers—PJM Industrial Customer Coalition, NEPOOL Industrial Customer Coalition and Coalition of Midwest Transmission Customers.
187. Platte River—Platte River Power Authority.
188. PNGC—Pacific Northwest Generating Cooperative.
189. Powerex—British Columbia Power Exchange Corporation.
190. PP&L Companies—PP&L Inc., PP&L EnergyPlus Co., L.L.C., PP&L Montana, L.L.C.
191. PPC—Public Power Council.
192. Professor Hogan—Professor William W. Hogan.
193. Professor Joskow—Professor Paul L. Joskow.
194. Professor Koch—Professor Charles H. Koch, Jr.
195. Project Groups—Alliance for Affordable Energy, American Wind Energy Association, Center for Clean Air Policy, Center for Energy Efficiency and Renewable Technologies, Citizen Power, Inc., Citizens

- for Pennsylvania's Future, Delaware Division of the Public Advocate, Environmental Law & Policy Center of the Midwest, Land & Water Fund of the Rockies, Legal Environmental Assistance Foundation, Minnesotans for an Energy-Efficient Economy, Natural Resources Defense Council, Northwest Energy Coalition, Office of the People's Counsel of the District of Columbia, Pace Energy Project, Pennsylvania Energy Project, Public Citizen, PJM Public Interest/Environmental User Group, Renew Wisconsin, Southern Environmental Law Center, Tennessee Valley Energy Reform Coalition, Union of Concerned Scientists, Wisconsin's Environmental Decade.
196. PSE&G—Public Service Electric and Gas Company.
197. PSNM—Public Service Company of New Mexico.
198. Public Citizen—Public Citizen.
199. Puget—Puget Sound Energy, Inc.
200. Rayburn—Rayburn Country Electric Cooperative, Inc.
201. RECA—Residential Electric Consumers Association.
202. Reliant—Reliant Energy, Incorporated.
203. RUS—Rural Utilities Service of the Department of Agriculture.
204. Salomon Smith Barney—Global Power Group of Salomon Smith Barney.
205. San Francisco—City and County of San Francisco.
206. SCE&G—South Carolina Electric & Gas Company.
207. Seattle—Seattle City Light Department.
208. SERC—Southeastern Electric Reliability Council.
209. Sierra Pacific—Sierra Pacific Resources, Inc.
210. Sithe—Sithe Energies, Inc.
211. SMUD—Sacramento Municipal Utility District.
212. Snohomish—Public Utility District No. 1 of Snohomish County, Washington.
213. SNWA—Southern Nevada Water Authority.
214. SoCal Cities—Cities of Anaheim, Azusa, Banning, Colton, and Riverside, California.
215. SoCal Edison—Southern California Edison Company.
216. Sonat—Sonat Power Marketing, L.P.
217. South Carolina Authority—South Carolina Public Service Authority.
218. South Carolina Commission—Public Service Commission of South Carolina.
219. Southern Company—Southern Company Services, Inc., acting as agent for Alabama Power Company, Georgia Power Company, GulfPower Company, Mississippi Power Company and Savannah Electric and Power Company.
220. SPP—Southwest Power Pool, Inc.
221. SPRA—Southwestern Power Resources Association.
222. SRP—Salt River Project Agricultural Improvement and Power District.
223. St. Joseph—St. Joseph Light & Power Company.
224. Statoil—Statoil Energy, Inc.
225. STDUG—Southwest Transmission Dependent Utility Group.
226. Steel Dynamics—Steel Dynamics, Inc.
227. Tacoma Power—City of Tacoma, Department of Public Utilities, Light Division.
228. Tallahassee—City of Tallahassee, Florida.
229. Tampa Electric—Tampa Electric Company.
230. TANC—Transmission Agency of Northern California.
231. TAPS—Transmission Access Policy Study Group.
232. TDU Systems—Alabama Electric Cooperative, Inc., Arkansas Electric Cooperative Corporation, Golden Spread Electric Cooperative, Kansas Electric Power Cooperative, Inc., North Carolina Electric Membership Corporation, Old Dominion Electric Cooperative, Seminole Electric Cooperative, Inc., and South Mississippi Electric Power Association.
233. Tennessee Authority—Tennessee Regulatory Authority.
234. TEP—Tucson Electric Power Company.
235. Texas Commission—Public Utility Commission of Texas.
236. Trans-Elect—Trans-Elect, Inc.
237. Transénergie—Transénergie.
238. Transmission ISO Participants—Baltimore Gas & Electric, Boston Edison Company, Cambridge Electric Light Company, Commonwealth Energy Company, Conectiv, GPU Energy, Niagara Mohawk Power Company, Northeast Utilities Service Company, PECO Energy Company, PP&L, Inc., Potomac Electric Power Company, Public Service Electric and Gas Company, Vermont Electric Power Company, Inc.
239. Tri-State—Tri-State Generation and Transmission Association, Inc.
240. Turlock—Turlock Irrigation District.
241. TVA—Tennessee Valley Authority.
242. TXU Electric—TXU Electric Company.
243. UAMPS—Utah Associated Municipal Power Systems.
244. UMPA—Utah Municipal Power Agency.
245. United Illuminating—United Illuminating Company.
246. UtiliCorp—UtiliCorp United, Inc.
247. Utility Engineers—Utility Economic Engineers.
248. Vernon—City of Vernon, California.
249. Virginia Commission—Virginia State Corporation Commission.
250. Virginia Power—Virginia Electric and Power Company.
251. Washington Commission—Washington Utilities and Transportation Commission.
252. WEPCO—Wisconsin Electric Power Company.
253. WICF—Western Interconnection Coordination Forum.
254. Williams—Williams Companies, Inc.
255. Wisconsin Commission—Public Service Commission of Wisconsin.
256. Wolverine Cooperative—Wolverine Power Supply Cooperative, Inc.
257. WPPI—Wisconsin Public Power, Inc.
258. WPSC—Wisconsin Public Service Corporation.
259. Wyoming Commission—Wyoming Public Service Commission.

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Federal Register

Thursday
January 6, 2000

Part III

**Department of
Veterans Affairs**

38 CFR Parts 17 et al.

**Per Diem for Nursing Home Care of
Veterans in State Homes; Final Rule**

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Parts 17, 51, and 58

RIN 2900-AE87

Per Diem for Nursing Home Care of Veterans in State Homes

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document amends regulations regarding the payment of per diem to State homes that provide nursing home care to eligible veterans. The intended effect of the final rule is to ensure that veterans receive high quality care in State homes.

DATES: *Effective date:* February 7, 2000.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of February 7, 2000.

FOR FURTHER INFORMATION CONTACT: L. Nan Stout, Chief, State Home Per Diem Program (114), Veterans Health Administration, 202-273-8538.

SUPPLEMENTARY INFORMATION: In a document published in the *Federal Register* on November 9, 1998 (63 FR 60227), we proposed to establish a new part 51 setting forth a mechanism for paying per diem to State homes providing nursing home care to eligible veterans. We provided a 60-day comment period which ended January 8, 1999. We received responses from 20 commenters. The issues raised in the comments are discussed below.

Based on the rationale set forth in the proposed rule and in this document, we are adopting the provisions of the proposed rule as a final rule with changes explained below. Under the final rule, VA will pay per diem to a State for providing nursing home care to eligible veterans in a facility if the Under Secretary for Health recognizes the facility as a State home based on a current VA certification that the facility meets the standards set forth in subpart D.

Section 51.2 Definitions

We proposed to define "physician assistant" to mean a person who meets the applicable State requirements for physician assistants, is currently certified by the National Commission on Certification of Physician Assistants (NCCPA) as a physician assistant, and has an individualized written scope of practice that determines the authorization to write medical orders, prescribe medications and other clinical tasks under appropriate physician

supervision which is approved by the primary care physician.

One commenter asserted that the definition should not include a requirement that a physician assistant be currently certified by the National Commission on Certification of Physician Assistants. In this regard, the commenter argued that the imposition of a national certification requirement would be cumbersome to administer and create confusion regarding which physician assistants regulated by the State could provide services to veterans in State homes. No changes are made based on this comment. We believe this certification is necessary to ensure that physician assistants meet uniform standards necessary to ensure that they are qualified to provide adequate care at a State nursing home facility. In our view, this will not cause significant administrative work. The State home merely will have to determine whether the individual has the appropriate certification.

Under the proposed definition of "State home," a State home may provide domiciliary care, nursing home care, adult day health care, and hospital care. Also, under the definition, hospital care may be provided only when the State home also provides domiciliary and/or nursing home care.

One commenter asserted the definition should replace "domiciliary care" with "assisted living." No changes are made based on this comment. The statutory authority for levels of care at State homes includes domiciliary care, but not assisted living. (See 38 U.S.C. 1741-1743).

Section 51.10 Per Diem based on Recognition and Certification

The provisions of § 51.10 state that after recognition has been granted, VA will continue to pay per diem to a State for providing nursing home care to eligible veterans in such a facility for a temporary period based on a certification that the facility and facility management provisionally meet the standards of subpart D. One commenter asked how long the temporary period would be if a facility receives a "provisionally meets" certification.

The temporary period related to provisionally meeting the standards could vary. Under the provision of § 51.30(a)(2) the temporary period is based on time frames provided by the State home in a written plan of correction and approved by the director of VA medical center of jurisdiction.

Section 51.30 Recognition and Certification

The provisions of § 51.30 state that the Under Secretary for Health will make the determination regarding recognition and the initial determination regarding certification, after receipt of a tentative determination from the director of the VA medical center of jurisdiction regarding whether, based on a VA survey, the facility and facility management meet or do not meet the standards of subpart D.

Commenters asserted that we should establish a time limit for the determination for recognition, initial certification, notification regarding failure to meet standards, and re-certification by VA. No changes are made based on these comments. We are committed to making decisions as quickly as possible. However, VA must take whatever time is necessary to make accurate decisions. Section 51.30 provides for recognition and certification based on surveys establishing that the standards in subpart D are met.

One commenter asserted that § 51.30 is reactive and punitive by anticipating deficiencies and precluding a deficiency-free review. The commenter further stated that a paper compliance review should be established for the year following a review that did not cite deficiencies. No changes are made based on these comments. We believe that the yearly review must be adequate to ensure compliance with the provision in subpart D. This will require more than a paper review regardless of previous compliance.

With respect to the provisions of § 51.30(a)(2), one commenter inquired about when a facility would be determined to "provisionally" meet the standards and continue to receive per diem. In this regard, the provisions of § 51.30(a)(2) allow for provisional certification only if all of the following are met: the facility or facility management does not meet one or more of the standards in subpart D, that the deficiencies do not jeopardize the health or safety of the residents, and that the facility management and the director have agreed to a plan of correction to remedy the deficiencies in a specified amount of time (not more time than the VA medical center of jurisdiction director determines is reasonable for correcting the specific deficiencies). If the facility does not meet one or more of the standards in subpart D and also does not meet the criteria for provisional certification, VA must take action to withhold per diem payments and withdraw recognition.

One commenter asserted that the final rule should provide for an informal dispute resolution process regarding the existence and scope of potential deficiencies. No changes are made based on this comment. The authority and responsibility for the per diem program have been delegated solely to VA by statute. (See 38 U.S.C. 1741-1743). There is no basis for delegating this authority outside VA.

One commenter questioned whether Veterans Integrated Service Network (VISN) entities would conduct annual certification surveys. No changes are made based on this comment. The director of the VA Medical Center of jurisdiction is responsible for the annual certification survey and may delegate any qualified VA official to conduct the survey.

One commenter asserted that VA should accept Joint Commission on Accreditation Healthcare Organizations (JCAHO) and Medicaid/Medicare inspections in lieu of annual VA inspections. The commenter also asserted that State homes that are licensed as nursing homes by the State should be exempt from annual VA inspections. The commenter further asserted that annual VA inspections should occur only if there is reason to believe that a facility is not substantially in compliance with VA regulations. No changes are made based on this comment. It is solely VA's responsibility to ensure that VA's regulations are met. Further, non-VA inspections do not cover all of the standards in the final rule and compliance with State standards would not be sufficient to ensure compliance with all of the standards in the final rule. Furthermore, we believe that in order to ensure compliance with our standards, VA must conduct reviews at least on a yearly basis. Even so, under § 51.30(a) the judgement of VA officials concerning compliance with the requirements of the final rule may be made in part based on reviews of reports of inspection by other entities.

Section 51.31 Automatic Recognition

Under the final rule VA would pay per diem to a State for providing nursing home care to eligible veterans in a facility if the Under Secretary for Health recognizes the facility as a State home based on a current VA certification that the facility meets the standards set forth in subpart D. One commenter questioned whether previously recognized facilities would be required to submit a new request for recognition and certification under the final rule.

We have added a new § 51.31 to explain that a facility that already is recognized by a VA as a State home for nursing home care at the time this part becomes effective, automatically will continue to be recognized as a State home for nursing home care. This new section further explains that even though the facility would continue to be recognized, it is subject to all of the provisions of this part that apply to facilities that have achieved recognition, including the provisions for withholding payment and withdrawal of recognition.

Section 51.40 Monthly Payment

The provisions of § 51.40(a)(1) specify that during fiscal year 2000 VA will pay monthly one-half of the cost of each eligible veteran's nursing home care for each day the veteran is in a facility recognized as a State home for nursing home care, not to exceed \$50.55 per diem. Five commenters asserted that the currently applicable rate should not be included in the regulations. In this regard, they were concerned that a delay in publishing changed amounts could delay the receipt of increases in per diem. No changes are made based on these comments. The amount of per diem to be paid is based on provisions of 38 U.S.C. 1741. We intend to change the per diem amount in the regulations as quickly as possible after there is a basis for doing so.

The provisions of § 51.40(a)(5) state that as a condition for receiving payment of per diem the State must submit to the VA medical center of jurisdiction for each veteran completed VA Forms 10-10EZ, Application for Medical Benefits, and 10-10SH, State Home Program Application for Care—Medical Certification, at the time of admission and with any request for a change in the level of care (domiciliary, hospital, or adult day health care). The 10-10SH form provides that it is to be completed by the "primary physician assigned" at the State facility. One commenter suggested that any physician (State, VA, or personal) should be allowed to complete the form. They further asserted that this could be a hardship for veterans "who live around the State". No changes are made based on this comment. The purpose of the forms, among other things, is to obtain information regarding whether the veteran has been admitted to the nursing home as a resident and whether the veteran meets eligibility criteria for per diem payments. It was not intended to be used by the State facility for an earlier State determination concerning whether a veteran should become a resident at the facility.

The commenter further questioned whether VA would conduct any screening of applicants for admission to State homes. The commenter further questioned whether the facility needs to obtain prior approval before admitting a veteran as a resident or whether they can assume approval based on the submission of the appropriate forms. No changes are made based on these comments. In our view, the provisions for determining eligibility for placement for nursing home care are sufficiently clear so that State homes can make appropriate determinations without prior approval of residents by VA.

The provisions of § 51.40(a)(5) also provide that if the facility is eligible to receive per diem payments for a veteran, VA will pay per diem from the date of receipt of the completed forms required by this paragraph, except that VA will pay per diem from the day on which the veteran was admitted to the facility if the completed forms are received within 10 days after admission. One commenter asserted that the 10-day requirement is too short because information required by form 10-10EZ "may be difficult to get." No changes are made based on this comment. The information requested is the basic information required for eligibility determinations. We do not see any reason why the information requested cannot be obtained at the time the veteran is admitted to a State home.

As noted above, § 51.40(a)(5) provides that if the forms are submitted to the VA medical center of jurisdiction within 10 days after admission, VA will pay per diem from the day on which the veteran was admitted. One commenter suggested that VA clarify who in VA must receive the completed forms. No changes are made based on this comment. All that is necessary is that the forms be received by the VA medical center of jurisdiction and if received within the 10 day period, the requirement will be met. Officials at the medical center will ensure that the forms are sent to the appropriate VA officials for processing.

A veteran may be VA approved for nursing home care, then be approved for a different level of care (domiciliary, hospital, or adult day health care) for a period of time, and then be readmitted to nursing home care. One commenter asserted that the initial approval should be sufficient for any subsequent readmission. No changes are made based on this comment. The provisions of § 51.40(a)(5) state that information must be submitted for each admission. This is necessary to ensure that the veteran still meets VA requirements for

payment of per diem for that level of care.

Section 51.50 Eligible Veterans

Per diem payments may be paid only for eligible veterans. Section 51.50 specifies which individuals are eligible veterans. This includes paragraph (j) which consists of veterans who agree to pay to the United States the applicable co-payment determined under 38 U.S.C. 1710(f) and 1710(g). Four commenters asserted that paragraph (j) should be deleted. No changes are made based on these comments. The eligibility requirements are established by statute (see 38 U.S.C. 1710(a)). Accordingly, the requirement for this category of eligible veterans cannot be changed by regulation.

Section 51.70 Resident Rights

The advance directive provisions of § 51.70(b)(7) of this rule and the provisions of a separate VA proposed rulemaking regarding advanced directives (63 FR 58678) would not prohibit an advance directive from being honored at a VA facility if it has not been signed by a notary public or Justice of the Peace. One commenter noted that such an advance directive might not be effective if the veteran were moved to a State home in which a State law requires the use of a notary public or Justice of the Peace. No changes are made based on this comment. Since VA cannot reasonably administer all State laws regarding advanced directives, we believe the responsibility for ensuring that advanced directives are effective in State homes rests within State home officials and not VA.

One commenter asserted that § 51.70(b)(7) presents a dilemma. The commenter asserted that if a person is incapacitated and unable to receive/understand information on advanced directives and does not have a power of attorney, he/she would be unable to give informed consent to moving to the home in the first place and their right to "self-determination" § 51.70(7) would be violated. No changes are made based on this comment. The provisions of § 51.70(7) cover the issue of incapacitation. Section 51.70(7) states: "If an individual is incapacitated at the time of admission and is unable to receive information (due to the incapacitating conditions) or articulate whether or not he or she has executed an advance directive, the facility may give advance directive information to the individual's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated

individual or to a surrogate or other concerned persons in accordance with State laws."

The provisions of § 51.70(c)(1) state that the residents have a right to manage their financial affairs, and the facility and facility management may not require residents to deposit their personal funds with the facility. Commenters asserted that nursing home facilities should be allowed to require residents to deposit funds with the facility for payment of personal items. No changes are made based on these comments. Although many residents may choose to deposit an amount with the facility for personal items, we believe that residents should be allowed to pay for their personal items by check or other means they deem appropriate.

One commenter suggested that a resident who insists on carrying large sums of cash should be required to sign a waiver for lost or misplaced funds. No changes are made in § 51.70(c)(3) based on this comment. The final rule does not prohibit nursing homes from establishing such a policy.

The provisions of proposed § 51.70(c)(3) stated that the facility management must deposit any residents' personal funds in excess of \$50 in an interest bearing account (or accounts) that is separate from any of the facility's operating accounts, and that credits all interest earned on the resident's funds to that account. (In pooled accounts, there must be a separate accounting for each resident's share.) One commenter asserted that any resident's personal funds held by facility management should be allowed to accrue interest for projects for the benefit of all residents if allowed by State law. No changes are made based on this comment. In our view, the interest generated from personal funds belongs to the owner of the funds and, therefore, should be held for the owner.

One commenter suggested that the \$50 threshold amount should be raised to \$100. We agree and have changed the final rule accordingly. The larger amount will allow more flexibility for veterans and State homes and will still provide a reasonable threshold for requiring amounts to be placed in interest bearing accounts.

The provisions of § 51.70(c)(4)(ii) state that individual financial records must be available through quarterly statements and on request from the resident or legal representative. One commenter asserted that there is no need for any reports until requested. No changes are made based on this comment. We believe that residents who would not otherwise review their accounts would be more likely to do so

if statements were received on a periodic basis. Further, this will help to ensure that any differences would be resolved in a timely manner.

The provisions of proposed § 51.70(c)(5) stated that upon the death of a resident with personal funds deposited with the facility, the facility management must convey within 30 days the resident's funds, and a final accounting of those funds, to the individual or probate jurisdiction administering the resident's estate. One commenter asserted that sometimes the cost to the family or interested parties to probate an estate may be prohibitive compared to what is left in the estate. This commenter indicated that at least one State allows for the transfer of balances to an appropriate family member. We have changed our final rule to allow for this possibility.

The provisions of § 51.70(i) state that a State home resident must have the right to privacy in written communications, including the right to send and promptly receive mail that is unopened. One commenter stated that facility officials need to be allowed to open VA and Social Security mail with permission of the veteran. The commenter further asserted that otherwise the veteran might miss appointments. No changes are made based on this comment. The final rule merely states that a veteran has the right to send and receive mail that is unopened. This does not prohibit an agreement between the facility and the resident to allow the facility to open the veteran's mail.

The provisions of § 51.70(j)(1) state that a resident must have the right to, and the facility management must provide, immediate access to a physician of the resident's choice. One commenter asserted that a physician, acting as a physician on behalf of a resident should not be allowed to provide care to a resident in the nursing home if the physician is not approved by the Medical Director to practice in the nursing home. The final rule at § 51.210(j) already requires physicians practicing at the nursing home to be credentialed and privileged by the nursing home. The provisions of § 51.70(j)(1) are amended to clarify this issue.

The provisions of § 51.70(l) states that the resident has the right to retain and use personal possessions, including some furnishings, and appropriate clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents. One commenter asserted that the retention of personal furnishings should be at the sole discretion of the facility. No

changes are made based on this comment. The final rule allows the resident to retain and use personal possessions "as space permits." This gives the facility the needed discretion to ensure order within the facility.

Section 51.80 Admission, Transfer and Discharge Rights

The provisions of § 51.80(a)(1) state that transfer and discharge includes movement of a resident to a bed outside of the facility whether that bed is in the same physical plant or not. Transfer and discharge does not refer to movement of a resident to a bed within the same facility. One commenter asserted that the regulations were unclear as whether there would be transfer or discharge if a resident were moved from one level of care to another level of care in the same building or in the same complex of buildings. No changes are made based on this comment. The provisions of § 51.80(a)(1) read in conjunction with the definition of facility in § 51.2 clearly provide that a movement outside of the facility is any movement outside of the nursing home portion of the complex.

Section 51.100 Quality of Life

The provisions of § 51.100(g)(1)(2)(i) and (ii) state that the facility management must provide an ongoing program of activities designed to meet, in accordance with the comprehensive assessment, the interests and the physical, mental, and psychosocial well-being of each resident. The provisions require that the activities program be directed by a qualified professional who is a qualified therapeutic recreation specialist or an activities professional who is licensed or registered, if applicable, by the State in which practicing; and is certified as a therapeutic recreation specialist or as an activities professional by a recognized accrediting body. Two commenters asserted that these provisions are too stringent and that qualified personnel would be prohibited from working at the facility. No changes are made based on these comments. We believe these are the minimal criteria necessary to ensure that the ongoing program of activities is sufficient to meet, in accordance with the comprehensive assessment, the interests and the physical, mental, and psychological well-being of each veteran.

The proposed provisions of § 51.100(h)(3) stated that a social worker at a facility must have the following: a bachelor's degree in social work from a school accredited by the Council of Social Work Education and a social work license from the State in which the

State home is located, if offered by the State, and a minimum of one year of supervised social work experience, under the supervision of a social worker with a master's degree, in a health care setting working directly with individuals. Six commenters opposed the provision that would require the experience to be under the supervision of a social worker with a master's degree. We agree and eliminated this provision. We believe that a social worker can provide adequate service without meeting such requirement.

The provisions of § 51.100(i)(6) state that facility management must provide comfortable and safe temperature levels. In this regard, it states that facilities must maintain a temperature range of 71–81 degrees Fahrenheit. One commenter asserted that this requirement should be waived in older facilities where central air conditioning is not available. No changes are made based on this comment. The specified temperatures are necessary to ensure that residents are comfortable and safe.

Section 51.110 Resident Assessment

The provisions of § 51.110(b)(1)(iii) state that the facility management must make a comprehensive assessment of a resident's needs using the Health Care Financing Administration Long Term Care Resident Assessment Instrument Version 2.0; and describing the resident's capability to perform daily life functions, strengths, performances, needs as well as significant impairments in functional capacity. All nursing homes must be in compliance with this standard by no later than January 1, 2000. Two commenters asserted that the compliance date of January 1, 2000, must be extended. The commenters essentially asserted that more time is needed to computerize the process and train staff. No changes are made based on these comments. Most facilities report that they already are in compliance. Compliance is needed to ensure that facilities have standardized comprehensive assessments of resident needs.

Section 51.120 Quality of Care

The proposed provisions of § 51.120(a)(3) state that the facility management must report sentinel events to the director of the VA medical center of jurisdiction, VA Network Director (10N 1–22), Chief Network Officer (10N), and Chief Consultant, Geriatrics and Extended Care Strategic Healthcare Group (114) within 24 hours of identification. Nine commenters objected to reporting the same information to so many VA entities. They asserted that they should have to

report only to one VA entity and that VA could report internally as it sees fit. We agree and have changed the final rule to provide for reporting to the VA medical center of jurisdiction. We also have added language requiring the VA medical center to immediately report to the other listed VA entities.

One commenter also asserted that the report should be required to be submitted within 7 days rather than with 24 hours of identification of the event. No changes are made based on this comment. The sentinel events often reflect need for immediate review.

Section 51.130 Nursing Services

The provisions of § 51.130(d) state that the facility management must provide nursing services to ensure that there is direct care nurse staffing of no less than 2.5 hours per patient per 24 hours, 7 days per week. One commenter questioned whether managers would be included for calculating the 2.5 hours. No changes are made based on this comment. The provisions of paragraph (d) made clear that the 2.5 hours consist only of "direct care nurse staffing". Supervisory nurses normally would not meet these criteria.

One commenter questioned whether the 2.5 hours requirement would be based on a facility-wide average or based on each individual nursing station. This was intended to apply to all or portion of a facility where the direct care nurses would have immediate access to nursing home care. In our view, this would be accomplished if the 2.5 hours requirement were met for all of any building providing nursing home care. We have clarified the final rule accordingly.

In the past, we administratively imposed a 2.0 hours per patient per day requirement. One commenter asserted that we should retain the 2.0 hour requirement. No changes are based on this comment. Although the 2.0 hour requirement was appropriate in the past, there has been a significant increase in patient acuity that requires the increase to 2.5 hours.

One commenter asserted that the 2.5 hours requirement should not become effective until January 2000. No changes are based on this comment. Almost all State homes providing nursing home care currently meet the 2.5 hours requirement. Further, we believe this is a minimal requirement for ensuring adequate care for nursing home care patients.

One commenter asserted that the 2.5 hours requirement should be allowed to include paid staff break times. No changes based on this comment. Breaks,

including lunch, are not included. The 2.5 hours constitute minimum criteria for ensuring the availability of adequate care.

One commenter asserted that an increase from the 2.0 hours requirement to a 2.5 hours requirement constitutes an unfunded mandate and, consequently, is subject to Federal unfunded mandate requirements. No changes are made based on this comment. The provisions of 2 U.S.C. 658 exclude from any Federal unfunded mandate requirements any regulation that imposes a duty on a State as a condition of Federal Assistance and (with exceptions not relevant to this care) any regulation that imposes a duty arising from participation in a voluntary Federal Program.

One commenter questioned whether certain circumstances might require 3.0 hours per patient. No changes are made based on this comment. The 2.5 hours requirement is a minimum requirement. The provision of paragraph (e) also require that nursing care must be adequate for meeting the standards of part D. A high patient acuity could require more nursing care than those set forth as minimum standards.

The provisions of § 51.130(e) state that nurse staffing must be based on a staffing methodology that applies case-mix and is adequate for meeting the standards of this part. One commenter argued that the final rule should establish a specific standard for staffing methodology. No changes are made based on this comment. Although the staffing methodology must apply case mix and be adequate for meeting the standards of subpart D, we believe that several methodologies would be adequate for meeting the requirement.

Section 51.140 Dietary Services

The provisions of § 51.140(f)(2) state that there must be no more than 14 hours between a substantial evening meal and breakfast the following day, except that the 14 hour period may be extended to 16 hours if a resident group agrees to the extension and a nourishing snack is provided at bedtime. Two commenters noted that some residents wish to sleep late and have a late breakfast that may exceed the 14 hours. They indicated that the breakfast meal should merely be available within the 14 hour time period. We agree and have made appropriate changes to the final rule.

Section 51.150 Physician Services

The provisions of § 51.150(d) state that the facility management must provide or arrange for the provision of physician services 24 hours a day, 7

days per week, in case of an emergency. One commenter asserted that physician assistants should be able to act for physicians within their scope of practice. No changes are made based on this comment. This must be limited to physicians since a need could arise that would be beyond the scope of practice of physician assistants.

Under the provisions of proposed § 51.150(e) the primary physician may not delegate a task when the regulations specify that the primary physician must perform it personally or when the delegation is prohibited under State law or by the facility's own policies. Otherwise, under these provisions a primary physician may delegate tasks to a certified physician assistant or a certified nurse practitioner, or a clinical nurse specialist who is acting within the scope of practice as defined by State law and who is under the supervision of the physician. These provisions also include a note stating that a certified clinical nurse specialist with experience in long term care is preferred. Two commenters asserted that the note should be clarified to reflect that experience in long term care is preferred for physician assistants and certified nurse practitioners as well as clinical nurse specialist. We have amended the note accordingly.

Section 51.180 Pharmacy Services

The provisions of § 51.180 state that the facility management must employ or obtain the services of a pharmacist licensed in a State in which the facility is located. One commenter asserted that the final rule should allow facilities to obtain the services of a VA pharmacist under a VA contract arrangement even if the VA pharmacist is not licensed in the State. We agree and have made appropriate changes. The purpose of this limitation is to ensure that the facility is able to obtain information for drug reviews and otherwise ensure appropriate on-site drug services. This purpose can be accomplished with VA pharmacist under VA contract.

Section 51.200 Physical Environment

The provisions of § 51.200(d) state that resident rooms must be designed and equipped for adequate nursing care, comfort, and privacy of residents. Bedrooms must accommodate no more than four residents; must measure at least 115 net square feet per resident in multiple resident bedrooms; must measure at least 150 net square feet in single resident bedrooms; must measure at least 245 net square feet in small double resident bedrooms; and measure at least 305 net square feet in large double resident bedrooms used for

spinal cord injury residents. It is recommended that the facility have one large double resident bedroom for every 30 resident bedrooms. Six commenters asserted that these square footage requirements should be reduced or apply only to new construction. No changes are made based on these comments. We believe that the square footage requirements are necessary to ensure sufficient space for normal daily living activities, including adequate room for movements of wheel chairs.

The provisions of § 51.200(d)(x) state that resident rooms must have a floor at or above grade level. One commenter asserted they have one subgrade unit that should be exempted from the requirement in § 51.200(d)(x). No changes are made based on this comment. We believe that nursing home care units must be at floor level or above to help ensure the availability of natural ventilation and opportunity for seeing outside.

Section 51.210 Administration

The provisions of proposed § 51.210(b)(3) provide that the State must give written notice to the Chief Consultant, Geriatrics and Extended Care Strategic Healthcare Group (114) at the time of the change of the State home director of nursing. One commenter argued that there is no need to give notice of a change regarding the State home director of nursing. We agree and have changed § 51.210(b)(3) accordingly. The notification requirement was intended to ensure that VA had a point of contact at the facility. The final rule requires written notice of a change in a State home administrator and the State employee responsible for oversight of the State home facility if a contractor operates the State home. This is sufficient for ensuring that VA has a current point of contact.

The provisions of § 51.210(c), among other things, state that the facility management must submit the following to the director of the VA medical center of jurisdiction as often as necessary to be current: The number of the staff by category indicating full-time, part-time and minority designation and the number of nursing home patients who are veterans and non-veterans, the number of veterans who are minorities and the number of non-veterans who are minorities.

One commenter suggested that changes should be required to be reported only on a semi-annual or annual basis. We have changed § 51.210(c) to state that the facility must submit the information in question annually. The reporting requirements raised by the commenter are necessary

for determining whether facilities continue to meet the standards in subpart D, for determining whether facilities meet the criteria for obtaining per diem, and to help ensure compliance with civil rights laws. We believe that annual reporting is sufficient to meet the intended purpose.

The provisions of § 51.210(d) state that the percent of the facility residents eligible for VA nursing home care must be at least 75 percent veterans except that the veteran percentage need only be more than 50 percent if the facility was constructed or renovated solely with State funds. This paragraph further states that all non-veteran residents must be spouses of veterans or parents all of whose children died while serving in the armed forces of the United States.

One commenter asserted that the definition of State home should include language stating that care may be provided for a spouse of a veteran as allowed by individual State law. Three commenters argued that honorably discharged members of the National Guard and certain non-listed individuals related to veterans should be allowed to be included as nonveterans at State nursing homes. No changes are made based on these comments. The requirements concerning non-veterans are necessary to ensure that the State homes are used for veterans as required by 38 U.S.C. 101(19). We believe the narrow exceptions are necessary for the well being of veterans and we do not believe that it is in the best interests of veterans to expand this further.

The provisions of proposed § 51.210(j) stated that the facility management must uniformly apply credentialing criteria to licensed independent practitioners applying to provide resident care or treatment under the facility's care. The provisions of proposed § 51.210(j) further state that the facility management must verify and uniformly apply the following core criteria: Current license; current certification, if applicable; relevant education, training, and experience; current competence; and a statement that the individual is able to perform the services he or she is applying to provide. One commenter asserted that the word "independent" be deleted so that credentialing criteria would apply to physician assistants. We agree and have deleted the word "independent" since physician assistants may be credentialed. Another commenter asserted that the requirements of § 51.210(j) are too stringent. No changes are made based on this comment. The required information is basic information needed to ensure

that the practitioners caring for the veterans are qualified to do so.

The provisions of proposed § 51.210(j)(5) stated that when reappointing a licensed independent practitioner, the facility management must review the individual's track record. Two commenters asserted that the term "track record" was too colloquial and should be replaced with "record of experience." We agree and have changed the final rule accordingly.

The provisions of proposed § 51.210(n)(2)(i) stated that the facility must provide or obtain radiology and other diagnostic services only when ordered by the primary physician. One commenter asserted that the final rule should reflect that radiology and other diagnostic services may be ordered by a physician assistant. We agree and have deleted the word "only." The authority and limitations for a physician assistant to order radiology and other diagnostic services are set forth at § 51.150(e) of the final rule.

VA Form 10-10SH

VA Form 10-10SH, State Home Program Application for Veteran Care—Medical Certification, provides a medical certification for individuals admitted to a State nursing home facility and for the State applying for per diem payments. The form is required to be signed by the primary physician as well as other staff members. One commenter asserted that the form should be amended to allow physician assistants to conduct medical evaluations and to sign the medical evaluation form. No changes are made based on this comment. Physician assistants would not have the privileges necessary for admitting patients.

Incorporation by Reference

In § 51.200, paragraphs (a), (b)(2), and (b)(4) incorporate by reference the National Fire Protection Association's NFPA 101, Life Safety Code, 1997 edition and the NFPA 99, Standard for Health Care Facilities, 1996 edition. This action would require State homes providing nursing home care to eligible veterans to comply with a national code based on actual fire experience across the country. This is necessary to help ensure that veterans are placed in facilities that are adequately protected against fires and the final rule is designed to ensure that State homes meet the fire and safety provisions of the Life Safety Code.

Forms

We have placed all forms that apply to this rule in a new Part 58 for the

purpose of making it easier to find the forms.

Executive Order 12866

This document was reviewed by the Office of Management and Budget under Executive Order 12866.

Unfunded Mandates

The Unfunded Mandates Reform Act requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits before developing any rule that may result in an expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any given year. This final rule will have no consequential effect on State, local or tribal governments.

Regulatory Flexibility Act

The Secretary hereby certifies that the adoption of this final rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601-612. All of the entities that are subject to this final rule are State government entities under the control of State governments. Of the 93 State homes, all are operated by State governments except for 16 that are operated by entities under contract with State governments. These contractors are not small entities. Therefore, pursuant to 5 U.S.C. 605(b), this final rule is exempt from the initial and final regulatory flexibility analysis requirement of §§ 603 and 604.

Paperwork Reduction Act of 1995

The collection of information contained in the notice of the proposed rulemaking was submitted to the Office of Management and Budget (OMB) for review in accordance with the Paperwork Reduction Act (44 U.S.C. 3540(h)). The information collections subject to this rulemaking are set forth in the provisions of §§ 51.20, 51.30, 51.40, 51.70, 51.80, 51.90, 51.100, 51.110, 51.120, 51.150, 51.160, 51.180, 51.190 and 51.210 of this final rule.

In this regard, the final rule requires facilities to supply various kinds of information regarding facilities providing nursing home care to ensure that high quality care is furnished to veterans who are residents in such facilities. The information includes an application for recognition based on certification; appeal information; application and justification for payment; records and reports which facility management must maintain regarding activities of residents; to include information relating to whether the facility meets standards concerning

residents rights and responsibilities prior to admission, during admission, and upon discharge; the records and reports which facility management and health care professionals must maintain regarding residents and employees; various types of documentation pertaining to the management of the facility; food menu planning; pharmaceutical records; and life safety documentation.

Interested parties were invited to submit comments on the collection of information. We received two comments from two commenters. One comment is discussed above under the heading VA Form 10-10SH. One commenter suggested that VA provide for electronic transmission of forms. No changes are made based on this comment. We are working on a system to allow the electronic transmission of forms. This is not available yet from VA.

One commenter asserted that the proposed rule did not identify how often information is required to be collected. No changes are made based on this comment. Each of the sections containing collections of information specify how often the information must be collected.

The proposed rule states that the average burden per collection is 14 minutes and that the annual reporting and recordkeeping burden for each State home is slightly less than 1 hour (12,467 total hours and 13,136 respondents). One commenter asserted that these numbers may not be accurate. No changes are made based on these comments. These figures are based on sampling in the field.

OMB has approved this information collection under control number 2900-0160 except for VA Form 10-10EZ which is approved under 2900-0091. This approval is through January 31, 2002, except for VA Form 10-10EZ, which is approved through October 31, 2001. VA is not authorized to impose a penalty on persons for failure to comply with information collection requirements which do not display a current OMB control number, if required.

List of Subjects in 38 CFR Parts 17, 51, and 58

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Foreign relations, Government contracts, Grant programs-health, Government programs-veterans, Health care, Health facilities, Health professions, Health records, Homeless, Incorporation by reference, Medical and dental schools, Medical devices, Medical research, Mental health

programs, Nursing homes, Philippines, Reporting and recordkeeping requirements, Scholarships and fellowships, Travel and transportation expenses, Veterans.

Approved: August 13, 1999.
Togo D. West, Jr.,
Secretary of Veterans Affairs.

For the reason set out in the preamble, 38 CFR Chapter I is amended as follows:

PART 17—MEDICAL

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

Authority: 38 U.S.C. 501, 1721, unless otherwise noted.

§ 17.190 [Amended]

2. In § 17.190, the introductory text is amended by removing "hospital, domiciliary or nursing home" and adding, in its place, "hospital or domiciliary;" paragraph (a) is amended by removing "or nursing home care;" paragraph (b) is amended by removing "nursing home care patients or;" and paragraph (d) is removed.

§ 17.191 [Amended]

3. Section 17.191 is amended by removing "domiciliary, nursing home" and adding, in its place, "domiciliary."

§ 17.192 [Amended]

4. Section 17.192 is amended by removing "nursing home or".

§ 17.193 [Amended]

5. Section 17.193 is amended by removing the second sentence thereof.

§ 17.195 [Removed]

6. Section 17.195 is removed.

§ 17.197 [Amended]

7. Section 17.197 is amended by removing "section 1741(a)(2) for nursing home care;."

§ 17.198 [Amended]

8. Section 17.198 is amended by removing "hospital, domiciliary or nursing home" and adding, in its place, "hospital or domiciliary."

§§ 17.190 through 17.199 [Amended]

9. A "Note" is added immediately following the undesignated center heading above § 17.190 to read as follows:

Note: Sections 17.190 through 17.200 do not apply to nursing home care in State homes. The provisions for nursing home care in State homes are set forth in 38 CFR part 51.

10. Part 51 is added to read as follows:

PART 51—PER DIEM FOR NURSING HOME CARE OF VETERANS IN STATE HOMES

Subpart A—General

Sec.

- 51.1 Purpose.
- 51.2 Definitions.

Subpart B—Obtaining Per Diem for Nursing Home Care in State Homes

- 51.10 Per diem based on recognition and certification.
- 51.20 Application for recognition based on certification.
- 51.30 Recognition and certification.
- 51.31 Automatic recognition.

Subpart C—Per Diem Payments

- 51.40 Monthly payment.
- 51.50 Eligible veterans.

Subpart D—Standards

- 51.60 Standards applicable for payment of per diem.
- 51.70 Resident rights.
- 51.80 Admission, transfer and discharge rights.
- 51.90 Resident behavior and facility practices.
- 51.100 Quality of life.
- 51.110 Resident assessment.
- 51.120 Quality of care.
- 51.130 Nursing services.
- 51.140 Dietary services.
- 51.150 Physician services.
- 51.160 Specialized rehabilitative services.
- 51.170 Dental services.
- 51.180 Pharmacy services.
- 51.190 Infection control.
- 51.200 Physical environment.
- 51.210 Administration.

Authority: 38 U.S.C. 101, 501, 1710, 1741-1743.

Subpart A—General

§ 51.1 Purpose.

This part sets forth the mechanism for paying per diem to State homes providing nursing home care to eligible veterans and is intended to ensure that veterans receive high quality care in State homes.

§ 51.2 Definitions.

For purposes of this part:
Clinical nurse specialist means a licensed professional nurse with a master's degree in nursing with a major in a clinical nursing specialty from an academic program accredited by the National League for Nursing and at least 2 years of successful clinical practice in the specialized area of nursing practice following this academic preparation.

Facility means a building or any part of a building for which a State has submitted an application for recognition as a State home for the provision of nursing home care or a building or any part of a building which VA has recognized as a State home for the provision of nursing home care.

Nurse practitioner means a licensed professional nurse who is currently licensed to practice in the State; who meets the State's requirements governing the qualifications of nurse practitioners; and who is currently certified as an adult, family, or gerontological nurse practitioner by the American Nurses' Association.

Nursing home care means the accommodation of convalescents or other persons who are not acutely ill and not in need of hospital care, but who require skilled nursing care and related medical services.

Physician means a doctor of medicine or osteopathy legally authorized to practice medicine or surgery in the State.

Physician assistant means a person who meets the applicable State requirements for physician assistant, is currently certified by the National Commission on Certification of Physician Assistants (NCCPA) as a physician assistant, and has an individualized written scope of practice that determines the authorization to write medical orders, prescribe medications and other clinical tasks under appropriate physician supervision which is approved by the primary care physician.

Primary physician or primary care physician means a designated generalist physician responsible for providing, directing and coordinating all health care that is indicated for the residents.

State means each of the several States, territories, and possessions of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

State home means a home approved by VA which a State established primarily for veterans disabled by age, disease, or otherwise, who by reason of such disability are incapable of earning a living. A State home may provide domiciliary care, nursing home care, adult day health care, and hospital care. Hospital care may be provided only when the State home also provides domiciliary and/or nursing home care.

VA means the U.S. Department of Veterans Affairs.

Subpart B—Obtaining Per Diem for Nursing Home Care in State Homes

§ 51.10 Per diem based on recognition and certification.

VA will pay per diem to a State for providing nursing home care to eligible veterans in a facility if the Under Secretary for Health recognizes the facility as a State home based on a current certification that the facility and facility management meet the standards of subpart D of this part. Also, after

recognition has been granted, VA will continue to pay per diem to a State for providing nursing home care to eligible veterans in such a facility for a temporary period based on a certification that the facility and facility management provisionally meet the standards of subpart D.

(Authority: 38 U.S.C. 101, 501, 1710, 1741–1743)

§ 51.20 Application for recognition based on certification.

To apply for recognition and certification of a State home for nursing home care, a State must:

(a) Send a request for recognition and certification to the Under Secretary for Health (10), VA Headquarters, 810 Vermont Avenue, NW., Washington, DC 20420. The request must be in the form of a letter and must be signed by the State official authorized to establish the State home;

(b) Allow VA to survey the facility as set forth in § 51.30(c); and

(c) Upon request from the director of the VA medical center of jurisdiction, submit to the director all documentation required under subpart D of this part.

(Authority: 38 U.S.C. 101, 501, 1710, 1741–1743)

§ 51.30 Recognition and certification.

(a)(1) The Under Secretary for Health will make the determination regarding recognition and the initial determination regarding certification, after receipt of a tentative determination from the director of the VA medical center of jurisdiction regarding whether, based on a VA survey, the facility and facility management meet or do not meet the standards of subpart D of this part. The Under Secretary for Health will notify the official in charge of the facility, the State official authorized to oversee operations of the State home, the VA Network Director (10N 1–22), Chief Network Officer (10N), and the Chief Consultant, Geriatrics and Extended Care Strategic Healthcare Group (114) of the action taken.

(2) For each facility recognized as a State home, the director of the VA medical center of jurisdiction will certify annually whether the facility and facility management meet, provisionally meet, or do not meet the standards of subpart D of this part (this certification should be made every 12 months during the recognition anniversary month or during a month agreed upon by the VA medical care center director and officials of the State home facility). A provisional certification will be issued by the director only upon a determination that the facility or facility management does not meet one or more

of the standards in subpart D, that the deficiencies do not jeopardize the health or safety of the residents, and that the facility management and the director have agreed to a plan of correction to remedy the deficiencies in a specified amount of time (not more time than the VA medical center of jurisdiction director determines is reasonable for correcting the specific deficiencies). The director of the VA medical center of jurisdiction will notify the official in charge of the facility, the State official authorized to oversee the operations of the State home, the VA Network Director (10N 1–22), Chief Network Officer (10N) and the Chief Consultant, Geriatrics and Extended Care Strategic Healthcare Group (114) of the certification, provisional certification, or noncertification.

(b) Once a facility has achieved recognition, the recognition will remain in effect unless the State requests that the recognition be withdrawn or the Under Secretary for Health makes a final decision that the facility or facility management does not meet the standards of subpart D. Recognition of a facility will apply only to the facility as it exists at the time of recognition; any annex, branch, enlargement, expansion, or relocation must be separately recognized.

(c) Both during the application process for recognition and after the Under Secretary for Health has recognized a facility, VA may survey the facility as necessary to determine if the facility and facility management comply with the provisions of this part. Generally, VA will provide advance notice to the State before a survey occurs; however, surveys may be conducted without notice. A survey, as necessary, will cover all parts of the facility, and include a review and audit of all records of the facility that have a bearing on compliance with any of the requirements of this part (including any reports from State or local entities). For purposes of a survey, at the request of the director of the VA medical center of jurisdiction, the State home facility management must submit to the director a completed VA Form 10–3567, Staffing Profile, set forth at § 58.10 of this chapter. The director of the VA medical center of jurisdiction will designate the VA officials to survey the facility. These officials may include physicians; nurses; pharmacists; dietitians; rehabilitation therapists; social workers; representatives from health administration, engineering, environmental management systems, and fiscal officers.

(d) If the director of the VA medical center of jurisdiction determines that

the State home facility or facility management does not meet the standards of this part, the director will notify the State home facility in writing of the standards not met. The director will send a copy of this notice to the State official authorized to oversee operations of the facility, the VA Network Director (10N 1-22), the Chief Network Officer (10N), and the Chief Consultant, Geriatrics and Extended Care Strategic Healthcare Group (114). The letter will include the reasons for the decision and indicate that the State has the right to appeal the decision.

(e) The State must submit the appeal to the Under Secretary for Health in writing, within 30 days of receipt of the notice of failure to meet the standards. In its appeal, the State must explain why the determination is inaccurate or incomplete and provide any new and relevant information not previously considered. Any appeal that does not identify a reason for disagreement will be returned to the sender without further consideration.

(f) After reviewing the matter, including any relevant supporting documentation, the Under Secretary for Health will issue a written determination that affirms or reverses the previous determination. If the Under Secretary for Health decides that the facility does not meet the standards of subpart D of this part, the Under Secretary for Health will withdraw recognition and stop paying per diem for care provided on and after the date of the decision. The decision of Under Secretary for Health will constitute a final VA decision. The Under Secretary for Health will send a copy of this decision to the State home facility and to the State official authorized to oversee the operations of the State home.

(g) In the event that a VA survey team or other VA medical center staff identifies any condition that poses an immediate threat to public or patient safety or other information indicating the existence of such a threat, the director of VA medical center of jurisdiction will immediately report this to the VA Network Director (10N 1-22), Chief Network Officer (10N), Chief Consultant, Geriatrics and Extended Care Strategic Healthcare Group (114) and State official authorized to oversee operations of the State home.

(Authority: 38 U.S.C. 101, 501, 1710, 1741-1743)

§ 51.31 Automatic recognition.

Notwithstanding other provisions of this part, a facility that already is recognized by VA as a State home for nursing home care at the time this part

becomes effective, automatically will continue to be recognized as a State home for nursing home care but will be subject to all of the provisions of this part that apply to facilities that have achieved recognition, including the provisions requiring that the facility meet the standards set forth in subpart D and the provisions for withholding per diem payments and withdrawal of recognition.

Subpart C—Per Diem Payments

§ 51.40 Monthly payment.

(a)(1) VA will pay per diem monthly for nursing home care provided to an eligible veteran in a facility recognized as a State home for nursing home care. During Fiscal Year 2000, VA will pay the lesser of the following:

(i) One-half of the cost of the care for each day the veteran is in the facility;

or

(ii) \$50.55 for each day the veteran is in the facility.

(2) Per diem will be paid only for the days that the veteran is a resident at the facility. For purposes of paying per diem, VA will consider a veteran to be a resident at the facility during each full day that the veteran is receiving care at the facility. VA will not deem the veteran to be a resident at the facility if the veteran is receiving care outside the State home facility at VA expense. Otherwise, VA will deem the veteran to be a resident at the facility during any absence from the facility that lasts for no more than 96 consecutive hours. This absence will be considered to have ended when the veteran returns as a resident if the veteran's stay is for at least a continuous 24-hour period.

(3) As a condition for receiving payment of per diem under this part, the State must submit a completed VA Form 10-5588, State Home Report and Statement of Federal Aid Claimed. This form is set forth in full at § 58.11 of this chapter.

(4) Initial payments will not be made until the Under Secretary for Health recognizes the State home. However, payments will be made retroactively for care that was provided on and after the date of the completion of the VA survey of the facility that provided the basis for determining that the facility met the standards of this part.

(5) As a condition for receiving payment of per diem under this part, the State must submit to the VA medical center of jurisdiction for each veteran the following completed VA Forms 10-10EZ, Application for Medical Benefits, and 10-10SH, State Home Program Application for Care—Medical Certification, at the time of admission

and with any request for a change in the level of care (domiciliary, hospital care or adult day health care). These forms are set forth in full at §§ 58.12 and 58.13 of this chapter, respectively, of this part. If the facility is eligible to receive per diem payments for a veteran, VA will pay per diem under this part from the date of receipt of the completed forms required by this paragraph, except that VA will pay per diem from the day on which the veteran was admitted to the facility if the completed forms are received within 10 days after admission.

(b) Total per diem costs for an eligible veteran's nursing home care consist of those direct and indirect costs attributable to nursing home care at the facility divided by the total number of patients at the nursing home. Relevant cost principles are set forth in the Office of Management and Budget (OMB) Circular number A-87, dated May 4, 1995, "Cost Principles for State, Local, and Indian Tribal Governments."

(Authority: 38 U.S.C. 101, 501, 1710, 1741-1743)

§ 51.50 Eligible veterans.

A veteran is an eligible veteran under this part if VA determines that the veteran needs nursing home care and the veteran is within one of the following categories:

(a) Veterans with service-connected disabilities;

(b) Veterans who are former prisoners of war;

(c) Veterans who were discharged or released from active military service for a disability incurred or aggravated in the line of duty;

(d) Veterans who receive disability compensation under 38 U.S.C. 1151;

(e) Veterans whose entitlement to disability compensation is suspended because of the receipt of retired pay;

(f) Veterans whose entitlement to disability compensation is suspended pursuant to 38 U.S.C. 1151, but only to the extent that such veterans' continuing eligibility for nursing home care is provided for in the judgment or settlement described in 38 U.S.C. 1151;

(g) Veterans who VA determines are unable to defray the expenses of necessary care as specified under 38 U.S.C. 1722(a);

(h) Veterans of the Mexican border period or of World War I;

(i) Veterans solely seeking care for a disorder associated with exposure to a toxic substance or radiation or for a disorder associated with service in the Southwest Asia theater of operations during the Persian Gulf War, as provided in 38 U.S.C. 1710(e);

(j) Veterans who agree to pay to the United States the applicable co-payment

determined under 38 U.S.C. 1710(f) and 1710(g).

(Authority: 38 U.S.C. 101, 501, 1710, 1741-1743)

Subpart D—Standards

§ 51.60 Standards applicable for payment of per diem.

The provisions of this subpart are the standards that a State home and facility management must meet for the State to receive per diem for nursing home care.

§ 51.70 Resident rights.

The resident has a right to a dignified existence, self-determination, and communication with and access to persons and services inside and outside the facility. The facility management must protect and promote the rights of each resident, including each of the following rights:

(a) *Exercise of rights.* (1) The resident has the right to exercise his or her rights as a resident of the facility and as a citizen or resident of the United States.

(2) The resident has the right to be free of interference, coercion, discrimination, and reprisal from the facility management in exercising his or her rights.

(3) The resident has the right to freedom from chemical or physical restraint.

(4) In the case of a resident determined incompetent under the laws of a State by a court of jurisdiction, the rights of the resident are exercised by the person appointed under State law to act on the resident's behalf.

(5) In the case of a resident who has not been determined incompetent by the State court, any legal-surrogate designated in accordance with State law may exercise the resident's rights to the extent provided by State law.

(b) *Notice of rights and services.* (1) The facility management must inform the resident both orally and in writing in a language that the resident understands of his or her rights and all rules and regulations governing resident conduct and responsibilities during the stay in the facility. Such notification must be made prior to or upon admission and periodically during the resident's stay.

(2) The resident or his or her legal representative has the right:

(i) Upon an oral or written request, to access all records pertaining to himself or herself including current clinical records within 24 hours (excluding weekends and holidays); and

(ii) After receipt of his or her records for review, to purchase at a cost not to exceed the community standard photocopies of the records or any

portions of them upon request and with 2 working days advance notice to the facility management.

(3) The resident has the right to be fully informed in language that he or she can understand of his or her total health status;

(4) The resident has the right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive as specified in paragraph (b)(7) of this section; and

(5) The facility management must inform each resident before, or at the time of admission, and periodically during the resident's stay, of services available in the facility and of charges for those services to be billed to the resident.

(6) The facility management must furnish a written description of legal rights which includes:

(i) A description of the manner of protecting personal funds, under paragraph (c) of this section;

(ii) A statement that the resident may file a complaint with the State (agency) concerning resident abuse, neglect, misappropriation of resident property in the facility, and non-compliance with the advance directives requirements.

(7) The facility management must have written policies and procedures regarding advance directives (e.g., living wills) that include provisions to inform and provide written information to all residents concerning the right to accept or refuse medical or surgical treatment and, at the individual's option, formulate an advance directive. This includes a written description of the facility's policies to implement advance directives and applicable State law. If an individual is incapacitated at the time of admission and is unable to receive information (due to the incapacitating conditions) or articulate whether or not he or she has executed an advance directive, the facility may give advance directive information to the individual's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated individual or to a surrogate or other concerned persons in accordance with State law. The facility management is not relieved of its obligation to provide this information to the individual once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to provide the information to the individual directly at the appropriate time.

(8) The facility management must inform each resident of the name and way of contacting the primary physician responsible for his or her care.

(9) Notification of changes. (i) Facility management must immediately inform the resident; consult with the primary physician; and if known, notify the resident's legal representative or an interested family member when there is—

(A) An accident involving the resident which results in injury and has the potential for requiring physician intervention;

(B) A significant change in the resident's physical, mental, or psychosocial status (i.e., a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications);

(C) A need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment); or

(D) A decision to transfer or discharge the resident from the facility as specified in § 51.80(a) of this part.

(ii) The facility management must also promptly notify the resident and, if known, the resident's legal representative or interested family member when there is—

(A) A change in room or roommate assignment as specified in § 51.100(f)(2); or

(B) A change in resident rights under Federal or State law or regulations as specified in paragraph (b)(1) of this section.

(iii) The facility management must record and periodically update the address and phone number of the resident's legal representative or interested family member.

(c) *Protection of resident funds.* (1) The resident has the right to manage his or her financial affairs, and the facility management may not require residents to deposit their personal funds with the facility.

(2) Management of personal funds. Upon written authorization of a resident, the facility management must hold, safeguard, manage, and account for the personal funds of the resident deposited with the facility, as specified in paragraphs (c)(3) through (c)(6) of this section.

(3) Deposit of funds. (i) Funds in excess of \$100. The facility management must deposit any residents' personal funds in excess of \$100 in an interest bearing account (or accounts) that is separate from any of the facility's operating accounts, and that credits all interest earned on resident's funds to that account. (In pooled accounts, there must be a separate accounting for each resident's share.)

(ii) Funds less than \$100. The facility management must maintain a resident's

personal funds that do not exceed \$100 in a non-interest bearing account, interest-bearing account, or petty cash fund.

(4) Accounting and records. The facility management must establish and maintain a system that assures a full and complete and separate accounting, according to generally accepted accounting principles, of each resident's personal funds entrusted to the facility on the resident's behalf.

(i) The system must preclude any commingling of resident funds with facility funds or with the funds of any person other than another resident.

(ii) The individual financial record must be available through quarterly statements and on request from the resident or his or her legal representative.

(5) Conveyance upon death. Upon the death of a resident with a personal fund deposited with the facility, the facility management must convey within 30 days the resident's funds, and a final accounting of those funds, to the individual or probate jurisdiction administering the resident's estate; or other appropriate individual or entity, if State law allows.

(6) Assurance of financial security. The facility management must purchase a surety bond, or otherwise provide assurance satisfactory to the Under Secretary for Health, to assure the security of all personal funds of residents deposited with the facility.

(d) *Free choice.* The resident has the right to—

(1) Be fully informed in advance about care and treatment and of any changes in that care or treatment that may affect the resident's well-being; and

(2) Unless determined incompetent or otherwise determined to be incapacitated under the laws of the State, participate in planning care and treatment or changes in care and treatment.

(e) *Privacy and confidentiality.* The resident has the right to personal privacy and confidentiality of his or her personal and clinical records.

(1) Residents have a right to personal privacy in their accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups. This does not require the facility management to give a private room to each resident.

(2) Except as provided in paragraph (e)(3) of this section, the resident may approve or refuse the release of personal and clinical records to any individual outside the facility;

(3) The resident's right to refuse release of personal and clinical records does not apply when—

(i) The resident is transferred to another health care institution; or

(ii) Record release is required by law.

(f) *Grievances.* A resident has the right to—

(1) Voice grievances without discrimination or reprisal. Residents may voice grievances with respect to treatment received and not received; and

(2) Prompt efforts by the facility to resolve grievances the resident may have, including those with respect to the behavior of other residents.

(g) *Examination of survey results.* A resident has the right to—

(1) Examine the results of the most recent VA survey with respect to the facility. The facility management must make the results available for examination in a place readily accessible to residents, and must post a notice of their availability; and

(2) Receive information from agencies acting as client advocates, and be afforded the opportunity to contact these agencies.

(h) *Work.* The resident has the right to—

(1) Refuse to perform services for the facility;

(2) Perform services for the facility, if he or she chooses, when—

(i) The facility has documented the need or desire for work in the plan of care;

(ii) The plan specifies the nature of the services performed and whether the services are voluntary or paid;

(iii) Compensation for paid services is at or above prevailing rates; and

(iv) The resident agrees to the work arrangement described in the plan of care.

(i) *Mail.* The resident must have the right to privacy in written communications, including the right to—

Send and promptly receive mail that is unopened; and

(2) Have access to stationery, postage, and writing implements at the resident's own expense.

(j) *Access and visitation rights.* (1)

The resident has the right and the facility management must provide immediate access to any resident by the following:

(i) Any representative of the Under Secretary for Health;

(ii) Any representative of the State;

(iii) Physicians of the resident's choice (to provide care in the nursing home, physicians must meet the provisions of § 51.210(j));

(iv) The State long term care ombudsman;

(v) Immediate family or other relatives of the resident subject to the resident's right to deny or withdraw consent at any time; and

(vi) Others who are visiting subject to reasonable restrictions and the resident's right to deny or withdraw consent at any time.

(2) The facility management must provide reasonable access to any resident by any entity or individual that provides health, social, legal, or other services to the resident, subject to the resident's right to deny or withdraw consent at any time.

(3) The facility management must allow representatives of the State Ombudsman Program, described in paragraph (j)(1)(iv) of this section, to examine a resident's clinical records with the permission of the resident or the resident's legal representative, subject to State law.

(k) *Telephone.* The resident has the right to reasonable access to use a telephone where calls can be made without being overheard.

(l) *Personal property.* The resident has the right to retain and use personal possessions, including some furnishings, and appropriate clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents.

(m) *Married couples.* The resident has the right to share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement.

(n) *Self-Administration of Drugs.* An individual resident may self-administer drugs if the interdisciplinary team, as defined by § 51.110(d)(2)(ii) of this part, has determined that this practice is safe.

(Authority: 38 U.S.C. 101, 501, 1710, 1741–1743)

§ 51.80 Admission, transfer and discharge rights.

(a) *Transfer and discharge.* (1)

Definition: Transfer and discharge includes movement of a resident to a bed outside of the facility whether that bed is in the same physical plant or not. Transfer and discharge does not refer to movement of a resident to a bed within the same facility.

(2) Transfer and discharge requirements. The facility management must permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless—

(i) The transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the nursing home;

(ii) The transfer or discharge is appropriate because the resident's health has improved sufficiently so the

resident no longer needs the services provided by the nursing home;

(iii) The safety of individuals in the facility is endangered;

(iv) The health of individuals in the facility would otherwise be endangered;

(v) The resident has failed, after reasonable and appropriate notice to pay for a stay at the facility; or

(vi) The nursing home ceases to operate.

(3) Documentation. When the facility transfers or discharges a resident under any of the circumstances specified in paragraphs (a)(2)(i) through (a)(2)(vi) of this section, the primary physician must document this in the resident's clinical record.

(4) Notice before transfer. Before a facility transfers or discharges a resident, the facility must—

(i) Notify the resident and, if known, a family member or legal representative of the resident of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand.

(ii) Record the reasons in the resident's clinical record; and

(iii) Include in the notice the items described in paragraph (a)(6) of this section.

(5) Timing of the notice. (i) The notice of transfer or discharge required under paragraph (a)(4) of this section must be made by the facility at least 30 days before the resident is transferred or discharged, except when specified in paragraph (a)(5)(ii) of this section,

(ii) Notice may be made as soon as practicable before transfer or discharge when—

(A) The safety of individuals in the facility would be endangered;

(B) The health of individuals in the facility would be otherwise endangered;

(C) The resident's health improves sufficiently so the resident no longer needs the services provided by the nursing home;

(D) The resident's needs cannot be met in the nursing home;

(6) Contents of the notice. The written notice specified in paragraph (a)(4) of this section must include the following:

(i) The reason for transfer or discharge;

(ii) The effective date of transfer or discharge;

(iii) The location to which the resident is transferred or discharged;

(iv) A statement that the resident has the right to appeal the action to the State official designated by the State; and

(v) The name, address and telephone number of the State long term care ombudsman.

(7) Orientation for transfer or discharge. A facility management must

provide sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility.

(b) *Notice of bed-hold policy and readmission.* (1) Notice before transfer. Before a facility transfers a resident to a hospital or allows a resident to go on therapeutic leave, the facility management must provide written information to the resident and a family member or legal representative that specifies—

(i) The duration of the facility's bed-hold policy, if any, during which the resident is permitted to return and resume residence in the facility; and

(ii) The facility's policies regarding bed-hold periods, which must be consistent with paragraph (b)(3) of this section, permitting a resident to return.

(2) Bed-hold notice upon transfer. At the time of transfer of a resident for hospitalization or therapeutic leave, facility management must provide to the resident and a family member or legal representative written notice which specifies the duration of the bed-hold policy described in paragraph (b)(1) of this section.

(3) Permitting resident to return to facility. A nursing facility must establish and follow a written policy under which a resident, whose hospitalization or therapeutic leave exceeds the bed-hold period is readmitted to the facility immediately upon the first availability of a bed in a semi-private room, if the resident requires the services provided by the facility.

(c) *Equal access to quality care.* The facility management must establish and maintain identical policies and practices regarding transfer, discharge, and the provision of services for all individuals regardless of source of payment.

(d) *Admissions policy.* The facility management must not require a third party guarantee of payment to the facility as a condition of admission or expedited admission, or continued stay in the facility. However, the facility may require an individual who has legal access to a resident's income or resources available to pay for facility care to sign a contract to pay the facility from the resident's income or resources.

(Authority: 38 U.S.C. 101, 501, 1710, 1741-1743)

§ 51.90 Resident behavior and facility practices.

(a) *Restraints.* (1) The resident has a right to be free from any chemical or physical restraints imposed for purposes of discipline or convenience. When a restraint is applied or used, the purpose

of the restraint is reviewed and is justified as a therapeutic intervention.

(i) Chemical restraint is the inappropriate use of a sedating psychotropic drug to manage or control behavior.

(ii) Physical restraint is any method of physically restricting a person's freedom of movement, physical activity or normal access to his or her body. Bed rails and vest restraints are examples of physical restraints.

(2) The facility management uses a system to achieve a restraint-free environment.

(3) The facility management collects data about the use of restraints.

(4) When alternatives to the use of restraint are ineffective, a restraint must be safely and appropriately used.

(b) *Abuse.* The resident has the right to be free from mental, physical, sexual, and verbal abuse or neglect, corporal punishment, and involuntary seclusion.

(1) Mental abuse includes humiliation, harassment, and threats of punishment or deprivation.

(2) Physical abuse includes hitting, slapping, pinching, or kicking. Also includes controlling behavior through corporal punishment.

(3) Sexual abuse includes sexual harassment, sexual coercion, and sexual assault.

(4) Neglect is any impaired quality of life for an individual because of the absence of minimal services or resources to meet basic needs. Includes withholding or inadequately providing food and hydration (without physician, resident, or surrogate approval), clothing, medical care, and good hygiene. May also include placing the individual in unsafe or unsupervised conditions.

(5) Involuntary seclusion is a resident's separation from other residents or from the resident's room against his or her will or the will of his or her legal representative.

(c) *Staff treatment of residents.* The facility management must develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property.

(1) The facility management must:

(i) Not employ individuals who—

(A) Have been found guilty of abusing, neglecting, or mistreating individuals by a court of law; or

(B) Have had a finding entered into an applicable State registry or with the applicable licensing authority concerning abuse, neglect, mistreatment of individuals or misappropriation of their property; and

(ii) Report any knowledge it has of actions by a court of law against an

employee, which would indicate unfitness for service as a nurse aide or other facility staff to the State nurse aide registry or licensing authorities.

(2) The facility management must ensure that all alleged violations involving mistreatment, neglect, or abuse, including injuries of unknown source, and misappropriation of resident property are reported immediately to the administrator of the facility and to other officials in accordance with State law through established procedures.

(3) The facility management must have evidence that all alleged violations are thoroughly investigated, and must prevent further potential abuse while the investigation is in progress.

(4) The results of all investigations must be reported to the administrator or the designated representative and to other officials in accordance with State law within 5 working days of the incident, and appropriate corrective action must be taken if the alleged violation is verified.

(Authority: 38 U.S.C. 101, 501, 1710, 1741-1743)

§ 51.100 Quality of life.

A facility management must care for its residents in a manner and in an environment that promotes maintenance or enhancement of each resident's quality of life.

(a) *Dignity.* The facility management must promote care for residents in a manner and in an environment that maintains or enhances each resident's dignity and respect in full recognition of his or her individuality.

(b) *Self-determination and participation.* The resident has the right to—

(1) Choose activities, schedules, and health care consistent with his or her interests, assessments, and plans of care;

(2) Interact with members of the community both inside and outside the facility; and

(3) Make choices about aspects of his or her life in the facility that are significant to the resident.

(c) *Resident Council.* The facility management must establish a council of residents that meet at least quarterly. The facility management must document any concerns submitted to the management of the facility by the council.

(d) *Participation in resident and family groups.* (1) A resident has the right to organize and participate in resident groups in the facility;

(2) A resident's family has the right to meet in the facility with the families of other residents in the facility;

(3) The facility management must provide the council and any resident or family group that exists with private space;

(4) Staff or visitors may attend meetings at the group's invitation;

(5) The facility management must provide a designated staff person responsible for providing assistance and responding to written requests that result from group meetings;

(6) The facility management must listen to the views of any resident or family group, including the council established under paragraph (c) of this section, and act upon the concerns of residents, families, and the council regarding policy and operational decisions affecting resident care and life in the facility.

(e) *Participation in other activities.* A resident has the right to participate in social, religious, and community activities that do not interfere with the rights of other residents in the facility. The facility management must arrange for religious counseling by clergy of various faith groups.

(f) *Accommodation of needs.* A resident has the right to—

(1) Reside and receive services in the facility with reasonable accommodation of individual needs and preferences, except when the health or safety of the individual or other residents would be endangered; and

(2) Receive notice before the resident's room or roommate in the facility is changed.

(g) *Patient Activities.* (1) The facility management must provide for an ongoing program of activities designed to meet, in accordance with the comprehensive assessment, the interests and the physical, mental, and psychosocial well-being of each resident.

(2) The activities program must be directed by a qualified professional who is a qualified therapeutic recreation specialist or an activities professional who—

(i) Is licensed or registered, if applicable, by the State in which practicing; and

(ii) Is certified as a therapeutic recreation specialist or as an activities professional by a recognized accrediting body.

(h) *Social Services.* (1) The facility management must provide medically related social services to attain or maintain the highest practicable mental and psychosocial well-being of each resident.

(2) A nursing home with 100 or more beds must employ a qualified social worker on a full-time basis.

(3) Qualifications of social worker. A qualified social worker is an individual with—

(i) A bachelor's degree in social work from a school accredited by the Council of Social Work Education (Note: A master's degree social worker with experience in long-term care is preferred), and

(ii) A social work license from the State in which the State home is located, if offered by the State, and

(iii) A minimum of one year of supervised social work experience in a health care setting working directly with individuals.

(4) The facility management must have sufficient support staff to meet patients' social services needs.

(5) Facilities for social services must ensure privacy for interviews.

(i) *Environment.* The facility management must provide—

(1) A safe, clean, comfortable, and homelike environment, allowing the resident to use his or her personal belongings to the extent possible;

(2) Housekeeping and maintenance services necessary to maintain a sanitary, orderly, and comfortable interior;

(3) Clean bed and bath linens that are in good condition;

(4) Private closet space in each resident room, as specified in § 51.200(d)(2)(iv) of this part;

(5) Adequate and comfortable lighting levels in all areas;

(6) Comfortable and safe temperature levels. Facilities must maintain a temperature range of 71-81 degrees Fahrenheit; and

(7) For the maintenance of comfortable sound levels.

(Authority: 38 U.S.C. 101, 501, 1710, 1741-1743)

§ 51.110 Resident assessment.

The facility management must conduct initially, annually and as required by a change in the resident's condition a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity.

(a) *Admission orders.* At the time each resident is admitted, the facility management must have physician orders for the resident's immediate care and a medical assessment, including a medical history and physical examination, within a time frame appropriate to the resident's condition, not to exceed 72 hours after admission, except when an examination was performed within five days before admission and the findings were recorded in the medical record on admission.

(b) *Comprehensive assessments.* (1) The facility management must make a

comprehensive assessment of a resident's needs:

(i) Using the Health Care Financing Administration Long Term Care Resident Assessment Instrument Version 2.0; and

(ii) Describing the resident's capability to perform daily life functions, strengths, performances, needs as well as significant impairments in functional capacity.

(iii) All nursing homes must be in compliance with the use of the Health Care Financing Administration Long Term Care Resident Assessment Instrument Version 2.0 by no later than January 1, 2000.

(2) Frequency. Assessments must be conducted—

(i) No later than 14 days after the date of admission;

(ii) Promptly after a significant change in the resident's physical, mental, or social condition; and

(iii) In no case less often than once every 12 months.

(3) Review of assessments. The nursing facility management must examine each resident no less than once every 3 months, and as appropriate, revise the resident's assessment to assure the continued accuracy of the assessment.

(4) Use. The results of the assessment are used to develop, review, and revise the resident's individualized comprehensive plan of care, under paragraph (d) of this section.

(c) *Accuracy of assessments.* (1) Coordination—

(i) Each assessment must be conducted or coordinated with the appropriate participation of health professionals.

(ii) Each assessment must be conducted or coordinated by a registered nurse that signs and certifies the completion of the assessment.

(2) Certification. Each person who completes a portion of the assessment must sign and certify the accuracy of that portion of the assessment.

(d) *Comprehensive care plans.* (1) The facility management must develop an individualized comprehensive care plan for each resident that includes measurable objectives and timetables to meet a resident's physical, mental, and psychosocial needs that are identified in the comprehensive assessment. The care plan must describe the following—

(i) The services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being as required under § 51.120; and

(ii) Any services that would otherwise be required under § 51.120 of this part but are not provided due to the

resident's exercise of rights under § 51.70, including the right to refuse treatment under § 51.70(b)(4) of this part.

(2) A comprehensive care plan must be—

(i) Developed within 7 calendar days after completion of the comprehensive assessment;

(ii) Prepared by an interdisciplinary team, that includes the primary physician, a registered nurse with responsibility for the resident, and other appropriate staff in disciplines as determined by the resident's needs, and, to the extent practicable, the participation of the resident, the resident's family or the resident's legal representative; and

(iii) Periodically reviewed and revised by a team of qualified persons after each assessment.

(3) The services provided or arranged by the facility must—

(i) Meet professional standards of quality; and

(ii) Be provided by qualified persons in accordance with each resident's written plan of care.

(e) *Discharge summary.* Prior to discharging a resident, the facility management must prepare a discharge summary that includes—

(1) A recapitulation of the resident's stay;

(2) A summary of the resident's status at the time of the discharge to include items in paragraph (b)(2) of this section; and

(3) A post-discharge plan of care that is developed with the participation of the resident and his or her family, which will assist the resident to adjust to his or her new living environment.

(Authority: 38 U.S.C. 101, 501, 1710, 1741-1743)

§ 51.120 Quality of care.

Each resident must receive and the facility management must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

(a) *Reporting of Sentinel Events.* (1) Definition. A sentinel event is an adverse event that results in the loss of life or limb or permanent loss of function.

(2) Examples of sentinel events are as follows:

(i) Any resident death, paralysis, coma or other major permanent loss of function associated with a medication error; or

(ii) Any suicide of a resident, including suicides following elopement

(unauthorized departure) from the facility; or

(iii) Any elopement of a resident from the facility resulting in a death or a major permanent loss of function; or

(iv) Any procedure or clinical intervention, including restraints, that result in death or a major permanent loss of function; or

(v) Assault, homicide or other crime resulting in patient death or major permanent loss of function; or

(vi) A patient fall that results in death or major permanent loss of function as a direct result of the injuries sustained in the fall.

(3) The facility management must report sentinel events to the director of VA medical center of jurisdiction within 24 hours of identification. The VA medical center of jurisdiction must report sentinel events by calling VA Network Director (10N 1-22) and Chief Consultant, Geriatrics and Extended Care Strategic Healthcare Group (114) within 24 hours of notification.

(4) The facility management must establish a mechanism to review and analyze a sentinel event resulting in a written report no later than 10 working days following the event. The purpose of the review and analysis of a sentinel event is to prevent injuries to residents, visitors, and personnel, and to manage those injuries that do occur and to minimize the negative consequences to the injured individuals and facility.

(b) *Activities of daily living.* Based on the comprehensive assessment of a resident, the facility management must ensure that—

(1) A resident's abilities in activities of daily living do not diminish unless circumstances of the individual's clinical condition demonstrate that diminution was unavoidable. This includes the resident's ability to—

(i) Bathe, dress, and groom;

(ii) Transfer and ambulate;

(iii) Toilet;

(iv) Eat; and

(v) Talk or otherwise communicate.

(2) A resident is given the appropriate treatment and services to maintain or improve his or her abilities specified in paragraph (b)(1) of this section; and

(3) A resident who is unable to carry out activities of daily living receives the necessary services to maintain good nutrition, hydration, grooming, personal and oral hygiene, mobility, and bladder and bowel elimination.

(c) *Vision and hearing.* To ensure that residents receive proper treatment and assistive devices to maintain vision and hearing abilities, the facility must, if necessary, assist the resident—

(1) In making appointments, and

(2) By arranging for transportation to and from the office of a practitioner

specializing in the treatment of vision or hearing impairment or the office of a professional specializing in the provision of vision or hearing assistive devices.

(d) *Pressure sores.* Based on the comprehensive assessment of a resident, the facility management must ensure that—

(1) A resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable; and

(2) A resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.

(e) *Urinary and Fecal Incontinence.* Based on the resident's comprehensive assessment, the facility management must ensure that—

(1) A resident who enters the facility without an indwelling catheter is not catheterized unless the resident's clinical condition demonstrates that catheterization was necessary;

(2) A resident who is incontinent of urine receives appropriate treatment and services to prevent urinary tract infections and to restore as much normal bladder function as possible; and

(3) A resident who has persistent fecal incontinence receives appropriate treatment and services to treat reversible causes and to restore as much normal bowel function as possible.

(f) *Range of motion.* Based on the comprehensive assessment of a resident, the facility management must ensure that—

(1) A resident who enters the facility without a limited range of motion does not experience reduction in range of motion unless the resident's clinical condition demonstrates that a reduction in range of motion is unavoidable; and

(2) A resident with a limited range of motion receives appropriate treatment and services to increase range of motion and/or to prevent further decrease in range of motion.

(g) *Mental and Psychosocial functioning.* Based on the comprehensive assessment of a resident, the facility management must ensure that a resident who displays mental or psychosocial adjustment difficulty, receives appropriate treatment and services to correct the assessed problem.

(h) *Enteral Feedings.* Based on the comprehensive assessment of a resident, the facility management must ensure that—

(1) A resident who has been able to adequately eat or take fluids alone or with assistance is not fed by enteral

feedings unless the resident's clinical condition demonstrates that use of enteral feedings was unavoidable; and

(2) A resident who is fed by enteral feedings receives the appropriate treatment and services to prevent aspiration pneumonia, diarrhea, vomiting, dehydration, metabolic abnormalities, nasal-pharyngeal ulcers and other skin breakdowns, and to restore, if possible, normal eating skills.

(i) *Accidents.* The facility management must ensure that—

(1) The resident environment remains as free of accident hazards as is possible; and

(2) Each resident receives adequate supervision and assistance devices to prevent accidents.

(j) *Nutrition.* Based on a resident's comprehensive assessment, the facility management must ensure that a resident—

(1) Maintains acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's clinical condition demonstrates that this is not possible; and

(2) Receives a therapeutic diet when a nutritional deficiency is identified.

(k) *Hydration.* The facility management must provide each resident with sufficient fluid intake to maintain proper hydration and health.

(l) *Special needs.* The facility management must ensure that residents receive proper treatment and care for the following special services:

- (1) Injections;
- (2) Parenteral and enteral fluids;
- (3) Colostomy, ureterostomy, or ileostomy care;
- (4) Tracheostomy care;
- (5) Tracheal suctioning;
- (6) Respiratory care;
- (7) Foot care; and
- (8) Prostheses.

(m) *Unnecessary drugs.* (1) General. Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used:

- (i) In excessive dose (including duplicate drug therapy); or
- (ii) For excessive duration; or
- (iii) Without adequate monitoring; or
- (iv) Without adequate indications for its use; or
- (v) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or
- (vi) Any combinations of the reasons above.

(2) *Antipsychotic Drugs.* Based on a comprehensive assessment of a resident, the facility management must ensure that—

(i) Residents who have not used antipsychotic drugs are not given these

drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and

(ii) Residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.

(n) *Medication Errors.* The facility management must ensure that—

- (1) Medication errors are identified and reviewed on a timely basis; and
- (2) Strategies for preventing medication errors and adverse reactions are implemented.

(Authority: 38 U.S.C. 101, 501, 1710, 1741-1743)

§ 51.130 Nursing services.

The facility management must provide an organized nursing service with a sufficient number of qualified nursing personnel to meet the total nursing care needs, as determined by resident assessment and individualized comprehensive plans of care, of all patients within the facility 24 hours a day, 7 days a week.

(a) The nursing service must be under the direction of a full-time registered nurse who is currently licensed by the State and has, in writing, administrative authority, responsibility, and accountability for the functions, activities, and training of the nursing services staff.

(b) The facility management must provide registered nurses 24 hours per day, 7 days per week.

(c) The director of nursing service must designate a registered nurse as a supervising nurse for each tour of duty.

(1) Based on the application and results of the case mix and staffing methodology, the director of nursing may serve in a dual role as director and as an onsite-supervising nurse only when the facility has an average daily occupancy of 60 or fewer residents in nursing home.

(2) Based on the application and results of the case mix and staffing methodology, the evening or night supervising nurse may serve in a dual role as supervising nurse as well as provides direct patient care only when the facility has an average daily occupancy of 60 or fewer residents in nursing home.

(d) The facility management must provide nursing services to ensure that there is direct care nurse staffing of no less than 2.5 hours per patient per 24 hours, 7 days per week in the portion of any building providing nursing home care.

(e) Nurse staffing must be based on a staffing methodology that applies case

mix and is adequate for meeting the standards of this part.

(Authority: 38 U.S.C. 101, 501, 1710, 1741-1743)

§ 51.140 Dietary services.

The facility management must provide each resident with a nourishing, palatable, well-balanced diet that meets the daily nutritional and special dietary needs of each resident.

(a) *Staffing.* The facility management must employ a qualified dietitian either full-time, part-time, or on a consultant basis.

(1) If a dietitian is not employed, the facility management must designate a person to serve as the director of food service who receives at least a monthly scheduled consultation from a qualified dietitian.

(2) A qualified dietitian is one who is qualified based upon registration by the Commission on Dietetic Registration of the American Dietetic Association.

(b) *Sufficient staff.* The facility management must employ sufficient support personnel competent to carry out the functions of the dietary service.

(c) *Menus and nutritional adequacy.* Menus must—

(1) Meet the nutritional needs of residents in accordance with the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences;

(2) Be prepared in advance; and

(3) Be followed.

(d) *Food.* Each resident receives and the facility provides—

(1) Food prepared by methods that conserve nutritive value, flavor, and appearance;

(2) Food that is palatable, attractive, and at the proper temperature;

(3) Food prepared in a form designed to meet individual needs; and

(4) Substitutes offered of similar nutritive value to residents who refuse food served.

(e) *Therapeutic diets.* Therapeutic diets must be prescribed by the primary care physician.

(f) *Frequency of meals.* (1) Each resident receives and the facility provides at least three meals daily, at regular times comparable to normal mealtimes in the community.

(2) There must be no more than 14 hours between a substantial evening meal and the availability of breakfast the following day, except as provided in (f)(4) of this section.

(3) The facility staff must offer snacks at bedtime daily.

(4) When a nourishing snack is provided at bedtime, up to 16 hours may elapse between a substantial

evening meal and breakfast the following day.

(g) *Assistive devices.* The facility management must provide special eating equipment and utensils for residents who need them.

(h) *Sanitary conditions.* The facility must—

(1) Procure food from sources approved or considered satisfactory by Federal, State, or local authorities;

(2) Store, prepare, distribute, and serve food under sanitary conditions; and

(3) Dispose of garbage and refuse properly.

(Authority: 38 U.S.C. 101, 501, 1710, 1741-1743)

§ 51.150 Physician services.

A physician must personally approve in writing a recommendation that an individual be admitted to a facility. Each resident must remain under the care of a physician.

(a) *Physician supervision.* The facility management must ensure that—

(1) The medical care of each resident is supervised by a primary care physician;

(2) Each resident's medical record lists the name of the resident's primary physician, and

(3) Another physician supervises the medical care of residents when their primary physician is unavailable.

(b) *Physician visits.* The physician must—

(1) Review the resident's total program of care, including medications and treatments, at each visit required by paragraph (c) of this section;

(2) Write, sign, and date progress notes at each visit; and

(3) Sign and date all orders.

(c) *Frequency of physician visits.*

(1) The resident must be seen by the primary physician at least once every 30 days for the first 90 days after admission, and at least once every 60 days thereafter, or more frequently based on the condition of the resident.

(2) A physician visit is considered timely if it occurs not later than 10 days after the date the visit was required.

(3) Except as provided in paragraphs (c)(4) of this section, all required physician visits must be made by the physician personally.

(4) At the option of the physician, required visits in the facility after the initial visit may alternate between personal visits by the physician and visits by a physician assistant, nurse practitioner, or clinical nurse specialist in accordance with paragraph (e) of this section.

(d) *Availability of physicians for emergency care.* The facility management must provide or arrange for

the provision of physician services 24 hours a day, 7 days per week, in case of an emergency.

(e) *Physician delegation of tasks.* (1) Except as specified in paragraph (e)(2) of this section, a primary physician may delegate tasks to:

(i) a certified physician assistant or a certified nurse practitioner, or

(ii) a clinical nurse specialist who—

(A) Is acting within the scope of practice as defined by State law; and

(B) Is under the supervision of the physician.

Note to paragraph (e): An individual with experience in long term care is preferred.

(2) The primary physician may not delegate a task when the regulations specify that the primary physician must perform it personally, or when the delegation is prohibited under State law or by the facility's own policies.

(Authority: 38 U.S.C. 101, 501, 1710, 1741-1743)

§ 51.160 Specialized rehabilitative services.

(a) *Provision of services.* If specialized rehabilitative services such as but not limited to physical therapy, speech therapy, occupational therapy, and mental health services for mental illness are required in the resident's comprehensive plan of care, facility management must—

(1) Provide the required services; or

(2) Obtain the required services from an outside resource, in accordance with § 51.210(h) of this part, from a provider of specialized rehabilitative services.

(b) Specialized rehabilitative services must be provided under the written order of a physician by qualified personnel.

(Authority: 38 U.S.C. 101, 501, 1710, 1741-1743)

§ 51.170 Dental services.

(a) A facility must provide or obtain from an outside resource, in accordance with § 51.210(h) of this part, routine and emergency dental services to meet the needs of each resident;

(b) A facility may charge a resident an additional amount for routine and emergency dental services; and

(c) A facility must, if necessary, assist the resident—

(1) In making appointments;

(2) By arranging for transportation to and from the dental services; and

(3) Promptly refer residents with lost or damaged dentures to a dentist.

(Authority: 38 U.S.C. 101, 501, 1710, 1741-1743)

§ 51.180 Pharmacy services.

The facility management must provide routine and emergency drugs

and biologicals to its residents, or obtain them under an agreement described in § 51.210(h) of this part. The facility management must have a system for disseminating drug information to medical and nursing staff.

(a) *Procedures.* The facility management must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.

(b) *Service consultation.* The facility management must employ or obtain the services of a pharmacist licensed in a State in which the facility is located or a VA pharmacist under VA contract who—

(1) Provides consultation on all aspects of the provision of pharmacy services in the facility;

(2) Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and

(3) Determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.

(c) *Drug regimen review.* (1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.

(2) The pharmacist must report any irregularities to the primary physician and the director of nursing, and these reports must be acted upon.

(d) *Labeling of drugs and biologicals.* Drugs and biologicals used in the facility management must be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date when applicable.

(e) *Storage of drugs and biologicals.*

(1) In accordance with State and Federal laws, the facility management must store all drugs and biologicals in locked compartments under proper temperature controls, and permit only authorized personnel to have access to the keys.

(2) The facility management must provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse.

(Authority: 38 U.S.C. 101, 501, 1710, 1741–1743)

§ 51.190 Infection control.

The facility management must establish and maintain an infection control program designed to provide a

safe, sanitary, and comfortable environment and to help prevent the development and transmission of disease and infection.

(a) *Infection control program.* The facility management must establish an infection control program under which it—

(1) Investigates, controls, and prevents infections in the facility;

(2) Decides what procedures, such as isolation, should be applied to an individual resident; and

(3) Maintains a record of incidents and corrective actions related to infections.

(b) *Preventing spread of infection.* (1) When the infection control program determines that a resident needs isolation to prevent the spread of infection, the facility management must isolate the resident.

(2) The facility management must prohibit employees with a communicable disease or infected skin lesions from engaging in any contact with residents or their environment that would transmit the disease.

(3) The facility management must require staff to wash their hands after each direct resident contact for which hand washing is indicated by accepted professional practice.

(c) *Linens.* Personnel must handle, store, process, and transport linens so as to prevent the spread of infection.

(Authority: 38 U.S.C. 101, 501, 1710, 1741–1743)

§ 51.200 Physical environment.

The facility management must be designed, constructed, equipped, and maintained to protect the health and safety of residents, personnel and the public.

(a) *Life safety from fire.* The facility must meet the applicable provisions of the National Fire Protection Association's NFPA 101, Life Safety Code (1997 edition) and the NFPA 99, Standard for Health Care Facilities (1996 edition). Incorporation by reference of these materials was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. These materials incorporated by reference are available for inspection at the Office of the Federal Register, Suite 700, 800 North Capitol Street, NW., Washington, DC, and the Department of Veterans Affairs, Office of Regulations Management (02D), Room 1154, 810 Vermont Avenue, NW., Washington, DC 20420. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269–9101. (For ordering

information, call toll-free 1–800–344–3555.)

(b) *Emergency power.* (1) An emergency electrical power system must be provided to supply power adequate for illumination of all exit signs and lighting for the means of egress, fire alarm and medical gas alarms, emergency communication systems, and generator task illumination.

(2) The system must be the appropriate type essential electrical system in accordance with the applicable provisions of the National Fire Protection Association's NFPA 101, Life Safety Code (1997 edition) and the NFPA 99, Standard for Health Care Facilities (1996 edition). Incorporation by reference of these materials was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of these materials is described in paragraph (a) of this section.

(3) When electrical life support devices are used, an emergency electrical power system must also be provided for devices in accordance with NFPA 99, Standard for Health Care Facilities (1996 edition).

(4) The source of power must be an on-site emergency standby generator of sufficient size to serve the connected load or other approved sources in accordance with the National Fire Protection Association's NFPA 101, Life Safety Code (1997 edition) and the NFPA 99, Standard for Health Care Facilities (1996 edition). Incorporation by reference of these materials was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of these materials is described in paragraph (a) of this section.

(c) *Space and equipment.* Facility management must—

(1) Provide sufficient space and equipment in dining, health services, recreation, and program areas to enable staff to provide residents with needed services as required by these standards and as identified in each resident's plan of care; and

(2) Maintain all essential mechanical, electrical, and patient care equipment in safe operating condition.

(d) *Resident rooms.* Resident rooms must be designed and equipped for adequate nursing care, comfort, and privacy of residents: (1) Bedrooms must—

(i) Accommodate no more than four residents;

(ii) Measure at least 115 net square feet per resident in multiple resident bedrooms;

(iii) Measure at least 150 net square feet in single resident bedrooms;

(iv) Measure at least 245 net square feet in small double resident bedrooms; and

(v) Measure at least 305 net square feet in large double resident bedrooms used for spinal cord injury residents. It is recommended that the facility have one large double resident bedroom for every 30 resident bedrooms.

(vi) Have direct access to an exit corridor;

(vii) Be designed or equipped to assure full visual privacy for each resident;

(viii) Except in private rooms, each bed must have ceiling suspended curtains, which extend around the bed to provide total visual privacy in combination with adjacent walls and curtains;

(ix) Have at least one window to the outside; and

(x) Have a floor at or above grade level.

(2) The facility management must provide each resident with—

(i) A separate bed of proper size and height for the safety of the resident;

(ii) A clean, comfortable mattress;

(iii) Bedding appropriate to the weather and climate; and

(iv) Functional furniture appropriate to the resident's needs, and individual closet space in the resident's bedroom with clothes racks and shelves accessible to the resident.

(e) *Toilet facilities.* Each resident room must be equipped with or located near toilet and bathing facilities. It is recommended that public toilet facilities be also located near the resident's dining and recreational areas.

(f) *Resident call system.* The nurse's station must be equipped to receive resident calls through a communication system from—

(1) Resident rooms; and

(2) Toilet and bathing facilities.

(g) *Dining and resident activities.* The facility management must provide one or more rooms designated for resident dining and activities. These rooms must—

(1) Be well lighted;

(2) Be well ventilated;

(3) Be adequately furnished; and

(4) Have sufficient space to

accommodate all activities.

(h) *Other environmental conditions.*

The facility management must provide a safe, functional, sanitary, and comfortable environment for the residents, staff and the public. The facility must—

(1) Establish procedures to ensure that water is available to essential areas when there is a loss of normal water supply;

(2) Have adequate outside ventilation by means of windows, or mechanical ventilation, or a combination of the two;

(3) Equip corridors with firmly secured handrails on each side; and

(4) Maintain an effective pest control program so that the facility is free of pests and rodents.

(Authority: 38 U.S.C. 101, 501, 1710, 1741–1743)

§ 51.210 Administration.

A facility must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well being of each resident.

(a) *Governing body.* (1) The State must have a governing body, or designated person functioning as a governing body, that is legally responsible for establishing and implementing policies regarding the management and operation of the facility; and

(2) The governing body or State official with oversight for the facility appoints the administrator who is—

(i) Licensed by the State where licensing is required; and

(ii) Responsible for operation and management of the facility.

(b) *Disclosure of State agency and individual responsible for oversight of facility.* The State must give written notice to the Chief Consultant, Geriatrics and Extended Care Strategic Healthcare Group (114), VA Headquarters, 810 Vermont Avenue, NW, Washington, DC 20420, at the time of the change, if any of the following change:

(1) The State agency and individual responsible for oversight of a State home facility;

(2) The State home administrator; and

(3) The State employee responsible for oversight of the State home facility if a contractor operates the State home.

(c) *Required Information.* The facility management must submit the following to the director of the VA medical center of jurisdiction as part of the application for recognition and thereafter as often as necessary to be current or as specified:

(1) The copy of legal and administrative action establishing the State-operated facility (e.g., State laws);

(2) Site plan of facility and surroundings;

(3) Legal title, lease, or other document establishing right to occupy facility;

(4) Organizational charts and the operational plan of the facility;

(5) The number of the staff by category indicating full-time, part-time and minority designation (annual at time of survey);

(6) The number of nursing home patients who are veterans and non-veterans, the number of veterans who are minorities and the number of non-veterans who are minorities (annual at time of survey);

(7) Annual State Fire Marshall's report;

(8) Annual certification from the responsible State Agency showing compliance with Section 504 of the Rehabilitation Act of 1973 (Public Law 93–112) (VA Form 10–0143A set forth at § 58.14 of this chapter);

(9) Annual certification for Drug-Free Workplace Act of 1988 (VA Form 10–0143 set forth at § 58.15 of this chapter);

(10) Annual certification regarding lobbying in compliance with Public Law 101–121 (VA Form 10–0144 set forth at § 58.16 of this chapter); and

(11) Annual certification of compliance with Title VI of the Civil Rights Act of 1964 as incorporated in Title 38 CFR 18.1–18.3 (VA Form 10–0144A located at § 58.17 of this chapter).

(d) *Percentage of Veterans.* The percent of the facility residents eligible for VA nursing home care must be at least 75 percent veterans except that the veteran percentage need only be more than 50 percent if the facility was constructed or renovated solely with State funds. All non-veteran residents must be spouses of veterans or parents all of whose children died while serving in the armed forces of the United States.

(e) *Management Contract Facility.* If a facility is operated by an entity contracting with the State, the State must assign a State employee to monitor the operations of the facility on a full-time onsite basis.

(f) *Licensure.* The facility and facility management must comply with applicable State and local licensure laws.

(g) *Staff qualifications.* (1) The facility management must employ on a full-time, part-time or consultant basis those professionals necessary to carry out the provisions of these requirements.

(2) Professional staff must be licensed, certified, or registered in accordance with applicable State laws.

(h) *Use of outside resources.* (1) If the facility does not employ a qualified professional person to furnish a specific service to be provided by the facility, the facility management must have that service furnished to residents by a person or agency outside the facility under a written agreement described in paragraph (h)(2) of this section.

(2) Agreements pertaining to services furnished by outside resources must specify in writing that the facility

management assumes responsibility for—

(i) Obtaining services that meet professional standards and principles that apply to professionals providing services in such a facility; and

(ii) The timeliness of the services.

(i) *Medical director.* (1) The facility management must designate a primary care physician to serve as medical director.

(2) The medical director is responsible for—

(i) Participating in establishing policies, procedures, and guidelines to ensure adequate, comprehensive services;

(ii) Directing and coordinating medical care in the facility;

(iii) Helping to arrange for continuous physician coverage to handle medical emergencies;

(iv) Reviewing the credentialing and privileging process;

(v) Participating in managing the environment by reviewing and evaluating incident reports or summaries of incident reports, identifying hazards to health and safety, and making recommendations to the administrator; and

(vi) Monitoring employees' health status and advising the administrator on employee-health policies.

(j) *Credentialing and Privileging.*

Credentialing is the process of obtaining, verifying, and assessing the qualifications of a health care practitioner, which may include physicians, podiatrists, dentists, psychologists, physician assistants, nurse practitioners, licensed nurses to provide patient care services in or for a health care organization. Privileging is the process whereby a specific scope and content of patient care services are authorized for a health care practitioner by the facility management, based on evaluation of the individual's credentials and performance.

(1) The facility management must uniformly apply credentialing criteria to licensed practitioners applying to provide resident care or treatment under the facility's care.

(2) The facility management must verify and uniformly apply the following core criteria: current licensure; current certification, if applicable, relevant education, training, and experience; current competence; and a statement that the individual is able to perform the services he or she is applying to provide.

(3) The facility management must decide whether to authorize the independent practitioner to provide resident care or treatment, and each credentials file must indicate that these

criteria are uniformly and individually applied.

(4) The facility management must maintain documentation of current credentials for each licensed independent practitioner practicing within the facility.

(5) When reappointing a licensed independent practitioner, the facility management must review the individual's record of experience.

(6) The facility management systematically must assess whether individuals with clinical privileges act within the scope of privileges granted.

(k) *Required training of nursing aides.*

(1) Nurse aide means any individual providing nursing or nursing-related services to residents in a facility who is not a licensed health professional, a registered dietitian, or a volunteer who provide such services without pay.

(2) The facility management must not use any individual working in the facility as a nurse aide whether permanent or not unless:

(i) That individual is competent to provide nursing and nursing related services; and

(ii) That individual has completed a training and competency evaluation program, or a competency evaluation program approved by the State.

(3) *Registry verification.* Before allowing an individual to serve as a nurse aide, facility management must receive registry verification that the individual has met competency evaluation requirements unless the individual can prove that he or she has recently successfully completed a training and competency evaluation program or competency evaluation program approved by the State and has not yet been included in the registry. Facilities must follow up to ensure that such an individual actually becomes registered.

(4) *Multi-State registry verification.* Before allowing an individual to serve as a nurse aide, facility management must seek information from every State registry established under HHS regulations at 42 CFR 483.156 which the facility believes will include information on the individual.

(5) *Required retraining.* If, since an individual's most recent completion of a training and competency evaluation program, there has been a continuous period of 24 consecutive months during none of which the individual provided nursing or nursing-related services for monetary compensation, the individual must complete a new training and competency evaluation program or a new competency evaluation program.

(6) *Regular in-service education.* The facility management must complete a

performance review of every nurse aide at least once every 12 months, and must provide regular in-service education based on the outcome of these reviews.

The in-service training must—

(i) Be sufficient to ensure the continuing competence of nurse aides, but must be no less than 12 hours per year;

(ii) Address areas of weakness as determined in nurse aides' performance reviews and may address the special needs of residents as determined by the facility staff; and

(iii) For nurse aides providing services to individuals with cognitive impairments, also address the care of the cognitively impaired.

(l) *Proficiency of Nurse aides.* The facility management must ensure that nurse aides are able to demonstrate competency in skills and techniques necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care.

(m) *Level B Requirement Laboratory services.* (1) The facility management must provide or obtain laboratory services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.

(i) If the facility provides its own laboratory services, the services must meet all applicable certification standards, statutes, and regulations for laboratory services.

(ii) If the facility provides blood bank and transfusion services, it must meet all applicable certification standards, statutes, and regulations.

(iii) If the laboratory chooses to refer specimens for testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of services and meet certification standards, statutes, and regulations.

(iv) The laboratory performing the testing must have a current, valid CLIA number (Clinical Laboratory Improvement Amendments of 1988). The facility management must provide VA surveyors with the CLIA number and a copy of the results of the last CLIA inspection.

(v) Such services must be available to the resident seven days a week, 24 hours a day.

(2) The facility management must—

(i) Provide or obtain laboratory services only when ordered by the primary physician;

(ii) Promptly notify the primary physician of the findings;

(iii) Assist the resident in making transportation arrangements to and from the source of service, if the resident needs assistance; and

(iv) File in the resident's clinical record laboratory reports that are dated and contain the name and address of the testing laboratory.

(n) *Radiology and other diagnostic services.* (1) The facility management must provide or obtain radiology and other diagnostic services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.

(i) If the facility provides its own diagnostic services, the services must meet all applicable certification standards, statutes, and regulations.

(ii) If the facility does not provide its own diagnostic services, it must have an agreement to obtain these services. The services must meet all applicable certification standards, statutes, and regulations.

(iii) Radiologic and other diagnostic services must be available 24 hours a day, seven days a week.

(2) The facility must—

(i) Provide or obtain radiology and other diagnostic services when ordered by the primary physician;

(ii) Promptly notify the primary physician of the findings;

(iii) Assist the resident in making transportation arrangements to and from the source of service, if the resident needs assistance; and

(iv) File in the resident's clinical record signed and dated reports of x-ray and other diagnostic services.

(o) *Clinical records.* (1) The facility management must maintain clinical records on each resident in accordance with accepted professional standards and practices that are—

(i) Complete;

(ii) Accurately documented;

(iii) Readily accessible; and

(iv) Systematically organized.

(2) Clinical records must be retained for—

(i) The period of time required by State law; or

(ii) Five years from the date of discharge when there is no requirement in State law.

(3) The facility management must safeguard clinical record information against loss, destruction, or unauthorized use;

(4) The facility management must keep confidential all information contained in the resident's records, regardless of the form or storage method of the records, except when release is required by—

(i) Transfer to another health care institution;

(ii) Law;

(iii) Third party payment contract;

(iv) The resident or;

(v) The resident's authorized agent or representative.

(5) The clinical record must contain—
(i) Sufficient information to identify the resident;

(ii) A record of the resident's assessments;

(iii) The plan of care and services provided;

(iv) The results of any pre-admission screening conducted by the State; and

(v) Progress notes.

(p) *Quality assessment and assurance.*

(1) Facility management must maintain a quality assessment and assurance committee consisting of—

(i) The director of nursing services;

(ii) A primary physician designated by the facility; and

(iii) At least 3 other members of the facility's staff.

(2) The quality assessment and assurance committee—

(i) Meets at least quarterly to identify issues with respect to which quality assessment and assurance activities are necessary; and

(ii) Develops and implements appropriate plans of action to correct identified quality deficiencies; and
(3) Identified quality deficiencies are corrected within an established time period.

(4) The VA Under Secretary for Health may not require disclosure of the records of such committee unless such disclosure is related to the compliance with requirements of this section.

(q) *Disaster and emergency preparedness.* (1) The facility management must have detailed written plans and procedures to meet all potential emergencies and disasters, such as fire, severe weather, and missing residents.

(2) The facility management must train all employees in emergency procedures when they begin to work in the facility, periodically review the procedures with existing staff, and carry out unannounced staff drills using those procedures.

(r) *Transfer agreement.* (1) The facility management must have in effect a written transfer agreement with one or more hospitals that reasonably assures that—

(i) Residents will be transferred from the nursing home to the hospital, and ensured of timely admission to the hospital when transfer is medically appropriate as determined by the primary physician; and

(ii) Medical and other information needed for care and treatment of residents, and, when the transferring facility deems it appropriate, for determining whether such residents can be adequately cared for in a less expensive setting than either the nursing home or the hospital, will be exchanged between the institutions.

(2) The facility is considered to have a transfer agreement in effect if the facility has an agreement with a hospital sufficiently close to the facility to make transfer feasible.

(s) *Compliance with Federal, State, and local laws and professional standards.* The facility management must operate and provide services in compliance with all applicable Federal, State, and local laws, regulations, and codes, and with accepted professional standards and principles that apply to professionals providing services in such a facility. This includes the Single Audit Act of 1984 (Title 31, Section 7501 *et seq.*) and the Cash Management Improvement Acts of 1990 and 1992 (Public Laws 101-453 and 102-589, see 31 USC 3335, 3718, 3720A, 6501, 6503)

(t) *Relationship to other Federal regulations.* In addition to compliance with the regulations set forth in this subpart, facilities are obliged to meet the applicable provisions of other Federal laws and regulations, including but not limited to those pertaining to nondiscrimination on the basis of race, color, national origin, handicap, or age (38 CFR part 18); protection of human subjects of research (45 CFR part 46), section 504 of the Rehabilitation Act of 1993, Public Law 93-112; Drug-Free Workplace Act of 1988, 38 CFR part 44, section 44.100 through 44.420; section 319 of Public Law 101-121; Title VI of the Civil Rights Act of 1964, 38 CFR 18.1-18.3. Although these regulations are not in themselves considered requirements under this part, their violation may result in the termination or suspension of, or the refusal to grant or continue payment with Federal funds.

(u) *Intermingling.* A building housing a facility recognized as a State home for providing nursing home care may only provide nursing home care in the areas of the building recognized as a State home for providing nursing home care.

(v) *VA Management of State Veterans Homes.* Except as specifically provided by statute or regulations, VA employees have no authority regarding the management or control of State homes providing nursing home care.

(Authority: 38 U.S.C. 101, 501, 1710, 1741-1743, 8135)

11. Part 58 is added to read as follows:

PART 58—FORMS

Sec.

58.10 VA Form 10-3567—State Home Inspection: Staffing Profile.

58.11 VA Form 10-5588—State Home Report and Statement of Federal Aid Claimed.

- 58.12 VA Form 10-10EZ—Application for Health Benefits.
- 58.13 VA Form 10-10SH—State Home Program Application for Veteran Care—Medical Certification.
- 58.14 VA Form 10-0143A—Statement of Assurance of Compliance with Section 504 of The Rehabilitation Act of 1973.
- 58.15 VA Form 10-0143—Department of Veterans Affairs Certification Regarding Drug-Free Workplace Requirements for Grantees Other Than Individuals.
- 58.16 VA Form 10-0144—Certification Regarding Lobbying.
- 58.17 VA Form 10-0144A—Statement of Assurance of Compliance with Equal Opportunity Laws.
- Authority:** 38 U.S.C. 101, 501, 1710, 1741-1743.
- BILLING CODE** 8320-01-C

§ 58.10 VA Form 10-3567—State Home Inspection Staffing Profile.

OMB Approved No. 2900-0160
Estimated Burden Avg. 20 min.



Department of Veterans Affairs

STATE HOME INSPECTION

NAME OF HOME				DATE OF INSPECTION
PART I	TOTAL FACILITY	HOSPITAL	NHC	DOM
OPERATING BEDS				
AUTHORIZED APPROVALS				
PATIENT CENSUS				
POSITIONS AUTHORIZED				
STAFF AVAILABLE				
PART II - STAFF	TOTAL FACILITY	HOSPITAL	NHC	DOM
PHYSICIANS:				
PHYSICIANS ASSISTANTS				
DENTISTS				
SOCIAL WORK: MSW				
BSW				
SOCIAL WORK ASSISTANT				
PHARMACY: REG. PHARMACIST				
DIETETICS: REG. DIETITIAN				
FOOD SUPERVISOR				
DIETARY ASSISTANTS				
NURSING:				
NURSING ADM./SUP.				
DIRECT CARE: CERT. N.P./C.N.S.				
R.N.				
L.P.N./L.V.N.				
N.A.				
REHABILITATION THERAPY				
REG. P.T./P.T. AIDES				
REG. O.T./O.T. AIDES				
MENTAL HEALTH: PSYCHOLOGIST				
PSYCHIATRIST				
PSYCHIATRIC SOCIAL WORKER				
COUNSELOR				
SPEECH AND AUDIOLOGY				
OPHTHALMOLOGY/OPTOMETRY				
PODIATRY				
RADIOLOGY/LABORATORY				
RECREATION/ACTIVITIES				
DIRECTOR				
ASSISTANTS				
VOLUNTEERS				
CHAPLAIN				
ADMINISTRATION				
ENGINEERING				
MAINTENANCE/HOUSEKEEPING				
MEDICAL RECORDS				
OTHER (Specify)				

NAME OF HOME	DATE OF INSPECTION
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NURSING SERVICE STAFFING PATTERN
(Four Week Average)

PART III HOSPITAL (Average hours Hosp. _____)																					
SHIFT	SUNDAY			MONDAY			TUESDAY			WEDNESDAY			THURSDAY			FRIDAY			SATURDAY		
	RN	LPN	NA	RN	LPN	NA	RN	LPN	NA	RN	LPN	NA	RN	LPN	NA	RN	LPN	NA	RN	LPN	NA
DAY																					
EVENING																					
NIGHT																					

PART IV NURSING HOME (Average hours NHC _____)																					
SHIFT	SUNDAY			MONDAY			TUESDAY			WEDNESDAY			THURSDAY			FRIDAY			SATURDAY		
	RN	LPN	NA	RN	LPN	NA	RN	LPN	NA	RN	LPN	NA	RN	LPN	NA	RN	LPN	NA	RN	LPN	NA
DAY																					
EVENING																					
NIGHT																					


PART V DOMICILIARY (Average hours Dom. _____)																					
SHIFT	SUNDAY			MONDAY			TUESDAY			WEDNESDAY			THURSDAY			FRIDAY			SATURDAY		
	RN	LPN	NA	RN	LPN	NA	RN	LPN	NA	RN	LPN	NA	RN	LPN	NA	RN	LPN	NA	RN	LPN	NA
DAY																					
EVENING																					
NIGHT																					

NAME OF HOME	DATE OF INSPECTION

The Paperwork Reduction Act of 1995 requires us to notify you that this information collection is in accordance with the clearance requirements of section 3507 of the Paperwork Reduction Act of 1995. We may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a valid OMB number. We anticipate that the time expended by all individuals who must complete this form will average 30 minutes. This includes the time it will take to read instructions, gather the necessary facts and fill out the form.

§ 58.11 VA Form 10-5588—State Home Report and Statement of Federal Aid Claimed.

OMB Approval No. 2900-0160
Estimated Burden: Avg. 30 min.

 Department of Veterans Affairs						
STATE HOME REPORT AND STATEMENT OF FEDERAL AID CLAIMED						
	VA FACILITY		FROM	NAME AND ADDRESS OF STATE HOME		
PAY TO				FOR MONTH ENDING		
LINE NO.	ITEM	DOMICILIARY (A)	NURSING HOME CARE (B)	HOSPITAL (C)	ADULT DAY HEALTH CARE (D)	
1	TOTAL VETERAN RESIDENTS REMAINING AT END OF PRIOR MONTH					
2	GAINS					
3		ADMISSIONS (<i>Change of status</i>)				
4		ADMISSIONS (<i>Other</i>)				
5		RETURNS FROM LEAVE OF ABSENCE OF MORE THAN 96 HOURS				
6	LOSSES					
7		DISCHARGES (<i>Change of status</i>)				
8		DISCHARGES (<i>Other</i>)				
9		DEATHS				
10	LEAVES OF ABSENCE OF MORE THAN 96 HOURS					
9	TOTAL VETERAN RESIDENTS REMAINING AT END OF THE MONTH					
10	TOTAL VETERAN DAYS OF CARE FURNISHED					
11	FEMALE VETERAN RESIDENTS REMAINING AT END OF THE MONTH					
12	NON-VETERAN RESIDENTS REMAINING AT END OF THE MONTH					
MONTHLY STATEMENT OF ACCOUNT						
LINE NO.	FEDERAL AID CLAIMED UNDER SEC. 1741, TITLE 38, U.S.C., AS AMENDED	DAYS OF CARE (J)	AVERAGE DAILY CENSUS (K)	TOTAL PER DIEM COST (L)	PER DIEM CLAIMED (M)	TOTAL AMOUNT CLAIMED (N)
13	DOMICILIARY CARE			\$	\$	\$
14	NURSING HOME CARE			\$	\$	\$
15	HOSPITAL CARE			\$	\$	\$
16	ADULT DAY HEALTH CARE			\$	\$	\$
17	TOTAL AMOUNT CLAIMED					\$
FOR DEPARTMENT OF VETERANS AFFAIR USE ONLY						
RECEIVING REPORT - Services authorized under provisions of Sec. 1741, 1742 and 1743, Title 38, U.S.C., have been rendered in the quantity claimed and payment is recommended except as follows:			SIGNATURE AND TITLE OF STATE HOME COORDINATOR			DATE
			ACCOUNTING CERTIFICATION - AUDIT BLOCK			
			AMOUNT DUE	DATE	VOUCHER AUDITOR	



Department of Veterans Affairs

STATE HOME REPORT AND STATEMENT OF FEDERAL AID CLAIMED

I certify that this report is correct, that all residents included in the report were physically present during the period for which Federal aid is claimed, except for authorized absences of 96 hours or less, and that facility management has complied with all provisions of Title VI, Public Law 88-352, entitled Civil Rights Act of

TOTAL STATE OPERATING BEDS AT END OF THE MONTH

DOMICILIARY CARE	NURSING HOME CARE	HOSPITAL CARE	ADULT DAY HEALTH CARE
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BED CAPACITY APPROVED BY VA

DOMICILIARY CARE	NURSING HOME CARE	HOSPITAL CARE	ADULT DAY HEALTH CARE
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SIGNATURE OF STATE HOME ADMINISTRATOR

DATE

SIGNATURE OF STATE EMPLOYEE WHEN APPLICABLE


DATE

REMARKS

The Paperwork Reduction Act of 1995 requires us to notify you that this information collection is in accordance with the clearance requirements of section 3507 of the Paperwork Reduction Act of 1995. We may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a valid OMB number. We anticipate that the time expended by all individuals who must complete this form will average 30 minutes. This includes the time it will take to read instructions, gather the necessary facts and fill out the form.

§ 58.12 VA Form 10-10EZ—Application for Health Benefits


OMB Approved No. 2900-0097
Estimated Burden Avg. 20 min

 Department of Veterans Affairs		APPLICATION FOR HEALTH BENEFITS			
SECTION I - GENERAL INFORMATION					
1A TYPE OF BENEFIT(S) APPLIED FOR (You may check more than one)					
<input type="checkbox"/> HEALTH SERVICES		<input type="checkbox"/> NURSING HOME		<input type="checkbox"/> DOMICILIARY	
<input type="checkbox"/> DENTAL		<input type="checkbox"/> ENROLLMENT			
1B IF APPLYING FOR HEALTH SERVICES, WHICH VA MEDICAL CENTER OR OUTPATIENT CLINIC DO YOU PREFER					
2 VETERAN'S NAME (Last, First, MI)			3 OTHER NAMES USED		4 GENDER (Check one) <input type="checkbox"/> M <input type="checkbox"/> F
5 SOCIAL SECURITY NUMBER		6 CLAIM NUMBER	7 DATE OF BIRTH (mm.dd/yyyy)		8 RELIGION
9A CURRENT MAILING ADDRESS (Street)			9B CITY	9C STATE	9D ZIP
9E COUNTY		10 HOME TELEPHONE NUMBER		11 WORK TELEPHONE NUMBER	
12 CURRENT MARITAL STATUS (Check one)					
<input type="checkbox"/> MARRIED		<input type="checkbox"/> NEVER MARRIED		<input type="checkbox"/> SEPARATED	
<input type="checkbox"/> WIDOWED		<input type="checkbox"/> DIVORCED		<input type="checkbox"/> UNKNOWN	
13A LAST BRANCH OF SERVICE	13B LAST ENTRY DATE	13C LAST DISCHARGE DATE	13D DISCHARGE TYPE	13E MILITARY SERVICE NUMBER	
14. CIRCLE YES OR NO					
A ARE YOU A FORMER PRISONER OF WAR		YES	NO	H DO YOU HAVE A MILITARY DENTAL INJURY	
B DO YOU HAVE A VA SERVICE CONNECTED RATING		YES	NO	I DO YOU HAVE A SPINAL CORD INJURY	
B1 IF YES, WHAT IS YOUR RATED PERCENTAGE		%	J ARE YOU ELIGIBLE FOR MEDICAID	YES	
C ARE YOU RECEIVING A VA PENSION		YES	NO	K ARE YOU ENROLLED IN MEDICARE HOSPITAL INSURANCE PART A	
D ARE YOU RETIRED FROM THE MILITARY		YES	NO	K1 EFFECTIVE DATE	
D1 WAS YOUR RETIREMENT THE RESULT OF A DISABILITY		YES	NO	L ARE YOU ENROLLED IN MEDICARE HOSPITAL INSURANCE PART B	
D2 WERE YOU REGULARLY RETIRED (120 - yrs)		YES	NO	L1 EFFECTIVE DATE	
E WERE YOU EXPOSED TO TOXINS IN THE GULF W/AR		YES	NO	M MEDICARE CLAIM NUMBER	
F WERE YOU EXPOSED TO AGENT ORANGE		YES	NO	N NAME EXACTLY AS IT APPEARS ON YOUR MEDICAID CARD	
G WERE YOU EXPOSED TO RADIATION		YES	NO	15B COMPANY NAME, ADDRESS AND TELEPHONE NUMBER	
15A VETERAN'S EMPLOYMENT STATUS (check one)		<input type="checkbox"/> NOT EMPLOYED	// //	15B COMPANY NAME, ADDRESS AND TELEPHONE NUMBER	
If employed or retired, complete item 15B		<input type="checkbox"/> EMPLOYED	// //	15B COMPANY NAME, ADDRESS AND TELEPHONE NUMBER	
<input type="checkbox"/> RETIRED		Date of retirement	16B COMPANY NAME, ADDRESS AND TELEPHONE NUMBER		
16A SPOUSE'S EMPLOYMENT STATUS (check one)		<input type="checkbox"/> NOT EMPLOYED	// //	16B COMPANY NAME, ADDRESS AND TELEPHONE NUMBER	
If employed or retired, complete item 16B		<input type="checkbox"/> EMPLOYED	// //	16B COMPANY NAME, ADDRESS AND TELEPHONE NUMBER	
<input type="checkbox"/> RETIRED		Date of retirement	17A VETERAN'S HEALTH INSURANCE COMPANY		
17A VETERAN'S HEALTH INSURANCE COMPANY			17B NAME OF POLICY HOLDER		
17B NAME OF POLICY HOLDER			17C POLICY NUMBER	17D GROUP CODE	17C POLICY NUMBER
17C POLICY NUMBER			17D GROUP CODE	17C POLICY NUMBER	17D GROUP CODE
19A NAME, ADDRESS AND RELATIONSHIP OF NEXT OF KIN			19B NEXT OF KIN'S HOME TELEPHONE NUMBER		
19A NAME, ADDRESS AND RELATIONSHIP OF NEXT OF KIN			19C NEXT OF KIN'S WORK TELEPHONE NUMBER		
20A NAME, ADDRESS AND RELATIONSHIP OF EMERGENCY CONTACT			20B EMERGENCY CONTACT'S HOME TELEPHONE NUMBER		
20A NAME, ADDRESS AND RELATIONSHIP OF EMERGENCY CONTACT			20C EMERGENCY CONTACT'S WORK TELEPHONE NUMBER		
21 I DESIGNATE THE FOLLOWING INDIVIDUAL TO RECEIVE POSSESSION OF ALL MY PERSONAL PROPERTY LEFT ON PREMISES UNDER VA CONTROL AFTER MY DEPARTURE OR AT THE TIME OF MY DEATH (Check one) (This does not constitute a will or transfer of title)					
<input type="checkbox"/> EMERGENCY CONTACT			<input type="checkbox"/> NEXT OF KIN		
22A IS NEED FOR CARE DUE TO ON THE JOB INJURY (Check one)			22B IS NEED FOR CARE DUE TO ACCIDENT (Check one)		
<input type="checkbox"/> YES			<input type="checkbox"/> YES		
<input type="checkbox"/> NO			<input type="checkbox"/> NO		

APPLICATION FOR HEALTH BENEFITS, Continued		VETERAN'S NAME	SOCIAL SECURITY NUMBER
SECTION II - FINANCIAL ASSESSMENT			
IIA - DEPENDENT INFORMATION (Use a separate sheet for additional dependents)			
1 SPOUSE'S NAME (Last, First, MI)		2 CHILD'S NAME (Last, First, MI)	
3 SPOUSE'S SOCIAL SECURITY NUMBER	4 SPOUSE'S DATE OF BIRTH (mm/dd/yyyy)	5 CHILD'S DATE OF BIRTH (mm/dd/yyyy)	
6 SPOUSE'S ADDRESS (Street, City, State, ZIP)		7 CHILD'S SOCIAL SECURITY NUMBER	
8 SPOUSE'S TELEPHONE NUMBER	9 CHILD'S RELATIONSHIP TO YOU (Circle one) Son Daughter Stepson Stepdaughter		
10 DATE OF MARRIAGE (mm/dd/yyyy)	11 DATE CHILD BECAME YOUR DEPENDENT		
12 IF YOUR SPOUSE OR DEPENDENT CHILD DID NOT LIVE WITH YOU LAST YEAR ENTER THE AMOUNT YOU CONTRIBUTED TO THEIR SUPPORT SPOUSE \$ CHILD \$		13 EXPENSES PAID BY YOUR DEPENDENT CHILD FOR COLLEGE VOCATIONAL REHABILITATION OR TRAINING (tuition, books, materials, etc.) \$	
14. WAS CHILD PERMANENTLY AND TOTALLY DISABLED BEFORE THE AGE OF 18? <input type="checkbox"/> YES <input type="checkbox"/> NO		15. IF CHILD IS BETWEEN 18 AND 23 YEARS OF AGE DID CHILD ATTEND SCHOOL LAST CALENDAR YEAR? <input type="checkbox"/> YES <input type="checkbox"/> NO	
IIB - FINANCIAL DISCLOSURE			
You are not required to provide the financial information in this Section. However, current law may require VA to consider your household financial situation to determine your eligibility for enrollment and/or cost-free care of your nonservice-connected (NSC) conditions. If you are 0% SC noncompensable or NSC (and are not an Ex-POW, WWI veteran or VA pensioner) and your annual household income (or combined income and net worth) exceeds the established threshold, you must agree to pay VA co-payments for care of your NSC conditions to be eligible for enrollment. See Section III - Consent and Signature.			
<input type="checkbox"/> YES , I WILL PROVIDE SPECIFIC INCOME AND/OR ASSET INFORMATION TO HAVE ELIGIBILITY FOR CARE DETERMINED. Complete all sections below that apply to you with last calendar year's information. Sign and date the application.			
<input type="checkbox"/> NO , I DO NOT WISH TO PROVIDE MY DETAILED FINANCIAL INFORMATION. I understand I will be assigned the appropriate enrollment priority based on nondisclosure of my financial information. By checking NO and signing below, I am agreeing to pay the applicable VA co-payment. Sign and date the application.			
IIC - PREVIOUS CALENDAR YEAR GROSS ANNUAL INCOME OF VETERAN, SPOUSE AND DEPENDENT CHILDREN			
	VETERAN	SPOUSE	CHILDREN
1 WHAT WAS YOUR GROSS ANNUAL INCOME FROM EMPLOYMENT (wages, bonuses, tips, etc.), AS WELL AS INCOME FROM YOUR FARM, RANCH, PROPERTY OR BUSINESS	\$	\$	\$
2 LIST OTHER INCOME AMOUNTS (Social Security, compensation, pension, interest, dividends). Exclude welfare	\$	\$	\$
3 WAS INCOME FROM YOUR FARM, RANCH, PROPERTY OR BUSINESS (If yes, refer to page 2 Section IIC of the instructions) <input type="checkbox"/> YES <input type="checkbox"/> NO			
IID - DEDUCTIBLE EXPENSES			
1. NON-REIMBURSED MEDICAL EXPENSES PAID BY YOU OR YOUR SPOUSE (payments for doctors, dentists, drugs, Medicare, health insurance, hospital and nursing home)			\$
2. AMOUNT YOU PAID LAST CALENDAR YEAR FOR FUNERAL AND BURIAL EXPENSES FOR YOUR DECEASED SPOUSE OR DEPENDENT CHILD (Also enter spouse or child's information in Section IIA)			\$
3. AMOUNT YOU PAID LAST CALENDAR YEAR FOR YOUR COLLEGE OR VOCATIONAL EDUCATIONAL EXPENSES (tuition, books, fees, materials, etc.) DO NOT LIST YOUR DEPENDENTS' EDUCATIONAL EXPENSES.			\$
IIE - NET WORTH			
	VETERAN	SPOUSE	
1. CASH, AMOUNT IN BANK ACCOUNTS (Checking and savings accounts, certificates of deposit, individual retirement accounts, etc.)	\$	\$	
2. MARKET VALUE OF LAND AND BUILDINGS MINUS MORTGAGES AND LIENS. Do not count your primary home. Include value of farm, ranch, or business assets	\$	\$	
3. STOCKS AND BONDS AND VALUE OF OTHER PROPERTY OR ASSETS (art, rare coins, etc.) MINUS THE AMOUNT YOU OWE ON THESE ITEMS. Exclude household effects and family vehicles.	\$	\$	
SECTION III - CONSENT AND SIGNATURE			
CO-PAYMENT NOTICE: If you are a 0% service-connected noncompensable or a nonservice-connected veteran (and are not an Ex-POW, WWI veteran or VA pensioner) and your household income (or combined income and net worth) exceeds the established threshold, you may be eligible for enrollment only if you agree to pay VA co-payments for treatment of your NSC conditions. By signing this application you are agreeing to pay the applicable VA co-payment if required by law.			
I CERTIFY THE FOREGOING STATEMENT(S) ARE TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE AND ABILITY.			DATE (mm/dd/yyyy)
SIGN HERE (Signature of applicant or applicant's representative)			
THE LAW PROVIDES SEVERE PENALTIES FOR WILLFUL SUBMISSION OF FALSE INFORMATION.			

§ 58.13 VA Form 10-10SH—State Home Program Application for Veteran Care Medical Certification.

OMB Approval No. 2900-0160
Estimated Burden: Avg. 30 min.

 Department of Veterans Affairs		STATE HOME PROGRAM APPLICATION FOR VETERAN CARE MEDICAL CERTIFICATION					
PART I - ADMINISTRATIVE							
STATE HOME FACILITY				DATE ADMITTED	GENDER M F		
RESIDENT'S NAME (Last, First, Middle)				SOCIAL SECURITY NUMBER			
RESIDENT'S STREET ADDRESS				AGE	DATE OF BIRTH		
CITY, STATE AND ZIP CODE				ADVANCED MEDICAL DIRECTIVE NO YES			
PART II - HISTORY AND PHYSICAL (Use separate sheet if necessary)							
HISTORY							
HEIGHT	WEIGHT	TEMP	PULSE	BP	HEAD/EYES/EAR/NOSE AND THROAT		
NECK				CARDIOPULMONARY			
ABDOMEN				GENITOURINARY			
RECTAL				EXTREMITIES			
NEUROLOGICAL				ALLERGY/DRUG SENSITIVITY			
X-RAY/ LAB	CHEST X-RAY	DATE:	RESULTS		CBC	DATE:	RESULTS
	SEROLOGY						
	URINALYSIS	DATE	ALBUMEN	SUGAR	ACETONE		
CHECK ALL BOXES THAT APPLY OR CIRCLE NA							
IS DEMENTIA THE PRIMARY DIAGNOSIS YES NO		IS THERE A DIAGNOSIS OF MENTAL ILLNESS YES NO		HAS RESIDENT RECEIVED MENTAL SERVICES WITHIN THE PAST 2 YEARS YES NO		IS CLIENT A DANGER TO SELF OR OTHERS YES NO	
IS THERE ANY PRESSING EVIDENCE OF MENTAL ILLNESS SUCH AS:							
SCHIZOPHRENIA		PARANOIA		OTHER PSYCHOTIC OR MENTAL DISORDERS LEADING TO CHRONIC DISABILITY		PERSONALITY DISORDER	
MOOD SWINGS		SOMATOFORM DISORDER		PANIC OR SEVERE ANXIETY DISORDER		PERSONALITY DISORDER	
OXYGEN MASK PRN NASAL CANULAR CONTINUOUS		TUBE FEEDING OSTOMY TRACHOSTOMY		DECUBITUS ULCERS DRAINING WOUND WOUND CULTURED		FOLEY CATHETER TEMPORARY PERMANENT	
REFERRING PHYSICIAN				PRIMARY DIAGNOSIS			
SECONDARY DIAGNOSIS				TERTIARY DIAGNOSIS			
TYPE OF CARE RECOMMENDED: SKILLED NURSING HOME CARE DOMICILIARY CARE ADULT DAY HEALTH CARE HOSPITAL							
MEDICATION AND TREATMENT ORDERS ON ADMISSION. CONTINUE ON SEPARATE SHEET IF NECESSARY							
.....							
PRINTED OR TYPED NAME OF PRIMARY PHYSICIAN ASSIGNED				SIGNATURE OF PRIMARY PHYSICIAN ASSIGNED			

STATE HOME PROGRAM APPLICATION FOR VETERAN CARE - MEDICAL CERTIFICATION, CONTINUED			
RESIDENT'S NAME (Last, First, Middle)		SOCIAL SECURITY NUMBER	
EVALUATION (Circle appropriate number in each category)			
COMMUNICATION	1. Transmits messages/receives information 2. Limited ability 3. Nearly or totally unable	SPEECH	1. Speaks clearly with others of same language 2. Limited ability 3. Unable to speak clearly or not at all
HEARING	1. Good 2. Hearing slightly impaired. 3. Limited hearing (e.g. - must speak loudly) 4. Virtually/completely deaf	SIGHT	1. Good 2. Vision adequate - Unable to read/see details 3. Vision limited - Gross object differentiation 4. Blind
TRANSFER	1. No assistance 2. Equipment only 3. Supervision only 4. Requires human transfer w/wo equipment 5. Bedfast	AMBULATION	1. Independence w/wo assistive device 2. Walks with supervision 3. Walks with continuous human support 4. Bed to chair (total help) 5. Bedfast
ENDURANCE	1. Tolerates distances (250 feet sustained activity) 2. Needs intermittent rest 3. Rarely tolerates short activities 4. No tolerance	MENTAL AND BEHAVIOR STATUS	1. Alert 2. Confused 3. Disoriented 4. Comatose 5. Agreeable 6. Disruptive 7. Apathetic 8. Well motivated
TOILETING	1. No assistance 2. Assistance to and from and transfer 3. Total assistance including personal hygiene, help with clothes	BATHING	1. No assistance 2. Supervision only 3. Assistance 4. Is bathed A. Bathroom B. Bedside commode C. Bedpan A. Tub B. Shower C. Sponge bath
DRESSING	1. Dresses self 2. Minor assistance 3. Needs help to complete dressing 4. Has to be dressed	FEEDING	1. No assistance 2. Minor assistance, needs tray set up only 3. Help feeding/encouraging 4. Is fed
BLADDER CONTROL	1. Continent 2. Rarely incontinent 3. Occasional - once/week or less 4. Frequent - up to once a day 5. Total incontinence 6. Catheter, indwelling	BOWEL CONTROL	1. Continent 2. Rarely incontinent 3. Occasional - once/week or less 4. Frequent, - up to once a day 5. Total incontinence 6. Ostomy
SKIN CONDITION	1. Intact 2. Dry/Fragile 3. Irritations (Rash) 4. Open wound 5. Decubitus	WHEEL CHAIR USE	1. Independence 2. Assistance in difficult maneuvering 3. Wheels a few feet 4. Unable to use <input type="checkbox"/> NA
SIGNATURE OF REGISTERED NURSE OR REFERRING PHYSICIAN			DATE
PHYSICAL THERAPY (To be completed by Physical Therapist or Referring Physician) <input type="checkbox"/> NEW REFERRAL <input type="checkbox"/> CONTINUATION OF THERAPY			
SENSATION IMPAIRED <input type="checkbox"/> YES <input type="checkbox"/> NO	RESTRICT ACTIVITY <input type="checkbox"/> YES <input type="checkbox"/> NO	PRECAUTIONS <input type="checkbox"/> CARDIAC <input type="checkbox"/> (OTHER Specify)	FREQUENCY OF TREATMENT
TREATMENT GOALS:			
<input type="checkbox"/> STRETCHING	<input type="checkbox"/> ACTIVE	<input type="checkbox"/> COORDINATING ACTIVITIES	<input type="checkbox"/> FULL WEIGHT BEARING
<input type="checkbox"/> PASSIVE ROM	<input type="checkbox"/> ACTIVE ASSISTIVE	<input type="checkbox"/> NON-WEIGHT BEARING	<input type="checkbox"/> WHEELCHAIR INDEPENDENT
	<input type="checkbox"/> PROGRESSIVE RESISTIVE	<input type="checkbox"/> PARTIAL WEIGHT BEARING	<input type="checkbox"/> COMPLETE AMBULATION
<input type="checkbox"/> RECOVERY TO FULL FUNCTION			
ADDITIONAL THERAPIES <input type="checkbox"/> O.T. <input type="checkbox"/> SPEECH <input type="checkbox"/> DIETARY		SIGNATURE OF AND TITLE OF THERAPIST	
		DATE	
SOCIAL WORK ASSESSMENT (To be completed by Social Worker)			
PRIOR LIVING ARRANGEMENTS		LONG RANGE PLAN	
ADJUSTMENT TO ILLNESS OR DISABILITY		SIGNATURE OF SOCIAL WORKER	
		DATE	
VA AUTHORIZATION FOR PAYMENT			
DATE RECEIVED BY VA	ELIGIBILITY FOR PER DIEM PAYMENT <input type="checkbox"/> APPROVED <input type="checkbox"/> DISAPPROVED	LEVEL OF CARE RECOMMENDED <input type="checkbox"/> NHC <input type="checkbox"/> DOMICILIARY <input type="checkbox"/> HOSPITAL <input type="checkbox"/> ADHC	
REASON FOR DISAPPROVAL		<input type="checkbox"/> APPROVED	REASON FOR DISAPPROVAL
		<input type="checkbox"/> DISAPPROVED	
SIGNATURE OF VA OFFICIAL		SIGNATURE OF VA PHYSICIAN	
		DATE	

PAPERWORK REDUCTION ACT AND PRIVACY ACT NOTICE

The Paperwork Reduction Act of 1995 requires us to notify you that this information collection is in accordance with the clearance requirements of section 3507 of the Paperwork Reduction Act of 1995. We may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a valid OMB number. We anticipate that the time expended by all individuals who must complete this form will average 30 minutes. This includes the time it will take to read instructions, gather the necessary facts and fill out the form.

Privacy Act Information The information requested on this form is solicited under the authority of Title 38, U.S.C., Sections 1741, 1742 and 1743. It is being collected to enable us to determine your eligibility for medical benefits in the State Home Program and will be used for that purpose. The income and eligibility you supply may be verified through a computer matching program at any time and information may be disclosed outside the VA as permitted by law; possible disclosures include those described in the "routine uses" identified in the VA system of records 24VA136, Patient Medical Record-VA, published in the Federal Register in accordance with the Privacy Act of 1974. Disclosure is voluntary; however, the information is required in order for us to determine your eligibility for the medical benefit for which you have applied. Failure to furnish the information will have no adverse affect on any other benefits to which you may be entitled. Disclosure of Social Security number(s) of those for whom benefits are claimed is requested under the authority of Title 38, U.S.C., and is voluntary. Social Security numbers will be used in the administration of veterans benefits, in the identification of veterans or persons claiming or receiving VA benefits and their records and may be used for other purposes where authorized by Title 38, U.S.C., and the Privacy Act of 1974 (5 U.S.C. 552a) or where required by other statute.

§ 58.14 VA Form 10-0143A—Statement of Assurance of Compliance with Section 504 of The Rehabilitation Act of 1973.

OMB Number: 2900-0160
Estimated Burden: 5 minutes

Department of Veterans Affairs

**STATEMENT OF ASSURANCE OF COMPLIANCE WITH SECTION 504 OF
THE REHABILITATION ACT OF 1973**

The Paperwork Reduction Act of 1995 requires us to notify you that this information collection is in accordance with the clearance requirements of section 3507 of the Paperwork Reduction Act of 1995. We may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a valid OMB number. We anticipate that the time expended by all individuals who must complete this form will average 5 minutes. This includes the time it will take to read instructions, gather the necessary facts and fill out the form.

(hereinafter called the "Signatory")

*(Name and location of State Veterans Home)***HEREBY AGREES THAT**

It will comply with section 504 of the Rehabilitation Act of 1973 (Pub. L. No. 93-112) and all regulations adopted pursuant to such section, for instance, VA Regulations 7800 Series (38 CFR Section 18), to the end that no person in the United States shall, on the ground of handicap, be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under any program or activity of the Signatory receiving Federal financial assistance or other benefits under statutes administered by the VA; and **HEREBY GIVES ASSURANCE THAT** it will immediately take any measures necessary to effectuate the agreement.

If any real property or structure thereon is provided or improved with the aid of the Federal financial assistance extended to the Signatory by the VA, this assurance shall obligate the Signatory, or in the case of transfer of such property, any transferee, for the period during which the real property or structure is used for a purpose for which the Federal financial assistance is extended or for another purpose involving the provision of similar services or benefits. In all cases this assurance shall obligate the Signatory for the period during which the Federal financial assistance is extended to any of its programs by the VA.

THIS ASSURANCE is given in consideration of and for the purpose of obtaining Federal financial assistance, including facilities furnished or payments made under Section 1741 of Title 38 USC. Federal financial assistance is understood to include benefits paid directly to the Signatory, and/or benefits paid to a beneficiary contingent upon such beneficiary being enrolled in a program offered by the Signatory.

The Signatory recognizes and agrees that such Federal financial assistance or other benefits will be extended in reliance on the representations and agreements made in this assurance, and that the VA will withhold financial assistance, facilities, or other benefits to ensure fulfillment of this assurance of compliance, and that the United States shall have the right to seek judicial enforcement of this assurance. This assurance is binding on the Signatory, its successors, transferees, and assignees. The person or persons whose signatures appear below are authorized to sign this assurance.

SIGNATURE OF AUTHORIZED OFFICIAL

TITLE

DATE

MAILING ADDRESS

§ 58.15 VA Form 10-0143—Department of Veterans Affairs Certification Regarding Drug-Free Workplace Requirements for Grantees Other Than Individuals.OMB Number: 2900-0160
Estimated Burden: 5 minutes**DEPARTMENT OF VETERANS AFFAIRS CERTIFICATION REGARDING DRUG-FREE WORKPLACE REQUIREMENTS FOR GRANTEEES OTHER THAN INDIVIDUALS**

The Paperwork Reduction Act of 1995 requires us to notify you that this information collection is in accordance with the clearance requirements of section 3507 of the Paperwork Reduction Act of 1995. We may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a valid OMB number. We anticipate that the time expended by all individuals who must complete this form will average 5 minutes. This includes the time it will take to read instructions, gather the necessary facts and fill out the form.

This certification is required by the regulations implementing the Drug-Free Workplace Act of 1988, 38 CFR 44, Subpart F. The regulations, published in the January 31, 1989, Federal Register (pages 4950-4952) require certification by grantees, prior to award, that they will maintain a drug-free workplace. The certification set out below is a material representation of fact upon which reliance will be placed when the agency determines to award the grant. False certification or violation of the certification shall be grounds for suspension of payments, suspension or termination of grants, or government-wide suspension or debarment (see CFR Part 44, Section 44.100 through 44.420).

The grantee certifies that it will provide a drug-free workplace by:

- (1) Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;
- (2) Establishing a drug-free awareness program to inform employees about
 - (a) The dangers of drug abuse in the workplace;
 - (b) The grantee's policy of maintaining a drug-free workplace;
 - (c) Any available drug counseling, rehabilitation, and employee assistance programs; and
 - (d) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;
- (3) Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (1);
- (4) Notifying the employee in the statement required by paragraph (1) that, as a condition of employment under the grant, the employee will
 - (a) Abide by the terms of the statement; and
 - (b) Notify the employer of any criminal drug statute conviction for a violation occurring in the workplace no later than five days after such conviction;
- (5) Notifying the agency within ten days after receiving notice under subparagraph (4) (b) from an employee or otherwise receiving actual notice of such convictions;
- (6) Taking one of the following actions, within 30 days of receiving notice under subparagraph (4) (b), with respect to any employee who is so convicted;
 - (a) Taking appropriate personnel action against such employee, up to and including termination; or
 - (b) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;
- (7) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (1), (2), (3), (4), (5) and (6).

§ 58.16 VA Form 10-0144—Certification Regarding Lobbying.

OMB Number: 2900-0160
Estimated Burden: 5 minutes
 Department of Veterans Affairs
CERTIFICATION REGARDING LOBBYING

The Paperwork Reduction Act of 1995 requires us to notify you that this information collection is in accordance with the clearance requirements of section 3507 of the Paperwork Reduction Act of 1995. We may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a valid OMB number. We anticipate that the time expended by all individuals who must complete this form will average 5 minutes. This includes the time it will take to read instructions, gather the necessary facts and fill out the form.

This certification is made in compliance with Section 319 of Public Law 101-121; and pursuant to the Interim Final guidance published as part VII of the December 20, 1989, Federal Register (Pages 57306-52332).

Certification for Contracts, Grants, Loans, and Cooperative Agreements

The undersigned certified, to the best of their knowledge and belief, that:

(1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

(2) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Forms-LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.


(3) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31 U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

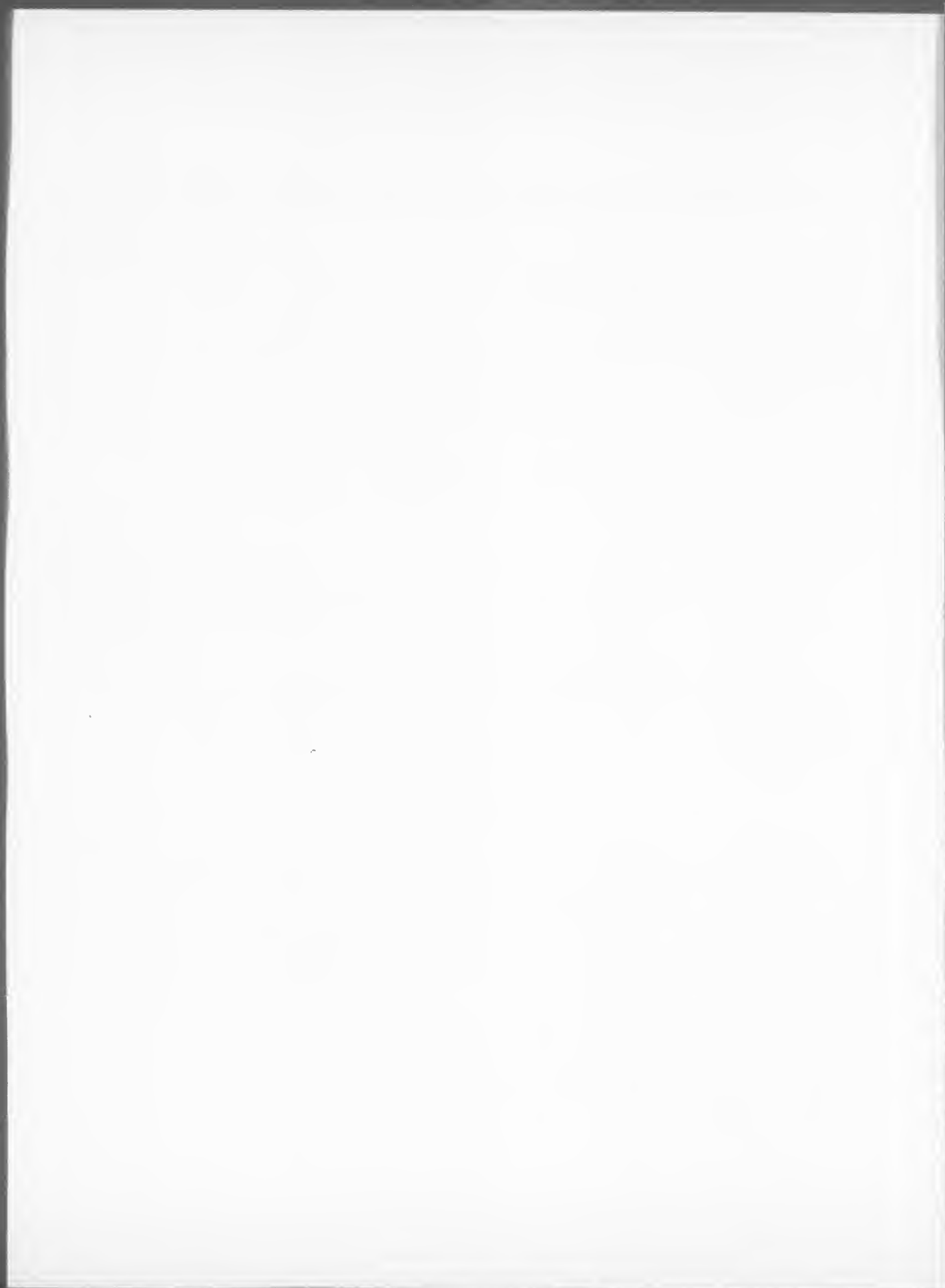
SIGNATURE OF CERTIFYING OFFICIAL	DATE
NAME AND TITLE OF CERTIFYING OFFICIAL	PROJECT (FAI NUMBER)
NAME AND ADDRESS OF STATE AGENCY	

§ 58.17 VA Form 10-0144A—Statement of Assurance of Compliance with Equal Opportunity Laws.

OMB Number: 2900-0160
Estimated Burden: 5 minutes

 Department of Veterans Affairs	
STATEMENT OF ASSURANCE OF COMPLIANCE WITH EQUAL OPPORTUNITY LAWS	
<p>The Paperwork Reduction Act of 1995 requires us to notify you that this information collection is in accordance with the clearance requirements of section 3507 of the Paperwork Reduction Act of 1995. We may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a valid OMB number. We anticipate that the time expended by all individuals who must complete this form will average 5 minutes. This includes the time it will take to read instructions, gather the necessary facts and fill out the form.</p>	
_____ (hereinafter called the "Signatory")	
(Name of Organization, Institution, or Individual)	
HEREBY AGREES THAT:	
<p>It will comply with Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), Title IX of the Education Amendments of 1972, as amended (20 U.S.C. 1681 et seq.), Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), and all Federal regulations adopted to carry out such laws. This assurance is directed to the end that no person in the United States shall, on the ground of race, color, national origin (Title VI), handicap (Section 504), sex (Title IX, in education programs and activities only), or age (Age Discrimination Act) be excluded from participation in , be denied the benefits of, or be subjected to discrimination under any program or activity of the Signatory receiving Federal financial assistance or other benefits under statutes administered by VA (Department of Veteran Affairs), the ED (Department of Education), or any other Federal agency. This assurance applies whether assistance is given directly to the recipient or indirectly through benefits paid to a student, trainee, or other beneficiary because of enrollment or participation in a program of the Signatory.</p>	
<p>The Signatory HEREBY GIVES ASSURANCE that it will promptly take measures to effect this agreement.</p>	
<p>If any real property or structure thereon is provided or improved with the aid of Federal financial assistance extended to the Signatory or ED, this assurance shall obligate the Signatory, or in the case of transfer of such property any transferee, for the period during which the real property or structure is used for a purpose for which the Federal financial assistance is extended or for another purpose involving the provision of similar services or benefits. In all cases, this assurance shall obligate the Signatory for the period during which the Federal financial assistance is extended to any of its programs by VA, ED or any other Federal agency.</p>	
<p>THIS ASSURANCE is given in consideration of and for the purpose of obtaining Federal financial assistance, including facilities furnished or payments made under sections 104 and 244(1) of Title 38, U.S.C. Also, sections 1713, 1720, 1720A, 1741-1743, 2408, 5902(a)(2), 8131-8137, 8151-8156 (formerly 613, 620, 620A, 641-643, 1008, 3402(a)(2), 5031-5037, 5051-5056 respectively) and 38 U.S.C. chapters 30, 31, 32, 35, 36, 82, and 10 U.S.C. chapter 106. Under the terms of an agreement between VA and ED, this assurance also includes Federal financial assistance given by ED through programs administered by that agency. Federal financial assistance is understood to include benefits paid directly to the Signatory and/or benefits paid to a beneficiary contingent upon the beneficiary's enrollment in a program or using services offered by the Signatory.</p>	
<p>The Signatory agrees that Federal financial assistance or other benefits will be extended in reliance on the representations and agreements made in this assurance; that VA or ED will withhold financial assistance, facilities, or other benefits to assure compliance with the equal opportunity laws; and that the United States shall have the right to seek judicial enforcement of this assurance.</p>	
<p>THIS ASSURANCE is binding on the Signatory, its successors, transferees, and assignees for the period during which assistance is provided. The Signatory assures that all contractors, subcontractors, subgrantees, or others with whom it arranges to provide services or benefits to its students or trainees in connection with the Signatory's programs or services are not discriminating against those students or trainees in violation of the above statutes.</p>	
SIGNATURE OF AUTHORIZED OFFICIAL	DATE
NAME AND TITLE OF AUTHORIZED OFFICIAL	
MAILING ADDRESS OF AUTHORIZED OFFICIAL	

VA FORM 10-0144A
APR 1999 (R)





Federal Register

Thursday
January 6, 2000

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 101
Regulations on Statements Made for
Dietary Supplements Concerning the
Effect of the Product on the Structure or
Function of the Body; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 101**

[Docket No. 98N-0044]

RIN 0910-AB97

Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing final regulations defining the types of statements that can be made concerning the effect of a dietary supplement on the structure or function of the body. The regulations also establish criteria for determining when a statement about a dietary supplement is a claim to diagnose, cure, mitigate, treat, or prevent disease. This action is intended to clarify the types of claims that may be made for dietary supplements without prior review by FDA and the types of claims that require prior authorization as health claims or prior approval as drug claims.

DATES: The final rule will become effective February 7, 2000.

FOR FURTHER INFORMATION CONTACT: Ann Marlin Witt, Office of Policy, Planning, and Legislation (HF-11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0084.

SUPPLEMENTARY INFORMATION:**I. Introduction**

In the *Federal Register* of April 29, 1998 (63 FR 23624), FDA proposed regulations to identify the types of statements that may be made without prior FDA review about the effects of dietary supplements on the structure or function of the body ("structure/function claims"), and to distinguish these claims from claims that a product diagnoses, treats, prevents, cures, or mitigates disease (disease claims). FDA received over 235,000 submissions in response to the proposed rule. Many of these were form letters, but over 22,000 were individual letters from the dietary supplement industry, trade associations, health professional groups, and consumers. Almost all the comments from the dietary supplement industry and from individuals, which made up the vast majority of the comments, objected to all or part of the proposed rule, arguing that it inappropriately

restricted the structure/function claims that could be made for dietary supplements. Most of the comments from health professional groups and groups devoted to particular diseases supported the proposed rule, or believed it did not go far enough in limiting structure/function claims for dietary supplements.

After reviewing the comments, FDA concluded that the comments had raised significant questions about some of the key provisions of the proposal such that a public meeting was warranted. In the *Federal Register* of July 8, 1999 (64 FR 36824), FDA announced a public meeting to be held on August 4, 1999, at which representatives of the dietary supplement industry, consumer groups, and health professionals were asked to address three major issues raised by the comments. The three issues, described in the *Federal Register* notice, were: (1) Whether to finalize the proposed definition of "disease" or retain a 1993 definition of "disease or health-related condition" that was in effect at the time the Dietary Supplement Health and Education Act (DSHEA) was enacted; (2) whether to modify one of the proposed criteria for assessing disease claims to permit structure/function claims related to certain conditions associated with natural states, such as hot flashes associated with menopause and decreased sexual function associated with aging; and (3) whether to permit implied disease claims structure/function claims. The July 8, 1999, notice also reopened the comment period until August 4, 1999, to receive written comments on these three issues.

This document addresses the comments received on the proposed rule, as well as comments received in response to the July 8, 1999, *Federal Register* notice. A few comments raised issues that are beyond the scope of this rule and generally will not be addressed in this document.

A. Highlights of the Final Rule

Like the proposed rule, the final rule contains criteria to determine when a labeling statement made about a dietary supplement constitutes a structure/function claim for which no prior FDA review is required and when it constitutes a disease-related claim that requires either authorization of a health claim or review under the drug provisions of Federal Food, Drug, and Cosmetic Act (the act). FDA has, however, made several important changes in the final rule in response to comments.

First, the agency has deleted the proposed definition of "disease." Rather than creating a new definition of

disease, FDA will use the preexisting definition of "disease or health-related condition" in § 101.14(a)(5) (21 CFR 101.14(a)(5)) (formerly § 101.14(a)(6)), which was issued as part of the implementation of the health claims provisions of the Nutrition Labeling and Education Act (NLEA). This change has been made in response to the large number of comments that objected to the proposed definition and urged that FDA retain the NLEA definition.

Second, FDA has revised the criterion that applies to conditions associated with such natural states or processes as menopause, aging, adolescence, and pregnancy. The proposed rule stated that menopause, aging, and pregnancy are not themselves diseases but that certain conditions associated with them are diseases if they are recognizable to consumers or health professionals as abnormal. Many comments objected to classifying as diseases such common conditions as hot flashes, premenstrual syndrome (PMS), and decreased sexual function associated with aging. In response to these comments, FDA has revised proposed § 101.93(g)(2)(iii). Common conditions associated with natural states or processes that do not cause significant or permanent harm will not be treated as diseases under the final rule. For example, hot flashes, common symptoms associated with the menstrual cycle, ordinary morning sickness associated with pregnancy, mild memory problems associated with aging, hair loss associated with aging, and noncystic acne will not be treated as diseases under this provision. Uncommon or serious conditions like senile dementia, toxemia of pregnancy, severe depression associated with the menstrual cycle, and cystic acne will continue to be treated as diseases under the final rule.

Third, FDA has revised the criterion that relates to the use in labeling of the titles of publications that refer to diseases. In response to comments objecting that, as proposed, this criterion would hamper manufacturers from providing consumers with information substantiating their claims, FDA has revised this criterion. Under the revised criterion, the use in labeling of a publication title that refers to a disease will be considered a disease claim only if, in context, it implies that the product may be used to diagnose, treat, mitigate, cure, or prevent disease. Highlighting, bolding, using large type size, or prominent placement of a citation that refers to a disease use in the title could suggest that the product has an effect on disease. Placing a citation to a scientific reference that refers to a disease in the title on the

immediate product label or packaging will be considered a disease claim for that product. The agency will also consider whether the cited article provides legitimate support for the express structure/function statement made for that dietary supplement. Enhancing the bibliography with citations to scientific references that refer to a disease in the title and that have no reasonable relation to the statement made will be considered a disease claim. Similarly, the agency will consider whether citations are to bona fide research.

B. Background

DSHEA created a new regime for the regulation of dietary supplements. These products were previously regulated either as foods or as drugs, depending upon whether they had the attributes of food and upon their intended uses. Before the passage of DSHEA, a dietary supplement for which a health-related claim was made was regulated either as a drug, which had to be shown to be safe and effective before marketing, or as a food, for which prior authorization to make a health claim was required if the claim concerned a disease or health-related condition. If the claim concerned a non-disease-related effect on the structure or function of the body and the claimed effect derived from a food attribute, such as nutritive value, the claim was considered a food claim, and prior authorization was not required. Under section 201(g)(1)(B) and (g)(1)(C) of the act (21 U.S.C. 321(g)(1)(B) and (g)(1)(C)), a drug is defined as "an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," or "an article (other than food) intended to affect the structure or any function of the body." Section 505 of the act (21 U.S.C. 355) requires that new drugs (see section 201(p) of the act) be shown to be safe and effective for their intended uses before marketing. Under sections 403(r)(1)(B) and (r)(5)(D) of the act (21 U.S.C. 343(r)(1)(B) and (r)(5)(D)) and § 101.14, prior authorization is required to make a health claim for a dietary supplement. A health claim is a claim that "characterizes the relationship of any nutrient * * * in the food to a disease or health-related condition" (section 403(r)(1)(B) of the act; see § 101.14(a)(1)).

DSHEA specifically authorized certain types of claims about the uses of dietary supplements, including some claims that formerly would have required review by FDA before the claim is made. Section 403(r)(6) of the act, added by DSHEA, allows dietary supplement labeling to bear, among

other types of statements, a statement that "describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans" or that "characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function." Such statements are generally referred to as "structure/function claims." Because many of these claims would previously have been covered by the drug definition in section 201(g)(1)(C) of the act, section 201(g)(1) was amended by DSHEA to provide that a dietary supplement "for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement."

Although a dietary supplement manufacturer who wishes to make a statement permitted under section 403(r)(6) of the act need not obtain prior review of the statement, the manufacturer must possess substantiation that the statement is truthful and not misleading, and must include in the statement the following disclaimer: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." DSHEA also requires the manufacturer of a dietary supplement bearing a statement under section 403(r)(6) of the act to notify FDA, no later than 30 days after the first marketing of the dietary supplement with the statement, that such a statement is being made for the product. Regulations implementing these requirements were published in the *Federal Register* of September 23, 1997, and are codified at § 101.93 (21 CFR 101.93) (62 FR 49883 at 49886, September 23, 1997).

DSHEA did not alter the statutory treatment of dietary supplement claims related to disease ("disease claims"). Section 403(r)(6) of the act, specifically provides that statements permitted under that section "may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases," except that such statements may claim a benefit related to a classical nutrient deficiency disease, provided that they also disclose the prevalence of the disease in the United States. Consistent with the quoted provision, Congress did not modify section 201(g)(1)(B) of the act to exclude disease claims for dietary supplements from use as evidence of intended use as a drug, as it had done for section 201(g)(1)(C) of the act. Thus, dietary supplements "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of

disease" remain within the definition of a "drug." In enacting DSHEA, Congress also maintained the requirement of prior authorization of a claim that characterizes the relationship of a nutrient in a dietary supplement to a disease (section 403(r)(1)(B) and (r)(5)(D) of the act). An interested person may submit a petition to FDA requesting the agency to issue a regulation authorizing the health claim (see § 101.70 (21 CFR 101.70)). The petitioner must demonstrate, among other things, that the use of the substance at levels necessary to justify the claim is safe and that there is "significant scientific agreement" among qualified experts that the claim is supported by the totality of publicly available scientific evidence (§ 101.14(b)(3)(ii) and (c)). The agency notes that for health claims to be used on conventional foods, an interested person may submit to FDA a notification of an authoritative statement by one of certain designated scientific bodies concerning the substance-disease relationship to which the claim refers (see section 403(r)(3)(C) of the act). Unless FDA issues a regulation modifying or prohibiting the claim, or a Federal district court finds that applicable statutory requirements have not been met, the claim may be used 120 days after the notification has been submitted (see section 403(r)(3)(C)(ii) and (r)(3)(D) of the act). This alternative authorization procedure does not apply to dietary supplements by statute, but FDA has proposed to extend it to dietary supplements by regulation (see 64 FR 3250, January 21, 1999).

Although FDA believes that dietary supplements have potential benefits for consumers, dietary supplements labeled with unproven disease claims, i.e., those that have not met the requirements for health claim authorization or new drug approval, can pose serious risks. Such claims may encourage consumers to self-treat for a serious disease without benefit of a medical diagnosis or treatment. They may also cause consumers to substitute potentially ineffective products for proven ones, foregoing or delaying effective treatment for serious and life-threatening illnesses. Reliance on disease prevention claims may encourage consumers to feel sufficiently protected from developing serious diseases (e.g., cancer or human immunodeficiency virus (HIV) infection) that they delay or forego regular screening, and forfeit the opportunity for early medical treatment that may be critical to survival. Finally, use of dietary supplements to treat

disease may increase the risk of adverse reactions due to the interaction of the dietary supplement with other compounds a consumer is taking for that disease or for other conditions, e.g., prescription medications.

This final rule is intended to apply only to structure/function claims and disease claims within the meaning of section 403(r)(6) of the act. DSHEA, generally, and section 403(r)(6) of the act, specifically, apply only to dietary supplements for human consumption and were enacted to provide a unique regulatory regime for these products. Thus, this rule is neither intended to apply to products other than dietary supplements for human consumption nor to interpret other provisions of the act.

The final rule establishes criteria for determining whether a statement made about a dietary supplement is acceptable as a structure/function claim under section 403(r)(6) of the act. The rule is neither intended to establish whether any particular structure/function claim is appropriate for any specific product, nor whether the claim would be permitted under other provisions of the act. Like the labeling of any other FDA-regulated product, the labeling of dietary supplements must comply with all applicable requirements of the act and regulations. For example, an otherwise acceptable structure/function claim might nevertheless be false or misleading for other reasons, causing the product to be misbranded under section 403(a)(1) of the act.

C. The Proposed Rule

The proposed rule defined criteria for determining when a statement about a dietary supplement is a claim to diagnose, cure, mitigate, treat, or prevent disease ("disease claim"), and thus requires prior approval as a drug or prior authorization as a health claim. The proposed rule included a definition of "disease," which was to replace a definition of "disease or health-related condition" issued for implementation of the health claims regulations, and 10 criteria for identifying express or implied disease claims. FDA proposed to treat a statement about a dietary supplement as a disease claim if the statement claimed, explicitly or implicitly, that the product: (1) Has an effect on a specific disease or class of diseases; (2) has an effect, using scientific or lay terminology, on one or more signs or symptoms that are recognizable to health care professionals or consumers as being characteristic of a specific disease or of a number of different specific diseases; (3) has an effect on a consequence of a natural

state that presents a characteristic set of signs or symptoms recognizable to health care professionals or consumers as constituting an abnormality of the body; (4) has an effect on disease through one or more of the following factors: (a) The name of the product; (b) a statement about the formulation of the product, including a claim that the product contains an ingredient that has been regulated by FDA as a drug and is well known to consumers for its use in preventing or treating a disease; (c) citation of a publication or reference, if the citation refers to a disease use; (d) use of the term "disease" or "diseased;" or (e) use of pictures, vignettes, symbols, or other means; (5) belongs to a class of products that is intended to diagnose, mitigate, treat, cure, or prevent a disease; (6) is a substitute for a product that is a therapy for a disease; (7) augments a particular therapy or drug action; (8) has a role in the body's response to a disease or to a vector of disease; (9) treats, prevents, or mitigates adverse events associated with a therapy for a disease and manifested by a characteristic set of signs or symptoms; or (10) otherwise suggests an effect on a disease or diseases.

Claims that did not fall within the proposed criteria for disease claims and that otherwise complied with the notification and disclaimer provisions of § 101.93(a) through (e) were to be eligible for use as structure/function claims. The proposed rule also provided examples of claims that would be permitted as structure/function claims and those that would require prior review as disease claims under each of the 10 criteria.

The basis for the proposed rule was the agency's experience in implementing section 403(r)(6) of the act, and the final report (the report) of the President's Commission on Dietary Supplement Labels (Ref. 1), which included a number of recommendations for distinguishing structure/function and disease claims and suggested that FDA issue further guidance on acceptable structure/function claims.

II. Comments

A. General Comments

(1.) Many comments focused on the impact of the rule on consumers. Many comments opposing the proposed rule said that consumers should be able to receive truthful and non-misleading information and that the proposed rule would curtail or restrict such information or restrict the focus of dietary supplements to preventive care and wellness. Some comments added that DSHEA, through the dissemination

of truthful and non-misleading information on health and promotion and disease prevention, makes consumers responsible for their own health. Other comments said that FDA should let the public educate itself. Other comments suggested that FDA simply adopt a "truthful and non-misleading" standard. Some comments added that full disclosure of all pertinent information (such as the preliminary status of scientific studies substantiating the claim) would be sufficient. Another comment questioned whether consumers would, as the preamble to the proposed rule stated, benefit from not having to search for information and from getting appropriate information. The comment argued that consumers would receive less information under the rule and would have to search more extensively for information.

Many comments supporting the proposed rule, including comments from nutrition counselors and health professionals, said that the proposal would reduce confusion among patients, prevent consumers from being misled, diminish the number of inappropriate disease claims, and help consumers decide when to seek medical attention. One comment added that, while it supported the need for consumers to have choice regarding dietary supplements, the choice should be made based on accurate information that is supported by appropriate scientific investigations. One comment argued that in the absence of valid effectiveness data, which does not exist for most dietary supplements, it is not possible to provide "truthful" information about the effects of these products. Some comments said that the proposal would protect consumers from harmful or potentially harmful products and save consumers from needless suffering and financial loss; others expressed concern that inappropriate statements would expose consumers to potentially harmful drug-supplement interactions, create "false hopes," and lead consumers to stop complying with advice from health care professionals or to avoid proven treatments.

FDA agrees that DSHEA encourages the dissemination of truthful and non-misleading information about the uses of dietary supplements to affect the structure or function of the body, and encourages full disclosure of information about claims authorized by the statute. To the extent that truthful and non-misleading information is being withheld from consumers in the context of structure/function claims for dietary supplements, it is the statute that, in the first instance, precludes

certain information from being included in such claims. Section 403(r)(6) of the act permits dietary supplement labels to carry structure/function claims without meeting the requirements for drug approval or health claim authorization, but precludes them from carrying unreviewed claims that the product diagnoses, treats, mitigates, cures, or prevents disease. (The statute does not ultimately prevent dissemination of information about disease uses to the consumer in labeling claims or otherwise. Instead, it requires that claims about disease uses meet certain standards of substantiation and undergo agency review.) This final rule differentiates between structure/function claims authorized by section 403(r)(6) of the act and disease claims that may not be made in dietary supplement labeling under the authority of section 403(r)(6). The agency notes that, in response to comments, the final rule classifies many more claims as structure/function claims than would have been so classified under the proposed rule, thus increasing the amount of information available to the consumer without prior FDA review.

The agency also declines to adopt a "truthful and non-misleading" standard instead of the final rule. Section 403(a)(1) of the act already subjects all food claims, including structure/function claims on dietary supplements, to the "truthful and non-misleading" standard, so promulgating the same standard through regulations is unnecessary. In addition, section 403(r)(6)(B) of the act already requires dietary supplement manufacturers to have substantiation that their statements are truthful and non-misleading. Finally a fundamental problem with this approach is that a "truthful and non-misleading" standard, unlike the final rule, would not provide any criteria for differentiating between structure/function claims and disease claims.

(2.) Some comments focused on product safety. One comment said that regulation of claims is unnecessary because dietary supplements are safe. Similarly, another comment claimed that "one million peer-reviewed studies" showed that dietary supplements provide benefits, whereas a recent medical journal reported deaths and other injuries to patients who use prescription drugs. Other comments declared that dietary supplements are safer than most regularly-used drug products. In contrast, other comments argued that the safety of many dietary supplements is unknown, and that risks have been documented with some supplements. Some comments claimed that dietary supplements pose risks

because they can cause consumers to avoid or delay more effective treatment. One comment stated that there is a substantial potential for public harm because of the unknown or unregulated source materials for many dietary supplements, the variety of suppliers, and the lack of regulatory production standards and quality control.

Although this final rule may not appear to be a safety measure because it addresses the labeling of dietary supplements rather than their composition, protecting consumer health and safety is one of its major purposes. Because structure/function claims are not subject to the new drug approval standard or the health claim authorization standard and do not undergo FDA review before marketing, FDA believes it is important to ensure that such claims do not promote products for disease treatment or prevention claims. Disease treatment or prevention claims can pose serious risks to consumers if they induce consumers to substitute ineffective or less effective treatments for proven ones, especially if the disease involved is serious or life-threatening. Therefore, the agency believes that ensuring that such claims cannot be made without a demonstration of safety and effectiveness will protect and promote public health.

FDA also believes that the safety and the effectiveness of products intended to promote health, including both dietary supplements and drugs, cannot be viewed independently of each other. FDA agrees that prescription drugs can and do cause adverse reactions. It is important to remember, however, that "safety" is relative. Products that are capable of treating diseases have powerful effects on the body and frequently carry risks. Before prescription drugs are marketed, both their risks and their benefits must be carefully investigated and documented in adequately designed clinical trials. Prescription drugs are permitted to be marketed only when the agency concludes that their documented benefits outweigh their known and potential risks. Those with significant risks are approved for marketing only if the benefits warrant those risks. And they are marketed as "prescription" drugs to ensure that health professionals manage their risks. Even over-the-counter (OTC) drugs are evaluated for both benefits and risks and are permitted to be marketed only when their established benefits outweigh their risks. There is no comparable testing and approval process for dietary supplements marketed with structure/function claims. The manufacturer must

have substantiation of the structure/function claim, but this substantiation is not reviewed before the product is marketed with the claim. Contrary to the suggestion in the comment, few dietary supplements have been the subjects of adequately designed clinical trials.

This does not mean that dietary supplements are unsafe or that they do not have benefits. Some have already been shown to be safe and to have benefits, and the safety and effectiveness of others are likely to be shown in the future. At this time, however, many marketed supplements have not been the subjects of adequate studies to establish whether or not they are safe or effective, or the nature of the benefits they may provide.

(3.) Many comments asserted that FDA had no authority to issue the proposed rule because it was inconsistent with DSHEA and congressional intent, in that it restricted rather than increased the amount of information given to consumers. Some comments said that Congress enacted DSHEA to reverse FDA's "overly restrictive" approach towards health claims and to increase the dissemination of truthful and non-misleading health information and that Congress repeatedly expressed its displeasure with FDA's regulatory approach. One comment said FDA must determine whether a proposed action is consistent with its statutory authority before it takes any regulatory action. The comment cited excerpts from congressional documents "condemning the agency's repeated penchant" for restricting statements on dietary supplement labels and labeling, and said that, given congressional intent and the act's language, FDA has no authority to proceed with rulemaking without a grant of authority from Congress. One comment cited section 403B of the act (21 U.S.C. 343-2) as evidence that Congress, by exempting certain publications from the definition of labeling, barred FDA from restricting in "any way whatsoever" the dissemination of such publications and information.

FDA agrees that DSHEA was intended to authorize the dissemination of more truthful and non-misleading information in dietary supplement labeling without the need for prior agency review. In response to comments that the proposed rule was too restrictive, FDA has modified the final rule to incorporate many of the changes requested by the comments, including a return to the preexisting definition of "disease or health-related condition," and a less restrictive interpretation of the types of structure/function claims

that can be made about conditions associated with such natural states as aging, pregnancy, and the menstrual cycle. The final rule classifies many more claims as structure/function claims than the proposed rule would have.

The agency does not agree, however, that section 403(r)(6) of the act authorizes dissemination of any and all information about dietary supplements without prior review. That section authorizes statements about the effects of dietary supplements on the structure or function of the body, but not statements that claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. Section 403B of the act exempts from being considered labeling certain balanced, third-party publications that are physically separate from product labeling and do not promote a particular brand or product. This provision does not authorize dietary supplement manufacturers to ignore the restrictions in section 403(r)(6) of the act on what structure/function claims may be made by a manufacturer about its product on the product label and in materials that are indisputably part of the product's labeling.

The agency also disagrees with the assertion that separate congressional authority is needed for this rulemaking. FDA issued the proposed rule, and this final rule, to implement section 403(r)(6) of the act. No independent authority to issue these regulations is necessary because section 701(a) of the act (21 U.S.C 371(a)) expressly gives FDA "the authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in (section 701 of the act) * * *." The proposed rule identified section 701(a) of the act as being part of the agency's legal authority (see 63 FR 23624 at 23628 and 23631), and there is no exception in the act that restricts or limits, either expressly or impliedly, the agency's ability to issue regulations to implement section 403(r)(6) of the act. Therefore, the rule is authorized by law and consistent with FDA's statutory authority.

(4.) Some comments contended that FDA did not provide a sufficient justification for issuing the rule. Two comments challenged FDA's assertion that the rule would reduce substantial confusion among manufacturers. The comments referred to statements in the preamble to the proposed rule which said FDA received approximately 2,300 notifications of structure/function claims and sent objection letters to approximately 150 notifications. One comment said the low objection rate did

not indicate "substantial confusion" among manufacturers, while the other comment hypothesized that, if FDA objected to a small number of claims in each notification, the number of objectionable claims was very small. Other comments contended that the Commission report did not support the proposed rule. These comments were divided in their reasons. Some comments argued that the Commission exceeded its statutory mandate under section 12 of DSHEA or failed to perform its statutory obligations. Thus, the comments stated, FDA cannot base any regulation on the Commission's findings, guidance, or recommendations and has no authority to proceed with the rulemaking. Other comments stated that FDA relied on statements from individual Commission members rather than the report itself, that the report did not suggest that FDA issue regulations, and that the report did not suggest that FDA issue a new definition of disease. One comment said that the Commission did not support a need for regulations. Another comment noted that the Commission did not recommend regulations and asserted that FDA had publicly said that DSHEA is self-implementing.

FDA does not agree that there is insufficient support for this rule. FDA's experience, the Commission report, and FDA's authority under section 701(a) of the act to issue regulations implementing statutory requirements provide more than adequate support for the rule. The preamble to the proposed rule referred to substantial confusion among manufacturers and consumers, rather than manufacturers alone. Comments received from other sources, particularly physicians, dieticians, and health professional organizations, agreed that consumers are confused and misled by claims. In addition, the number of objection letters is not the sole indicator of manufacturer confusion, for three reasons. First, manufacturers and consumers have asked FDA to provide clarification on structure/function and disease claims, and such requests for clarification would not necessarily have resulted in an objection letter from FDA. Second, the agency has repeatedly said that the absence of an objection letter does not necessarily indicate acceptance of the claim. Third, there are apparently a large number of marketed dietary supplement products making claims for which FDA has not received 30-day notification letters under section 403(r)(6) of the act. (In the proposed rule, FDA estimated that approximately 22,500 dietary supplement labels

carried structure/function claims. FDA had received 2,300 notifications at the time of the proposed rule. While some notifications contain more than one claim, they do not average 10 claims per notification.)

FDA also does not agree that the Commission report was necessary to provide support for this rule. The proposal was based not only on the Commission report, but also on the agency's experience in reviewing 30-day notification letters submitted under section 403(r)(6) of the act (63 FR 23624 at 23625). Although FDA believes the rule is consistent with the views expressed in the Commission report, the Commission report was not a necessary prerequisite for the agency to issue the rule. FDA issued the proposal under section 403(r)(6) of the act (section 6 of DSHEA) and the rulemaking authority of section 701(a) of the act, not under section 12 of DSHEA. FDA takes no view on whether the Commission met its statutory obligations in issuing its report. To the extent that the report is beyond the Commission's authority, FDA's experience and section 701(a) of the act provide adequate support for the rule. Thus, whether or not the Commission exceeded its mandate is irrelevant to the validity of the rule.

With regard to the issues raised about the consistency of the agency's approach with the Commission report, it is true that the Commission did not specifically recommend regulations, but the Commission did express the view that FDA guidance on claims under section 403(r)(6) of the act would be "appropriate and helpful in clarifying the appropriate scope" of such claims (the report, p. 38).

As to the agency's public statements that DSHEA is self-implementing, the comment took those statements out of context. When DSHEA was passed, there was confusion in the industry about whether the types of statements permitted by section 403(r)(6) of the act could be made under the authority of the statute alone, in the absence of implementing regulations. To clear up this confusion, at least one agency official publicly said that DSHEA was "self-implementing." Agency statements to this effect were intended to clarify that manufacturers were not required to wait for FDA to issue implementing regulations before making claims under section 403(r)(6) of the act; however, they were in no way intended to imply that the agency lacked authority to issue implementing regulations.

Contrary to the suggestion in one of the comments, FDA did not rely on the views of individual Commission members, but on the official 7-point

"guidance" developed by the Commission "as to what constitutes an acceptable statement of nutritional support of the structure function type" (the report at pp. 38 and 39). The criteria developed by FDA are highly consistent with the Commission's guidance. FDA also agrees that the Commission did not make any findings or recommendations on the definition of disease. As described elsewhere in this rule, the final rule does not modify the existing definition of disease found in FDA's health claims regulations.

(5.) One comment said that FDA should have admitted that there is and will be some overlap between disease and structure/function claims and that the agency should have drafted a rule to prevent extreme overlap between structure/function claims and drug or health claims.

FDA disagrees with this comment. In the proposed rule, FDA recognized that section 403(r)(6) of the act leaves open questions concerning the distinction between structure/function claims and disease claims. Diseases cause, and can be characterized as, abnormalities in the structure or function of the body. It would therefore be possible to describe almost all products intended to treat or prevent disease in terms of their effects on the structure or function of the body, without mentioning the disease itself.

The language of DSHEA, however, does not support treating those structure/function claims that are also disease claims as statements permitted under section 403(r)(6) of the act. As noted above, section 403(r)(6) of the act contains two passages that indicate Congress' intent to exclude from the scope of structure/function claims any claim that is also a disease claim. Section 403(r)(6) of the act provides that structure/function statements "may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases." It also requires structure/function claims to be accompanied by a disclaimer stating that the product "is not intended to diagnose, treat, cure, or prevent any disease."

In light of the statutory framework, FDA concluded in the preamble to the proposed rule that section 403(r)(6) of the act authorizes claims related to the effect of a product on the structure or function of the body only if they are not also disease claims. FDA's conclusion was consistent with the policy guidance offered by the President's Commission on Dietary Supplement Labels. In the report the Commission offered general guidance on structure/function claims, including the following:

3. Statements indicating the role of a nutrient or dietary ingredient in affecting the

structure or function of humans may be made when the statements do not suggest disease prevention or treatment. (The report, p. 38)

Accordingly, FDA believes that it is appropriate to define the universe of permitted structure/function claims by first identifying those claims that should be considered disease claims. Remaining claims about the effect of a dietary supplement on the structure or function of the body may be acceptable structure/function claims under section 403(r)(6) of the act, provided that they are consistent with the requirement in section 201(ff)(1) of the act that a dietary supplement be "intended to supplement the diet."

(6.) Some comments, particularly those received at the public hearing or during the reopened comment period, argued that it is difficult or impossible to draw principled distinctions between structure/function claims and disease claims. Some of these comments said that section 403(r)(6) of the act, which is premised on such a distinction, is not scientifically based. Other comments argued that it is not necessary or practical to draw clear lines between disease claims and structure/function claims, and that dietary supplement labeling should instead focus on educating consumers about the conditions for which a product may be used. According to these comments, if there are disease conditions that might be implied by a particular claim, the labeling should, for example, inform consumers of the symptoms of such conditions, the importance of seeking medical attention for them, and their health-related consequences. Other comments argued that consumers reading the labels of dietary supplements will incorrectly assume that the information provided therein has been reviewed by the government and that the claims, express or implied, are supported by the kind of scientific evidence that supports drugs with similar claims.

FDA agrees that it may be very difficult to draw clear lines between structure/function claims and disease claims. Despite the difficulty, implementing section 403(r)(6) of the act requires the agency to draw these lines. FDA would not be carrying out its statutory obligations if it abdicated responsibility for distinguishing between the two types of claims, and instead permitted dietary supplements to disseminate information about specific disease states. FDA agrees that scientifically valid information about diseases is helpful to consumers, if it is delivered consistently and accurately, but does not agree that section 403(r)(6)

of the act authorizes such dissemination. FDA strongly believes that the dissemination of such information on dietary supplement labels increases the likelihood that consumers will believe that the supplements are intended to treat or prevent the diseases described in the labeling. Therefore, it is important that any disease claims in dietary supplement labeling continue to be subject to prior FDA review to evaluate the safety and effectiveness of the product for the use described or suggested by the claim.

The agency also notes that there may be important health-related consequences associated with taking a dietary supplement, even if the product does not bear disease claims. For the labeling of a dietary supplement to be considered truthful and non-misleading (see sections 403(a) and (r)(6) and 201(g)(1) of the act), it must include all information that is material in light of the claims made for the product and the consequences that may result from its use (see section 201(m)) of the act.

(7.) Many comments discussed the rule's effect on scientific research. Some comments argued that the proposal would discourage scientific research on dietary supplements. One comment contended that such research might prompt FDA to consider a dietary supplement to be a drug. Another comment said the proposal would "chill" the availability of third-party information on dietary supplements.

The agency disagrees with the comments. The comments provided no evidence, and the agency is aware of none, that establishing criteria for distinguishing structure/function claims and disease claims will adversely affect the conduct or use of scientific research. In the agency's experience, establishing regulatory standards has generated more research rather than less. As described below, some comments from pharmaceutical companies and from patient organizations expressed the contrary concern that allowing dietary supplements to make disease claims without FDA review would undermine incentives for rigorous scientific research. The agency also notes that nothing in this rule would treat scientific research or the publication of research results in a scientific journal as evidence that a product is marketed as a dietary supplement or is a drug.

(8.) Several comments addressed the relationship between dietary supplements and drug products, and the effects of this regulation on drug products and drug development. Some comments suggested that the proposal represented an attempt by FDA to

regulate dietary supplements in a manner that benefits pharmaceutical interests or to regulate dietary supplements in a manner that is similar to European regulatory systems that apply drug requirements to such products.

In contrast, other comments expressed concern over the negative effects of DSHEA and the proposed rule on incentives for pharmaceutical drug development. One comment asked FDA to provide an "unambiguous demarcation" that would preserve research and development incentives for drug products and permit evaluation of opportunities in the dietary supplement marketplace. According to this comment, section 403(r)(6) of the act, and DSHEA generally, were intended to create "parity" between the dietary supplement and food industries without undermining research and development incentives for the pharmaceutical industry and to address a perceived failure by FDA to implement the health claims provision for dietary supplements in section 403(r)(5)(D) of the act. The comment contended that section 403(r)(6) of the act is intended to provide a limited statutory safe harbor for certain dietary supplements that might otherwise be subject to regulation under the health claim rules for food or as unapproved new drugs, but it does not permit any and all structure/function statements for dietary supplements. Thus, the comment said FDA should have "parallel interpretations" of sections 201(g)(1)(C) and 403(r)(6) of the act. The comment suggested that FDA enforce the requirement of a "documented mechanism" imposed in section 403(r)(6)(A) of the act, which permits claims that "characterize the documented mechanism by which a nutrient or dietary supplement acts to maintain" structure or function and that FDA limit claims to "maintaining," rather than "promoting" or "improving" structure or function.

FDA does not agree that this rule was designed to benefit the pharmaceutical industry or to establish rules that are consistent with European regulation of dietary supplements. As noted above, some pharmaceutical companies believe that the rule will harm them by permitting competition by products that have not had to undergo rigorous testing or review. Other pharmaceutical companies already produce dietary supplements and expressed the same reservations about the rule as other dietary supplement manufacturers. There was also no attempt to model this rule after European regulation of dietary supplements.

FDA recognizes the importance of maintaining incentives for research and product innovation. By establishing criteria for determining when a statement may be a disease claim, the final rule indirectly contributes towards preserving the incentives for pharmaceutical research and development by ensuring that products marketed for treatment or prevention of diseases must all meet the same regulatory standards. As stated below, FDA believes that if the rule were to permit dietary supplements to carry implied disease claims, the incentives for new drug development could be significantly undermined.

FDA agrees with the comment that the structure/function provisions of sections 403(r)(6) and 201(g)(1)(C) of the act are similar in scope. FDA also agrees that to make a statement about the mechanism by which a dietary supplement maintains structure or function, the mechanism of action must be "documented." FDA does not agree, however, that this is the only provision under which a dietary supplement may claim to maintain healthy structure or function. Maintenance claims also can be made under the provision that authorizes statements that "describe the role" of a supplement "intended to affect the structure or function" of the body (section 403(r)(6)(A) of the act).

In response to the comment asking FDA to limit claims to "maintaining," rather than "promoting" or "improving," structure/function, the agency agrees that "improving" often suggests some abnormality or deficiency that can be treated, so a claim to "improve" a structure or function of the body would be more likely to be a disease claim. On the other hand, a claim to improve memory or strength would be a permitted structure/function claim, unless disease treatment were implied. Use of the term "promote" may be acceptable under the portion of section 403(r)(6)(A) of the act which authorizes claims that "describe[] the role of a * * * dietary ingredient intended to affect the structure or function." Whether a claim for "promoting" structure or function is a disease claim will depend on the context and nature of the claim. For example, a claim that a product "helps promote digestion" would be a structure/function claim because it does not refer explicitly or implicitly to an effect on a disease state, but a claim that a product promotes low blood pressure would be considered a disease claim. Both the preamble to the proposed rule and the Commission recognized that statements using the word "promote" can be appropriate when the statements

do not suggest disease prevention or treatment or use for a serious health condition that consumers cannot evaluate (see 63 FR 23624 at 23626).

(9.) A few comments objected to the statement that a dietary supplement bearing an appropriate structure/function claim may be subject to regulation as a drug if there is other evidence that it is intended for the diagnosis, cure, mitigation, treatment, or prevention of disease. One comment argued that many dietary supplements are used for medicinal purposes and it would be "easy" for FDA to find evidence that they were intended for this purpose based on consumer use of the product.

Although FDA's longstanding interpretation of section 201(g)(1)(B) of the act authorizes the agency to rely on evidence outside the labeling and advertising of a product to establish its intended use, FDA does not rely on such evidence alone except in unusual circumstances. For example, the courts have suggested that if the agency seeks to rely solely on evidence that consumers use a product for a particular purpose to support a finding of intended use for that purpose, consumers must use the product predominantly or nearly exclusively for that purpose. (See, e.g., *Action on Smoking and Health (ASH) v. Harris*, 655 F.2d 236, 239-240 (D.C. Cir. 1980); *National Nutritional Foods (NNFA) v. Weinberger*, 512 F.2d 688, 702 (2d Cir. 1975), *cert. denied*, 423 U.S. 827 (1975).) The fact that some consumers used a dietary supplement for medicinal purposes would not by itself be sufficient to establish intended use as a drug, if use for medicinal purposes was not the predominant use.

FDA reiterates, however, that in appropriate circumstances, FDA may find that a dietary supplement for which only structure/function claims are made in labeling may nevertheless be a drug if there is other evidence of intended use to prevent or treat disease.

(10.) Some comments discussed the "disclaimer" statement required by section 403(r)(6)(C) of the act. The disclaimer reads as follows: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." One comment said the disclaimer resolves any consumer confusion between dietary supplement claims and drug claims. Another comment said the proposed rule showed that FDA was implicitly rejecting the disclaimer's meaning because the proposed rule would restrict the amount of information flowing to consumers. One comment said the disclaimer reflects

Congress' understanding of a tension between structure/function and disease claims, while another comment asserted that the disclaimers required on a label are an attempt to decrease the amount of space on a label for a structure/function claim.

Section 403(r)(6) of the act requires dietary supplement manufacturers who wish to make a structure/function statement to include the disclaimer, and, since 1997, FDA regulations regarding the disclaimer have been codified at § 101.93. However, the disclaimer's role does not eliminate the need for this final rule to establish criteria for determining whether a statement is a disease claim. Section 403(r)(6) of the act provides that a statement for a dietary supplement that is made under section 403(r)(6) "may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases." Had Congress thought the disclaimer, alone, was sufficient to distinguish between structure/function claims and disease claims, it would not have enacted the restriction against disease claims in section 403(r)(6) of the act.

FDA does not agree with the assertion that the disclaimer, which is expressly required by the act, is a scheme to decrease the space for structure/function claims on a label. FDA believes that the disclaimer is intended to make sure that consumers understand that structure/function claims, unlike health claims and claims that appear on the labels of drugs, are not reviewed by FDA prior to marketing, and to caution consumers that dietary supplements bearing such claims are not for therapeutic uses.

(11.) Several comments sought additional statements or language on product labels. One comment supported the marketing of dietary supplements and other substances whose effectiveness has not been established and that have no appreciable toxicity as long as the product's label stated that effectiveness had not been proven. Another comment said precautions, such as adverse reactions and contraindications to certain diseases and medications, are important information for labels. The comment also sought a description of a dietary supplement product's contents as a percentage of a person's recommended daily intake (RDI) and in actual units.

FDA declines to revise the rule as suggested by the comments. With regard to the marketing of dietary supplements with a label statement that the product's effectiveness has not been proven, the agency advises that dietary supplements that do not do what they claim to do are

misbranded. The act forbids false and misleading labeling and advertising claims and requires businesses to have substantiation for any structure/function claims they make for dietary supplements in labeling (see section 403(a) and (r)(6)(B)) of the act). The presence of a disclaimer indicating that effectiveness has not been established cannot vitiate these statutory obligations. Therefore, it would be inappropriate for FDA to sanction the use of effectiveness disclaimers.

Although the act does not prescribe any specific statements concerning adverse reactions or contraindications that dietary supplements must carry, the agency notes that dietary supplement labeling, like the labeling of all other FDA-regulated products, is required to include all information that is material in light of consequences that may result from the use of the product or representations made about it (see sections 403(a)(1) and 201(n) of the act).

As for requiring information on the percentage of RDI and actual units for dietary ingredients in dietary supplements, FDA agrees that such information is useful. In fact, FDA's nutrition labeling regulations for dietary supplements generally require the percentage of the RDI or daily reference value (DRV) that a dietary supplement contains to be given for dietary ingredients that have an RDI or DRV (see § 101.36(b)(2)(iii) (21 CFR 101.36(b)(2)(iii))). In addition, the amount in units must be given, regardless of whether an RDI or DRV has been established (see § 101.36(b)(2) and (b)(3) (21 CFR 101.36(b)(2) and (b)(3))). This information can be found on the Supplement Facts panel of dietary supplements.

(12.) One comment objected to referring to structure/function statements as "claims." The comment said that, under section 403(r)(6) of the act, such statements must be truthful and non-misleading, so they should be called "statements" instead of "claims." FDA has traditionally used the term "claim" to refer to any statement made by a manufacturer that recommends or suggests a particular use of a product. This term is used for all products regulated by FDA, including drugs, foods, devices, and dietary supplements. Use of the term "claim" is not intended to suggest that a statement is untrue or misleading in any way.

(13.) One comment said that any substance used with "pharmacologic intent" should be classified as a drug or biologic in order to ensure the efficacy, potency, and purity of medicines. The comment explained that such substances have a potential for

therapeutic benefit as well as harm, and suggested that existing and new dietary supplements that are marketed with health-related claims be required to provide scientific evidence of their safety and efficacy as a condition of their being marketed as a drug or biologic.

FDA declines to adopt the comment's suggestion. Section 403(r)(6) of the act expressly authorizes certain structure/function claims for dietary supplements. Many of these claims may be said to be "health-related." (The agency is uncertain what is meant by "pharmacologic intent.") Thus, the act does not require all substances with health-related claims to be classified as a drug or biologic.

Regarding safety and effectiveness evidence for dietary supplements that bear health-related claims, FDA agrees that such evidence should continue to be required where the claim is a health claim within the meaning of § 101.14(a)(1) or a claim that subjects the product to regulation as a drug under section 201(g)(1)(B) of the act. With regard to health-related claims that are authorized by section 403(r)(6) of the act, section 403(r)(6)(B) does require manufacturers to have substantiation for their claims. However, the act does not generally require dietary supplement manufacturers that make claims for their products under section 403(r)(6) of the act to provide a premarket demonstration of safety and effectiveness to FDA.

(14.) One comment recommended that FDA not finalize the proposed rule because it claimed that the proposal's criteria were based on a subjective evaluation of claims and not on objective information from market research studies to determine whether consumers are confused by the claim. The comment also argued that FDA did not provide data and information regarding consumer confusion, and that all interested parties should be able to evaluate and comment on any data before FDA finalizes the proposal. The comment asserted that a significantly revised and limited final rule could provide a basic regulatory definition of disease and a "construct" for structure/function claims so that detailed regulatory criteria would be unnecessary.

The act does not require market research studies to determine whether a particular statement is a structure/function claim or disease claim, and it would be both impractical and inefficient to require such studies to decide the status of every possible claim that could be made under section 403(r)(6) of the act. FDA also does not

believe that market research studies are necessary to provide a reasonable basis for the agency's determinations concerning the meaning of labeling claims. The agency has extensive experience in interpreting such claims. The agency has, however, modified the second criterion in § 101.93(g)(2)(ii) to eliminate reference to recognition of signs and symptoms by consumers or health professionals because many comments objected that this standard would appear to require consumer testing. FDA has replaced the recognition standard with an objective standard.

(15.) One comment said that it would be inappropriate for FDA to issue any regulation that restricted the scope of statements of nutritional support related to a nutrient content claim or claims pertaining to a classical nutrient deficiency-related disease. The comment said that claims such as "calcium builds strong bones" are acceptable and that FDA should clarify this fact in the final rule.

FDA agrees that dietary supplements may carry structure/function statements concerning the relationship of nutrients and the structure or function of the body, such as "calcium builds strong bones." The preamble to the proposed rule also specifically acknowledged that although statements under section 403(r)(6) of the act generally may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases, "such statements may claim a benefit related to a classical nutrient deficiency disease, provided that they also disclose the prevalence of the disease in the United States" (63 FR 23624). The final rule codifies this exception at § 101.93(g)(2), which states that "FDA will find that a statement about a product claims to diagnose, mitigate, treat, cure, or otherwise prevent disease (*other than a classical nutrient deficiency disease*) * * *" (emphasis added). Classical nutrient diseases are also specifically excluded from the definition of disease in § 101.93(g)(1). Thus, because the final rule already contains the exception, no change to the rule is necessary.

(16.) Many comments suggested that FDA issue a guidance document instead of regulations. Some of the comments stated that regulations are neither desirable nor necessary. Others stated that a guidance document would be appropriate because it would permit new information to support new structure/function claims or because it would enable FDA to conduct consumer research and industry outreach programs before imposing new rules. Some comments also requested separate

guidance documents for specific claims or recommended that FDA create or use advisory committees to help draft guidance documents. Two comments said that the Commission report only provided guidance and suggestions, so FDA did not have to issue the proposed rule. Another comment said that publishing a guidance document would consume fewer agency resources and that a rule is unnecessary because the industry already knows the permissible scope of statements for dietary supplements.

FDA disagrees with the comments. The final rule creates uniform, enforceable requirements for structure/function claims. By doing so, the final rule establishes a "level playing field" for all members of the dietary supplement industry, and permits rational use of FDA's limited enforcement resources. In contrast, guidance documents, although they represent FDA's best advice on a particular matter, are not binding on any party. Relying solely on guidance documents would not be as effective in achieving consistency in the regulation of structure/function claims on dietary supplements and would lead to case-by-case enforcement.

FDA does, however, intend to issue a guidance document to provide additional information regarding structure/function and disease claims. The guidance document would complement rather than substitute for, the final rule.

As for those comments stating that a guidance document would permit new information to support new structure/function claims or that outreach programs are necessary, FDA notes that interested persons may generate such information regardless of the rule. FDA may also conduct research or other programs or consult advisory committees or other persons if such actions would be helpful. In short, gathering more information or conducting research and other programs is not dependent on whether FDA issues a guidance document instead of a rule.

(17.) A few comments stated that FDA should enforce existing laws and regulations, remove unsafe products from the market, take action against dietary supplements that make "extravagant, unsubstantiated" claims, or promote educational activities instead of issuing regulations. One comment suggested that FDA resources would be better spent reviewing notices sent to the agency instead of issuing regulations. Another comment suggested that FDA continue to clarify issues on a case-by-case basis.

FDA disagrees with the comments. Regulations offer several important advantages that case-by-case clarification, individual enforcement actions, and educational activities generally cannot. For example, when FDA develops a regulation, it provides notice, obtains public comment, considers alternatives, and evaluates the rule's potential impacts, costs, and benefits. Individual enforcement actions and educational activities are not subject to these considerations.

Regulations also establish uniform, industry-wide requirements in a single administrative proceeding (rulemaking). In contrast, individual enforcement actions focus on distinct facts that may not lend themselves to uniform application to an entire industry. Moreover, enforcement actions are resource-intensive and require multiple steps, such as inspections, warning letters, and sometimes litigation, before they are completed. Educational activities may deal with general topics and provide valuable opportunities for discussing issues with FDA, but they do not create uniform requirements.

Regulations are also easier to locate because they are published in the **Federal Register** when they are issued, are codified and published in the Code of Federal Regulations (CFR) and can be found in libraries and on government Internet sites (such as the Government Printing Office's website at www.gpo.gov). In contrast, agency correspondence and results of individual enforcement actions are not as widely available and may be difficult for some regulated entities and consumers to obtain.

Thus, when it comes to establishing uniform, industry-wide requirements, conserving agency resources, and providing public notice and an opportunity to comment, regulations are preferable to individual enforcement actions and educational activities.

(18.) A comment suggested that FDA adopt an approach like hazard analysis critical control point (HACCP) instead of issuing the rule.

FDA disagrees with the comment. HACCP is best suited for issues relating to how a product is manufactured. Here, the principal issue is the claims made for a product rather than how the product is made.

(19.) A comment stated that FDA lacks the expertise to determine whether a botanical is a drug or a dietary supplement. The comment explained that botanicals can be used for medicinal purposes, but that they can also be used for promoting general well being and supporting the structure or function of the body. According to the

comment, FDA declared Yellowdock, an herb, to have medicinal purposes only, when the herb also had a long history of use as a food source.

The comment may have misinterpreted the rule. The focus of this rule is not on whether a substance has a history of use as a food but on claims made in the product's labeling. The rule defines the types of statements that may be made concerning a dietary supplement's effect on the structure or function of the body. FDA has many years of experience in regulating and interpreting health-related product claims.

(20.) One comment said other countries (naming several European nations) and the World Health Organization have established lists of ingredients and botanical products that are safe and permitted for therapeutic purposes. The comment suggested that FDA consider assembling a committee to establish a similar list for the United States.

A list of dietary ingredients and botanical products and their therapeutic uses might provide valuable information. Nevertheless, section 403(r)(6) of the act permits only structure/function claims for dietary supplements that are not also disease claims, and so such a list would not be relevant to this rulemaking.

(21.) Two comments suggested that FDA list examples of structure/function claims in order to reduce confusion. Another comment would have FDA describe both disease claims and structure/function claims.

FDA intends to issue a guidance document that will provide examples of claims that would and would not be considered disease claims. This final rule also includes many examples of structure/function and disease claims.

B. Permitted Structure/Function Statements (§ 101.93(f))

Proposed § 101.93(f) stated that dietary supplement labels and labeling may bear structure/function statements that are not disease claims within the meaning of proposed § 101.93(g) and that otherwise comply with the notification and disclaimer provisions of § 101.93(a) through (e). FDA is revising § 101.93(f) on its own initiative to make it clear that a dietary supplement may bear a disease claim if it is the subject of an authorized health claim, but that otherwise disease claims will subject the product to regulation as a drug.

C. Definition of Disease (§ 101.93(g)(1))

To assist in describing what constitutes a disease claim, the

proposed rule contained a definition of "disease." The proposed definition was based on standard medical and legal definitions of the term (Refs. 2, 3, 4, and 5). Proposed § 101.93(g)(1) defined "disease" as:

any deviation from, impairment of, or interruption of the normal structure or function of any part, organ, or system (or combination thereof) of the body that is manifested by a characteristic set of one or more signs or symptoms, including laboratory or clinical measurements that are characteristic of a disease.

The proposed definition would have replaced an earlier definition issued in 1993 as part of the regulations implementing the health claims provisions of NLEA. The implementing regulations require dietary supplement manufacturers to obtain prior authorization of any labeling statement that characterizes the relationship between a substance in the supplement to a "disease or a health-related condition" (section 403(r)(1)(B) of the act: § 101.14(a)(1)). The phrase "disease or health-related condition" was defined in those regulations as:

damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition * * *. Section 101.14(a)(5) (formerly § 101.14(a)(6)). The definition was redesignated as § 101.14(a)(5) effective March 23, 1999 (see 62 FR 49859, 49867).

FDA tentatively concluded that it did not want to retain the older health claims definition because its use of the term "damage" could be interpreted to limit the definition to serious or long-term diseases, and could imply that there needed to be pathological evidence of damage, which is not always present. For example, most mental illnesses have no evidence of anatomic damage, yet are clearly diseases.

In the July 8, 1999, Federal Register notice announcing a public meeting and reopening the comment period, FDA requested additional comment on the definition of disease. The notice listed four questions on which it sought specific comment: (1) What are the consequences, with respect to the range of acceptable structure/function claims, of adopting: (a) The 1993 definition in § 101.14(a)(5), or (b) the definition in the proposed rule? (2) If FDA were to retain the 1993 definition, does the reference to "damage" exclude any conditions that are medically understood to be diseases? Please provide examples. (3) If

it does not exclude any such conditions, is the 1993 definition otherwise consistent with current medical definitions of disease? (4) If it does exclude conditions that are medically understood to be diseases, could it be revised in a way that would include such conditions?

(22.) Almost all of the comments from the dietary supplement industry and from individuals objected to the new definition of disease. Most of these comments argued that the new definition is too broad, sweeping in many minor deviations or abnormalities that are not diseases. (Many of these comments did not appear to have understood that the definition required not only a deviation, but one that "is manifested by a characteristic set of one or more signs or symptoms.") One comment said that under the new definition wrinkles and gray hair would qualify as diseases. Some comments objected to the fact that the proposed definition was not limited to adverse deviations from normal structure or function. Other comments argued that the breadth of the proposed definition is inconsistent with the intent of DSHEA. Some comments objected to the distinction between normal and abnormal functions, and argued that Congress did not intend to limit structure/function claims to normal structure or function. Some comments contended that the definition of disease should not include the phrase "structure or function." Other comments said that Congress should be presumed to have been aware of the 1993 definition of "disease or health-related condition" and to have intended FDA to use that definition. Several comments argued that the new definition of "disease or health-related condition" for health claims would inappropriately broaden the scope of health claims for conventional foods and concomitantly narrow the scope of acceptable structure/function claims for foods. One comment said that redefining "disease or health-related condition" in § 101.14(a)(5) would undermine the existing definition of "statement of nutritional support," and would violate DSHEA and the First Amendment. Most of the comments from the dietary supplement industry and from individuals recommended that FDA return to the 1993 definition.

Most of the comments from health professional groups and groups devoted to specific diseases, including those who participated in the August 4, 1999, public meeting, supported the new definition of disease as more consistent with a medical understanding of disease than the NLEA definition. Some of these

comments criticized the 1993 definition because of its reliance on "damage" and dysfunction and because of its failure to refer to signs and symptoms. While many comments from the dietary supplement industry said that no recognized diseases would be excluded by requiring evidence of "damage," comments from health professionals pointed out a number of recognized disease conditions for which it is not currently possible to identify physical damage to an organ, part, or system of the body, including most psychiatric diseases (depression, bipolar disorder, schizophrenia, and obsessive compulsive disorder, among others), and the early stages of certain metabolic diseases, including diabetes, genetic diseases, and nutritional deficiency diseases.

A few comments offered alternative definitions of disease. A major medical association contended that the proposed definition would be improved by the addition of the phrase "or a state of health leading to such deviation, impairment, or interruption." An OTC drug and dietary supplement trade association offered the following alternative definition of disease, which would modify the proposed definition:

A disease is any adverse deviation from, or impairment of, or interruption of the normal structure or function of any part, organ, or system (or combination thereof) of the body that is manifested by a characteristic set of one or more signs or symptoms that are not characteristic of a natural state or process. According to this comment, the addition of the word "adverse" appropriately narrows the nature of the deviation, "laboratory or clinical measurements" are appropriately deleted because they are already included under the concept of "signs," and the exclusion of natural states "encompasses Congress' intent to allow health promotion/maintenance claims." One comment suggested that, if FDA were to retain the 1993 definition, it add the word "impairment" after "damage" to cover those recognized disease conditions for which evidence of damage is missing. A pharmaceutical trade association urged FDA to convene a small workshop of physicians, patients, and other stakeholders to develop a consensus on the distinction between disease claims and structure/function claims.

In response to the comments, FDA has reconsidered the proposed definition of disease in § 101.93(g)(1), and has concluded that it is not necessary to change the 1993 health claims definition, because it can be construed in a manner that covers conditions that are medically understood to be diseases. In light of Congress' desire to increase

the number of claims that could be made for dietary supplements without subjecting them to drug regulation, FDA is persuaded that it is therefore appropriate to retain a narrower definition of disease at this time.

FDA has concluded that the older health claims definition, read as a whole, will not exclude any significant conditions that are medically understood to be diseases. For example, the requirement of "damage to an organ, part, structure, or system of the body such that it does not function properly" indicates that a condition may be considered a disease if there is direct evidence of structural damage to an organ, part, structure, or system of the body, or indirect evidence of damage, indicated by the failure of the organ, part, structure, or system of the body to function properly. This interpretation is appropriate because otherwise well-recognized psychiatric diseases, migraine headaches, hypertension, blood lipid disorders, and many other well-accepted diseases, could be excluded from coverage due to the lack of direct evidence of physical damage. The reference to "a state of health leading to such dysfunctioning" also permits the agency to look at evidence other than actual damage to an organ, part, structure, or system of the body.

FDA does not believe that it would be constructive to defer a decision on the definition of disease and seek a "consensus" of stakeholders. The agency believes that it is unlikely that diverse, strongly-held views expressed in written comments and at the public hearing could be forged into a consensus on this issue. FDA also believes that it is important to reach a decision as soon as possible to permit the issuance of clear, uniform rules that will apply to all dietary supplement labeling.

Accordingly, the final rule does not include a new definition of disease, but incorporates the definition of "disease or health-related condition" in § 101.14(a)(5). If experience shows a public health need for a different or broader definition, however, FDA will consider initiating a rulemaking to amend that definition.

(23.) One comment argued that it is unnecessary for FDA to define disease at all, but that the agency should use a "common sense" approach to distinguishing structure/function claims from disease claims. According to this comment, dietary supplements should be allowed to make any claim that does not contain express references "to specific diseases * * * or which can only be reasonably interpreted to refer

to a specific disease (e.g., 'helps prevent tumors')."

FDA does not agree that a definition of disease is unnecessary. The comment that made this argument went on to use the term disease in its "common sense" principle, apparently assuming that there is some common sense understanding of the term. FDA is not aware of any common sense understanding of "disease," and the diversity of comments received in this rulemaking on the appropriate definition of disease supports FDA's view that a definition is needed if FDA is to enforce section 403(r)(6) of the act fairly and consistently.

(24.) One comment argued that any definition of disease should exclude symptoms or diseases that do not normally require a drug or doctor's care because these states could be considered part of "normal" living.

FDA does not agree that DSHEA was intended to permit structure/function claims about diseases that can normally be treated without a physician's care. Nothing in the statute or its legislative history suggests that Congress intended to accord different treatment to this subset of diseases. Diseases that do not ordinarily require a physician's care are generally those for which drugs may be sold over OTC. (OTC drug claims include both disease claims and structure/function claims.) Drugs carrying OTC claims are already regulated under rules different from those applicable to prescription drugs. FDA has undertaken a comprehensive review of OTC drug claims and published monographs on these claims. Had Congress intended to permit dietary supplements to make all OTC claims (both disease claims and structure/function claims) without prior review, it could easily have so indicated. Because Congress did not do so, FDA does not believe that there is support for treating this subset of diseases differently from other diseases. As discussed elsewhere in this document, the structure/function claims made for OTC drugs also may be made, in appropriate circumstances, for dietary supplements under section 403(r)(6) of the act.

(25.) One comment argued that it was irrelevant whether the 1993 definition excluded conditions that were medically understood to be diseases. According to this comment, the definition of disease should be based on consumer understanding rather than medical understanding, because DSHEA was intended to educate consumers.

FDA does not agree that its interpretation of a medical term like "disease" should ignore medical definitions of the term, unless there is

clear guidance from Congress that it intended a nonmedical definition of the term. In any case, the comment provided no argument or evidence that the 1993 definition was based on, or reflects, consumer understanding of the term "disease."

D. Disease Claims (§ 101.93(g)(2))

(26.) Many comments agreed with the statement in proposed § 101.93(g)(2) that, in determining whether a statement is a disease claim, it is appropriate to consider the context in which the claim is presented. One comment argued, however, that language of the regulation and preamble showed that FDA was biased because the agency would only consider the context of a claim to convert a dietary supplement to a drug.

FDA does not agree that it will consider context only to convert an otherwise acceptable structure/function claim to a disease claim. The context in which a claim appears can provide evidence in either direction.

(27.) One comment argued that the rule should have only the following three criteria: (1) The words "diagnose," "prevent," "treat," "cure," and "mitigate" should not be used in a structure/function claim; (2) the words "stimulate," "maintain," "support," "regulate," and "promote"—or other similar words—may be used in a structure/function claim to distinguish the claim from a specific disease claim; and (3) clinical endpoints that are recognizable to health professionals or consumers as being related to a disease may be used in a structure/function claim.

FDA does not believe that the three suggested criteria provide a sufficient basis to distinguish between structure/function claims and disease claims. Nothing in these criteria would prevent a structure/function claim from discussing a specific disease, explicitly or implicitly, as long as the claim did not contain the specific verbs "diagnose," "prevent," "treat," "cure," or "mitigate."

(28.) Several comments from medical and consumer groups supported the establishment of criteria for structure/function claims, but were concerned that the criteria in the proposed rule were too vague and would fail to protect consumers from misleading claims. A major medical association contended that some of the structure/function claims listed as acceptable in the proposal were debatable and expressed doubt that the public health would be adequately protected. Some of these comments expressed the view that some of the structure/function claims listed in

the proposal in fact imply disease prevention. For example, some of these comments argued that health maintenance claims imply disease prevention. On the other hand, a comment from a major dietary supplement trade association argued that the overall impact of the criteria restricts the value of structure/function claims in providing consumers with useful information about dietary supplements.

FDA agrees that consumers should have access to, and be allowed to evaluate for themselves, as much truthful information about dietary supplements as is possible, consistent with the statutory restrictions on disease treatment and prevention claims. FDA believes that the criteria in this rule strike a reasonable balance between these competing goals. Undoubtedly, the criteria will not satisfy everyone. For example, some of the claims considered to be structure/function claims may imply specific disease prevention to some consumers. Because of the importance of the context in which a claim is presented, it will not always be possible to draw a line between structure/function and disease claims in this rule with great specificity. FDA believes that, within these constraints, the criteria, as finalized, adequately distinguish between structure/function claims and disease claims. In developing final criteria, the agency has tried to pay particularly close attention to claims that might relate to serious health conditions that patients cannot safely evaluate on their own. The question of whether health maintenance claims necessarily imply disease prevention is discussed in more detail below.

(29.) One comment, from a Commission member, said the "dietary relationship" of a structure/function claim is relevant in considering whether such a claim is appropriate. The comment said that statements for dietary ingredients should "relate to the role of the dietary ingredient in the diet in achieving effects like those associated with the effects of foods." The comment added that the claim "should be for an effect that is similar to the non-disease effects of a food on the body" and "phrased to indicate the role of the dietary ingredient in the diet in maintaining or supporting the ordinary functioning of the body in a manner similar to that achieved through foods." Thus, the comment would consider a claim such as "promotes relaxation" to be appropriate "only if it is indicated to be similar to the effects achieved from foods, such as by indicating that it provides a relaxing calming effect like a

cup of tea." While the preamble to the proposed rule considered the claim of "improves absentmindedness" to be a structure/function claim, the comment viewed the same claim as a disease claim "because of the association of absentmindedness with Alzheimer's disease." The comment continued, "That claim should not be permissible for the same reason that a claim that a dietary supplement is an 'oral contraceptive' is not permissible—the claim is simply not one for the effects of a dietary ingredient."

FDA agrees that dietary supplements must be "intended to supplement the diet" (section 201(ff) of the act). In interpreting section 403(r)(6) of the act, however, FDA believes that it is appropriate to focus on the claims made for the product. Unlike section 201(g)(1)(C) of the act, section 403(r)(6) of the act does not limit authorization to make structure/function claims (without triggering drug approval requirements) to substances that are "food." FDA notes that it is developing an overall dietary supplement strategy and will, when a document incorporating the strategy is released, state how the agency plans to address the requirement that dietary supplements be "intended to supplement the diet."

(30.) One comment said FDA should develop a list of "acceptable subclinical, pre-disease, and normal states" that may be used in structure/function claims.

FDA declines to adopt the comment's suggestion. However, this rule contains many examples of acceptable structure/function claims and FDA intends to issue further guidance listing acceptable claims.

(31.) One comment argued that all statements about effects on structure or function should be deemed permissible unless they are already approved drug claims. The comment noted that "reduces joint pain" and "relieves headache" would not be structure/function claims because they are OTC monograph claims.

FDA does not agree that such a criterion would appropriately discriminate between structure/function claims and disease claims. One kind of valid drug claim is a claim related to the effect of the product on the structure or function of the body (section 201(g)(1)(C) of the act) but not related to disease prevention or treatment. In other words, not all drug claims are disease claims. Congress specifically provided that structure/function claims authorized by section 403(r)(6) of the act do not, in themselves, subject a dietary supplement to regulation as a drug under 201(g)(1)(C) of the act. It thus would not be appropriate to exclude

from the scope of acceptable structure/function claims OTC monograph claims or other approved claims for products classified as drugs under section 201(g)(1)(C) of the act.

(32.) A national pharmacy group stated that the examples of structure/function and disease claims in the proposal were reasonable and based on good science and logic, but should be evaluated and revised as necessary over time.

FDA agrees that it will be necessary to evaluate the examples over time and to revise them as experience dictates.

(33.) Some comments argued that the types of claims permitted under the proposal may discourage serious approaches to substantiation because the terms used are not scientifically verifiable. Stating that the preferred method of substantiation is an adequate and well-controlled trial, one comment contended that the claims permitted under the rule are not amenable to such proof. According to this comment, this rule may preclude companies from meeting the substantiation rules of the Federal Trade Commission (FTC). A few comments said that manufacturers cannot substantiate claims that a product maintains healthy status. One of these comments stated that it was impossible to show by adequate studies that "cranberry extract supports healthy urinary tract functioning," and that companies should instead be able to show that cranberry extract reduces frequency of urinary tract infections in susceptible people. Similarly, because it is "impossible" to test whether St. John's Wort "supports mood" in the general population, companies need to be able to test its effect on depressed people.

FDA agrees that some structure/function claims that are acceptable under DSHEA may be difficult to substantiate. For example, some structure/function claims currently in the marketplace use terms that do not have clear scientific meaning. Other claims concern health maintenance in the general population and therefore could require studies in a large population for substantiation. FDA believes, however, that such claims are within the intended scope of section 403(r)(6) of the act. Difficulty in substantiating them does not alter the terms of the statute. Manufacturers are responsible for determining whether claims for their products can be appropriately substantiated, and to use only those claims for which they have substantiation. FDA does not agree that difficulty in substantiating a particular claim justifies the use of express or implied disease claims for which

methods of substantiation may be more straightforward. Such an approach would turn section 403(r)(6) of the act on its head.

FDA also does not agree that it is impossible to substantiate the claims described in the comments. For example, to substantiate the claim "supports mood," it is not necessary to study the effects of a substance on clinical depression. Instead, it is quite possible to assess the effects of a substance on mood changes that do not constitute clinical depression.

E. Effect on Disease or Class of Diseases (§ 101.93(g)(2)(i))

Under proposed § 101.93(g)(2)(i), a statement would be considered a disease claim if it explicitly or implicitly claimed an effect on a specific disease or class of diseases. FDA included the following examples of such disease claims: "Protective against the development of cancer," "reduces the pain and stiffness associated with arthritis," "decreases the effects of alcohol intoxication," or "alleviates constipation." FDA included the following examples of claims that do not refer explicitly or implicitly to an effect on a specific disease state: "Helps promote urinary tract health," "helps maintain cardiovascular function and a healthy circulatory system," "helps maintain intestinal flora," and "promotes relaxation." FDA proposed to treat both express and implied disease claims as disease claims that could not be made for dietary supplements without prior review either as health claims or as drug claims. Implied disease claims do not mention the name of a specific disease, but refer to identifiable characteristics of a disease from which the disease itself may be inferred. There are many possible ways to imply treatment or prevention of disease, from listing the characteristic signs and symptoms of the disease to providing images of people suffering from the disease. Nine of the 10 criteria proposed by FDA for identifying disease claims could be considered methods of implying disease treatment or prevention.

In the July 8, 1999, Federal Register notice announcing a public meeting and reopening the comment period, FDA sought additional comment on the applicability of the rule to implied disease claims. The discussion in the notice offered three examples of possible implied disease claims: (1) "shrinks tumors of the lung" or "prevents development of malignant tumors" ("treats cancer" would be the corresponding express claim); (2) "prevention of seizures" ("treatment of

epilepsy" would be the corresponding express claim); (3) "relief of sneezing, runny nose, and itchy watery eyes caused by exposure to pollen or other allergens" ("treatment of hayfever" would be the corresponding express claim). The notice listed four questions related to implied disease claims on which the agency sought specific comments: (1) If implied disease claims should be permitted, has FDA correctly drawn the line between what constitutes an express disease claim and what constitutes a permitted implied claim? (2) If such claims should be permitted, what are representative examples of the types of implied disease claims that should be permitted without prior review? (3) Are the examples of implied claims mentioned in the July 8 notice appropriate structure/function claims? (4) Is a claim that a product "maintains healthy function" an implied disease claim in all cases? If not, under what circumstances is such a claim not an implied disease claim?

(34.) Many comments agreed with proposed § 101.93(g)(2)(i) that structure/function statements should not explicitly or implicitly mention specific diseases or class of diseases. These comments contended that consumers cannot distinguish between implied and express disease claims and that permitting implied disease claims poses significant dangers to consumers with diseases. According to these comments, permitting implied disease claims on dietary supplements may cause consumers to delay or forego effective treatment for serious diseases without assurance that the dietary supplement that has been substituted is safe or effective for the disease. Some comments also argued that permitting implied disease claims on dietary supplements will undermine the drug approval process by permitting dietary supplement manufacturers to market products for essentially the same indications for which pharmaceutical companies have spent millions of dollars obtaining approval.

Many other comments objected to treating implied disease claims as disease claims, arguing that dietary supplements should be allowed to carry any truthful claim that does not explicitly refer to a specific disease. Some comments argued that Congress intended consumers to have access to as much information about supplements as possible. Other comments contended that barring implied disease claims eliminates any meaningful claims for dietary supplements. Other comments argued that treating implied claims as disease claims gives FDA "unlimited discretion" to treat structure/function

claims as disease claims. Some comments, however, agreed that disease claims may be implied as well as express, and said that it is appropriate to consider a structure/function statement in context to determine whether it conveys a disease claim.

FDA continues to believe that structure/function claims should not imply disease treatment or prevention. Most disease treatment or prevention claims, including claims about serious and life-threatening diseases, can be described in a manner that will be easily understood by consumers without express reference to a specific disease. The following examples of implied disease claims demonstrate that it is not difficult to convey prevention or treatment of a specific disease or class of diseases without actually mentioning the name of the disease, which are given in parentheses: "Relieves crushing chest pain" (angina or heart attack), "prevents bone fragility in post-menopausal women" (osteoporosis), "improves joint mobility and reduces joint inflammation and pain" (rheumatoid arthritis), "heals stomach or duodenal lesions and bleeding" (ulcers), "anticonvulsant" (epilepsy), "relief of bronchospasm" (asthma), "prevents wasting in persons with weakened immune systems" (AIDS) (acquired immune deficiency syndrome), "prevents irregular heartbeat" (arrhythmias), "controls blood sugar in persons with insufficient insulin" (diabetes), "prevents the spread of neoplastic cells" (prevention of cancer metastases); "antibiotic" (infections), "herbal Prozac" (depression). The distinction between implied and express disease claims is thus, in many cases, a semantic one that has little, if any, practical meaning to consumers. The argument that Congress intended to encourage the free flow of information about dietary supplements and therefore intended to permit implied disease claims is illogical. If Congress wanted to ensure that consumers receive information about how these products can treat or prevent diseases, it is difficult to imagine why it would have specifically denied the right to make such claims expressly, and allowed manufacturers to make the claims only by implication.

There are also serious public health questions raised by implied disease claims. Treatment and prevention of disease are serious matters, and the statute reflects a congressional judgment that consumers deserve to have claims for such uses reviewed by experts for proof of safety and effectiveness. In addition, permitting dietary supplement manufacturers to make implied disease claims without prior review would

allow them to compete unfairly with prescription and OTC drugs, which are required to establish their safety and effectiveness for disease treatment and prevention before being marketed. Pharmaceutical manufacturers, faced with this competition, might be less likely to undertake future research and development, compromising one of the nation's most important sources of therapeutic advances. Had Congress intended to allow implied disease claims when it authorized dietary supplement manufacturers to make structure/function claims without prior review, it could easily have made clear its intention through express statutory language or legislative history. As discussed below, Congress did not do so.

FDA does not agree that the final rule eliminates all meaningful claims for dietary supplements. FDA believes that there are many meaningful structure/function claims that can be made without implying disease treatment or prevention, and has listed a number of such claims in this preamble.

FDA does not agree that treating implied claims as disease claims gives the agency unfettered discretion to treat all structure/function claims as disease claims. The purpose of this rule is to clarify which claims are structure/function claims permitted under section 403(r)(6) of the act and which are disease claims. Both in the proposed rule and in this final rule, FDA has provided many examples of specific claims that would be acceptable structure/function claims.

(35.) Many comments pointed to three provisions of DSHEA as evidence that Congress intended to include implied disease claims among structure/function claims permitted under section 403(r)(6) of the act. First, the "Findings" section of DSHEA refers to the relationship between dietary supplements and disease prevention. Many comments argued that Congress would not have made statutory findings linking dietary supplements to disease prevention if it intended that FDA could prohibit such references.

Second, section 403(r)(6) of the act states that structure/function statements may not "claim" to treat or prevent disease, and, according to the comments, this term should be read to refer only to express claims. Some comments noted that section 403(r)(6) of the act does not use the word "implied" to qualify the term "claims," and contrasted the language of the drug definition in section 201(g)(1)(B) of the act ("articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease") with the

language of section 403(r)(6)(C) of the act, which states that a structure/function statement may not "claim" to diagnose, cure, mitigate, treat, or prevent disease. One comment agreed with the proposal's statement that while DSHEA authorizes structure/function claims that are not also disease claims, but nevertheless asserted that the statute authorizes structure/function claims that imply "some protection against disease." This comment reasoned that the act, as amended by DSHEA, allows dietary supplements to be "intended" to affect the structure or function of the body, provided that the product does not "expressly claim to prevent, etc. disease" (emphasis in original) and the product bears "an express, formal disclaimer of an intent to prevent, etc. disease." The comment also said that the Commission report only referred to express claims.

Third, DSHEA requires structure/function claims to be accompanied by a disclaimer that reads, in part: "[T]his product is not intended to diagnose, treat, cure, or prevent any disease." According to some comments, Congress understood that specific disease treatment or prevention effects can also be described as effects on the structure or function of the body, and resolved the tension by requiring the disclaimer. In contrast, however, another comment argued that the drug definition in section 201(g)(1)(B) of the act still applies to dietary supplements because the exemption for dietary supplements added to section 201(g)(1) applies only to the structure/function definition in section 201(g)(1)(C). Many comments argued generally that DSHEA was intended to promote the free flow of truthful information about dietary supplements, and that prohibiting implied disease claims is contrary to this legislative goal.

FDA does not agree that DSHEA authorizes dietary supplement manufacturers to make implied disease claims without prior review of the claims. There is no express provision of DSHEA that authorizes implied disease claims, and a construction of DSHEA that permitted such claims would be fundamentally incompatible with important provisions of the act that were squarely before Congress when it passed DSHEA, including the definitions of "drug" and "new drug" and the health claims provisions of NLEA.

As described above, Congress created a partial exemption for dietary supplements from the definition of drug in section 201(g)(1)(C) of the act by providing that truthful and non-misleading claims under section

403(r)(6) of the act do not in themselves trigger drug regulation. Congress did not, however, create any exemption from section 201(g)(1)(B) of the act for dietary supplements. Thus, dietary supplements that are "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" are subject to regulation as drugs under the act. It has been FDA's longstanding interpretation of section 201(g)(1)(B) of the act that the phrase "intended for use" refers to the objective intent of the manufacturer, which is not limited to a manufacturer's express representations. See § 201.128 (21 CFR 201.128); *NNFA v. Weinberger*, 557 F.2d 325, 334 (2d Cir. 1977) ("the FDA is not bound by the manufacturer's subjective claims of intent," but may establish intent "on the basis of objective evidence"). Evidence of objective intent can come from a variety of sources, and may include both implied and express claims (*United States v. Undetermined Quantities * * * Pets Smellfree*, 22 F.3d 235 (10th Cir. 1994); *United States v. Storage Spaces Designated Nos. "8" and "49"*, 777 F.2d 1363, 1366 (9th Cir. 1985) ("intent may be derived or inferred from labeling, promotional material, advertising, or any other relevant source"), *cert. denied*, 479 U.S. 1086 (1987); *United States v. Kasz Enterprises, Inc.* 855 F. Supp. 534, 539, 543-44 (D.R.I. 1994), *modified on other grounds*, 862 F. Supp. 717 (D.R.I. 1994); *United States v. Articles of Drug * * * Neptone*, 568 F. Supp. 1182 (N.D. Ca. 1983); *United States v. * * * Vitasafe*, 226 F. Supp. 266 (D.N.J. 1964); *United States v. 14 105 Pound Bags * * * Mineral Compound*, 118 F. Supp. 837 (D.C. Idaho 1953); *United States v. 43 1/2 Gross Rubber Prophylactics*, 65 F. Supp. 534, 535 (D. Minn. 1946), *aff'd sub nom. Gellman v. United States*, 159 F.2d 881 (8th Cir. 1947); 59 FR 6084, 6088 (February 9, 1994) (terms "antibacterial," "antimicrobial," "antiseptic," or "kills germs" constitute implied drug claims that cause products carrying them to be drugs); 58 FR 47611, 47612 (September 9, 1993) (labeling indicating that "hormones" are present in a product constitutes implied drug claim); 58 FR 28194, 28204 (May 12, 1993) (products carrying term "sunscreen" are drugs because "sunscreen" implies disease prevention, even if not expressly promoted for prevention of skin cancer)).

Thus, interpreting section 403(r)(6) of the act as permitting implied disease claims would be irreconcilable with FDA's longstanding interpretation of section 201(g)(1)(B) of the act, which treats such claims as drug claims.

Permitting implied disease claims as structure/function claims would also conflict with the health claims scheme established in section 403(r)(1) through (r)(1)(5) of the act, which requires food and dietary supplement manufacturers to obtain health claim authorization before making a claim "which expressly or by implication" characterizes the relationship of a nutrient to a disease or health-related condition. Under this provision, a claim that characterized, by implication, the relationship between a dietary supplement ingredient and a disease would require authorization as a health claim. Interpreting section 403(r)(6) of the act as permitting the same implied claim without authorization of a health claim directly conflicts with 403(r)(1) through (r)(1)(5) of the act.

None of the statutory provisions relied on by the comments provides persuasive support for the conclusion that structure/function claims can imply disease treatment or prevention.

FDA agrees that the Findings section of DSHEA includes statements linking dietary supplements and disease prevention. However, in addition to the types of claims authorized for dietary supplements in section 403(r)(6) of the act, the act specifically authorizes dietary supplements to bear health claims. Health claims are expressly described in the statute as claims that characterize the link between a nutrient and a disease or health-related condition (section 403(r)(1)(B) of the act). The statements in the "Findings" section of the DSHEA are entirely consistent with this scheme and do not compel the conclusion that claims linking dietary supplements and disease prevention may be made as structure/function claims.

The use of the word "claim" rather than "intended for use" in section 403(r)(6) of the act also does not show that Congress intended to permit implied disease claims. First, the comment cites no authority, and FDA is aware of none, for the proposition that the meaning of the word "claim" is limited to "express claim." More importantly, section 403(r)(6) of the act does not stand by itself. As Congress recognized when it provided that dietary supplements making appropriate claims under section 403(r)(6) of the act do not thereby become drugs under section 201(g)(1)(C) of the act, section 403(r)(6) must be read in conjunction with section 201(g)(1). As described above, section 201(g)(1)(B) of the act continues to apply to dietary supplements and treats them as drugs if they are "intended for use in the diagnosis, cure, mitigation, treatment, or

prevention of disease." FDA has interpreted section 201(g)(1)(B) of the act to cover both express and implied claims for more than 50 years. Had Congress intended 403(r)(6) of the act to permit any claims covered by section 201(g)(1)(B) of the act, it would have had to provide an exemption from the latter section.

Further, FDA does not agree that the Commission report referred only to express claims. In its guidance on statements under section 403(r)(6) of the act, the Commission specifically said that such statements "should be distinct from NLEA health claims in that they do not state or imply a link between a supplement and prevention of a specific disease or health-related condition" (the report, p. 38) (emphasis added). In addition, the Commission cautioned that claims using terms such as, e.g., "support," "maintain," or "promote" are appropriate only if they do not "suggest disease prevention or treatment or use for a serious health condition that is beyond the ability of the consumer to evaluate" (the report, p. 38) (emphasis added). Clearly, the Commission was concerned about implied claims as well as express claims.

FDA also does not agree that the required disclaimer demonstrates an intention to permit implied claims. To the contrary, FDA believes that the disclaimer language ("This product is not intended to diagnose, treat, cure, or prevent any disease"), which is virtually identical to the language of section 201(g)(1)(B) of the act, provides further evidence that Congress did not intend section 403(r)(6) of the act to overlap section 201(g)(1)(B) claims. As a practical matter, it is unreasonable to interpret section 403(r)(6) of the act as inviting a communication to consumers like the following: "This product prevents bone fractures in postmenopausal women due to bone loss. This product is not intended to diagnose, treat, cure, or prevent any disease." The comments suggested that the addition of the disclaimer would somehow clarify the product's purpose to consumers. The comments provided no support, however, for their view that consumers reading the disclaimer would interpret it as eliminating implications in the remainder of the labeling that the product treats or prevents disease. FDA believes that the two statements simply contradict one another and could confuse consumers. Indeed, FDA is concerned that juxtaposing two such contradictory statements is likely to cause consumers to ignore the disclaimer required by section 403(r)(6) of the act, undermining its effectiveness.

(36.) A few comments addressed the examples of implied claims listed in the July 8, 1999, **Federal Register** notice. Some comments said that all of the examples were appropriate structure/function claims. Two comments suggested that "shrinks tumors," "prevents development of malignant tumors," and "prevents seizures" are express disease claims because they employ "synonyms" for specific diseases. According to these comments, "tumor" is a synonym for cancer, and "seizure" is a synonym for epilepsy. Another comment said that FDA should treat as implied disease claims only those claims "where there is a direct causal relationship between the structure/function parameter identified in the claim and a specific known disease." According to this comment, a tumor is a "direct manifestation of cancer" and therefore reference to a tumor is a disease claim. In contrast, risk factors for disease, in which the comment includes elevated cholesterol, are not direct manifestations of a disease, and therefore may be the subject of structure/function claims. Another comment contended that disease claims should be limited to express claims and to terms or measurements that are "surrogates for the disease itself." According to this comment, tumors are a surrogate for cancer, but elevated cholesterol is not a surrogate for heart disease. One comment argued that "relief of sneezing, runny nose, and itchy watery eyes caused by exposure to pollen or other allergens" is an acceptable structure/function claim, but did not explain why.

FDA has considered these comments, but does not believe that any of them have provided a principle that distinguishes between claims that consumers will understand as disease claims and those that will not be understood as disease claims. According to the comments, some of the claims that FDA offered as examples of implied disease claims should not be allowed as structure/function claims. FDA agrees that claims that refer to synonyms for disease, direct manifestations of disease, and surrogates for disease are disease claims. Each of these principles, however, would permit many types of implied disease claims that would be clearly understood by consumers as disease claims, e.g., "Herbal Prozac" and "antibiotic."

(37.) Some comments argued that it is impossible to construct a structure/function claim that does not imply disease prevention or treatment. Several of these comments claimed that health promotion claims inevitably imply disease prevention.

FDA does not agree that every structure/function claim implies disease prevention or treatment. In the proposed rule, FDA provided examples of many types of claims that the agency would not consider implied disease claims, and has expanded that list in the final rule.

(38.) Some comments disagreed with FDA's examples of disease claims in the proposed rule. These comments stated that intoxication and constipation are not in and of themselves diseases, and that these conditions are not readily understood by consumers as diseases. A few comments argued that alcohol intoxication is a "self-induced condition" and not a disease.

FDA continues to believe that alcohol intoxication, like all poisonings (mushroom, digitalis, or any drug overdose), meets the definition of disease, albeit a transient disease. The definition in § 101.14(a)(5), which FDA is incorporating in this rule, states, in part, that a disease is "damage to an organ, part or structure, or system of the body such that it does not function properly * * *". All poisonings, like alcohol intoxication, cause dose-related dysfunctioning and damage, ranging from mild impairments to death. Alcohol intoxication causes temporary damage to brain function, causing impairments of judgment, attention, reflexes, and coordination. The fact that it is "self-induced" does not remove it from the definition of disease. Deliberate barbiturate overdoses are also self-induced, but clearly meet the definition of disease.

FDA has considered the comments on constipation and agrees that certain constipation claims should not be treated as disease claims. Constipation has a variety of causes, many of them unrelated to disease. For example, constipation can be caused by changes in diet and schedule, and by travel. Constipation can also, however, be a symptom of such serious diseases as bowel obstruction and irritable bowel syndrome. FDA is aware that there may be differences of opinion about whether occasional constipation, alone, constitutes a disease, but believes that treating it as a disease would not be consistent with the intent of DSHEA. "For relief of occasional constipation" would therefore not be considered a disease claim under the rule. The labeling of a product that claimed to treat occasional constipation should make clear, however, that the product is not intended to be used to treat chronic constipation, which may be a symptom of a serious disease.

(39.) One comment questioned whether a claim that begins, "According

to the National Cancer Institute" would be a disease claim because it used the word "cancer."

Although the National Cancer Institute (NCI) is associated with the treatment and prevention of cancer, such a statement will be considered a disease claim only if, within the context of the total labeling, the statement can be reasonably understood to relate the product to the disease listed in the organization's name, e.g., cancer. For example, FDA would regard as a disease claim "According to the National Cancer Institute, ingredient X protects smokers' lungs."

F. Signs or Symptoms of Disease (§ 101.93(g)(2)(ii))

Under proposed § 101.93(g)(2)(ii), a statement would be considered a disease claim if it explicitly or implicitly claimed an effect (using scientific or lay terminology) on one or more signs or symptoms that are recognizable to health care professionals or consumers as being characteristic of a specific disease or of a number of diseases. FDA provided as examples of such disease claims: "Improves urine flow in men over 50 years old," "lowers cholesterol," "reduces joint pain," and "relieves headache." Stating that claims of an effect on symptoms that are not recognizable as characteristic of a specific disease or diseases would not constitute disease claims, FDA provided the following examples of acceptable structure/function claims: "Reduces stress and frustration," "inhibits platelet aggregation," and "improves absentmindedness." The agency also stated that if the context did not suggest treatment or prevention of a disease, a claim that a substance helps maintain normal function would not ordinarily be a disease claim. Examples included: "Helps maintain a healthy cholesterol level," or "helps maintain regularity."

FDA specifically requested comment on the distinction between maintaining normal function, which is potentially the basis for an acceptable structure/function claim, and preventing or treating abnormal function, which is potentially a disease claim. FDA noted that the members of the Commission were divided on this issue, but that the final report concluded that "statements that mention a body system, organ, or function affected by the supplement using terms such as 'stimulate,' 'maintain,' 'support,' 'regulate,' or 'promote' can be appropriate when the statements do not suggest disease prevention or treatment or use for a serious health condition that is beyond the ability of the consumer to evaluate" (the report, p. 38). Recognizing that

claims relating to maintaining healthy cholesterol levels raise particularly difficult issues, FDA sought specific comment on these claims.

(40.) Many comments from manufacturers and individuals objected to proposed § 101.93(g)(2)(ii). Some of these comments argued that basing the criterion on which signs and symptoms were "recognizable" to health care professionals or consumers was too vague, and that it was unclear what proportion of health care professionals or consumers would be necessary to establish recognition. Some comments asked whether FDA expected manufacturers to conduct consumer surveys. Other comments urged that FDA itself conduct consumer surveys to determine which signs and symptoms were recognizable to consumers as implied disease claims. Other comments argued that the proposed provision would create a moving target because "as soon as consumers understood that certain signs and symptoms are characteristic of a disease—that is, as soon as consumers understood why they should take a particular supplement—FDA could *** prohibit a product label from bearing the substantive claims information."

FDA agrees with these comments that the proposal's focus on recognition of signs and symptoms by consumers or health professionals might have made the provision difficult to apply, both for manufacturers and for the agency. Accordingly, the agency has substituted a more objective criterion. The final rule eliminates the reference to recognition, and focuses simply on whether the labeling suggests that the product will produce a change in the characteristic signs or symptoms of a specific disease or class of diseases. FDA believes that it will be easier for manufacturers to verify whether symptoms are in fact characteristic of a disease. FDA and manufacturers may look to medical texts and other objective sources of information about disease to determine whether a label implies treatment or prevention of disease by listing the characteristic signs and symptoms of a disease or class of diseases.

FDA notes that the standard in the rule may be met if characteristic signs and symptoms are referred to either in technical or lay language. It also would not be necessary to mention every possible sign or symptom of a disease to meet this standard. Instead, the standard focuses on whether the labeling suggests that the product will produce a change in a set of one or more signs or symptoms that are characteristic of the disease.

FDA does not agree with the comment that objected to the recognition standard because it would prohibit a claim "as soon as consumers understood that certain signs and symptoms are characteristic of a disease—that is, as soon as consumers understood why they should take a particular supplement * * *." This comment assumes that the only reason people take dietary supplements is to treat or prevent disease and that it is appropriate to market supplements by implying that they can do so. Many people take dietary supplements for health-related reasons that do not involve treatment or prevention of specific diseases. As discussed elsewhere in this document, FDA does not believe that the act permits structure/function claims to imply treatment or prevention of specific diseases.

(41.) Several comments contended that the recognition standard was too restrictive because all signs or symptoms relating to the structure or function of the body are potentially recognizable to health care professionals and educated consumers as characteristic of some specific disease. Another comment argued that the proposal to treat references to signs and symptoms as disease claims was arbitrary and artificial. The comment said that specific examples of disease claims used in the proposal could as easily refer to nondisease states, e.g., "reduces joint pain" could refer to over-exercise. Conversely, "stress and frustration" could refer to anxiety and depression. Another comment contended that "reduces joint pain" is an acceptable structure/function claim if other language or graphics in the labeling clearly communicated treatment of conditions unrelated to arthritis. One comment asked whether "helps support cartilage and joint function" would constitute a permissible structure/function claim. Some comments said that references to signs and symptoms should not be evidence of a disease claim because signs and symptoms can be associated with a number of varying conditions. One comment claimed that "inhibits platelet aggregation" does not mean anything to most consumers. On the other hand, some medical groups, groups devoted to specific diseases, and others expressed concern that the examples of structure/function claims provided by FDA permitted references to signs or symptoms that imply disease treatment or prevention. According to one comment, "inhibits platelet aggregation" could be interpreted to mean "prevents heart attack," and

"improves absentmindedness" could be interpreted as a treatment for Alzheimer's disease.

FDA believes that removing the reference to recognition by consumers or health professionals from § 101.93(g)(2)(ii) will permit a clearer distinction between those signs and symptoms that imply a disease and those that do not. The focus will be on whether specific signs or symptoms are characteristic of a disease, based on objective sources. FDA does not believe that "improves absentmindedness" or "relieves stress and frustration" are characteristic of the specific diseases mentioned in the comments. FDA agrees that some signs and symptoms are associated with such a wide variety of diseases and nondisease states that they may not imply a specific disease or class of diseases. For example, FDA would not interpret "improves absentmindedness" as implying treatment of Alzheimer's disease because absentmindedness is not as serious as the type of memory loss characteristically suffered by Alzheimer's patients; absentmindedness is, in fact, suffered predominantly by people who do not have Alzheimer's disease or any other disease. Stress and frustration, while associated with some anxiety disorders, are not the characteristic symptoms of those disorders; in addition, these symptoms are equally associated with many other nondisease states.

The agency does agree, however, with the comment that "inhibits platelet aggregation" is an implied disease treatment or prevention claim. Although platelet aggregation is a normal function needed to maintain homeostasis, inhibiting or decreasing platelet aggregation is a well-recognized therapy for the prevention of stroke and recurrent heart attack (see, e.g., 63 FR 56802, October 23, 1998 (final rule for professional labeling of aspirin for cardiovascular, cerebrovascular, and rheumatologic uses); 53 FR 46204, November 16, 1988, (internal analgesic tentative final monograph)). Inhibiting or decreasing platelet aggregation is the mechanism of action of a number of drug products approved for the treatment or prevention of stroke and heart attack. Thus, the agency would consider a claim to inhibit normal platelet function to be an implied claim to treat or prevent these disease conditions.

FDA also believes that "joint pain" is characteristic of arthritis. According to the Merck Manual, joint tenderness is the most sensitive physical sign of rheumatoid arthritis (Ref. 6). The claim "helps support cartilage and joint

function," on the other hand, would be a permissible structure/function claim, because it relates to maintaining normal function rather than treating joint pain.

(42.) One comment suggested that claims about a physiologic marker or symptom should be regarded as disease claims in two situations: (1) If the physiologic marker or symptom of a disease is described as being quantifiably linked to that disease in an official government health agency summary statement or consensus report, or (2) if most clinicians treating patients with the condition prescribe prescription drugs to modify the marker and historically do so without including nutritional or dietary intervention as part of the treatment. According to this comment, references to cholesterol lowering or blood pressure reduction would be regarded as disease claims under the first suggested criterion, and white cell counts and fever would be disease claims under the second. This comment also suggested that FDA develop a list of disease markers and symptoms that fall under each of the proposed criteria.

FDA agrees in part and disagrees in part with this comment. The agency agrees that references in dietary supplement labeling to physiologic markers or symptoms of a disease that are quantifiably linked to that disease in an official government health agency summary statement or consensus report would be appropriately treated as implied disease claims. Indeed, in the cases described, elevated blood pressure (hypertension) and elevated cholesterol (hypercholesterolemia) are diseases themselves, with subsequent events (heart attack, stroke) the late consequences of those diseases. Although FDA agrees that fever and elevated white cell counts are almost always evidence of a disease, FDA does not agree that the second criterion appropriately describes the remaining circumstances in which references to signs or symptoms should be treated as disease claims. The appropriate test is whether: (1) The condition to be treated or prevented is a disease and (2) the signs and symptoms referred to in the labeling, in context, are characteristic of a disease and thus permit the inference that the product is intended to treat or prevent the disease. The second criterion offered by the comment does not provide information on either of these elements.

(43.) Some comments that objected to the proposed definition of disease argued that the inclusion of "signs or symptoms" as part of the definition of disease should not mean that a reference to the signs and symptoms of a disease

in dietary supplement labeling constitutes a disease claim. Another comment argued that because signs and symptoms do not appear in the definition of "drug," FDA is not authorized to treat a reference to characteristic signs and symptoms as a drug claim.

The health claims definition of "disease or health-related condition" in § 101.14(a)(5), which is being adopted as the definition of "disease" in this regulation, does not include reference to the signs and symptoms of disease. Nonetheless, dietary supplement labeling that refers to the characteristic signs or symptoms of a specific disease or class of diseases will still be considered to have made an implied disease claim. Labeling that claims a product "prevents bone fragility in postmenopausal women," clearly implies that the product prevents osteoporosis. Similarly, labeling that claims a product "prevents shortness of breath, an enlarged heart, inability to exercise, generalized weakness, and edema" has made a congestive heart failure claim.

The basis for determining whether such a reference to signs or symptoms constitutes an implied disease claim is not whether the definition of disease includes mention of signs or symptoms. Rather, FDA looks at whether the objective evidence shows that the product is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" within the meaning of section 201(g)(1)(B) of the act and § 201.128, or the claim constitutes a health claim within the meaning of section 403(r)(1)(B) of the act and § 101.14(a)(1). For example, § 201.128 provides that the objective intent of those responsible for the labeling of drugs "is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article." Section 101.14(a)(1) provides that "[i]mplied health claims include those statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition." Both of these provisions permit FDA to look at whether a reference to the characteristic signs or symptoms of a disease constitute an implied disease claim.

(44.) Many comments argued that the distinction between claims that a product maintains healthy function and that it prevents or treats abnormal function is artificial, and that consumers understand both types of claims as disease treatment or prevention claims.

Comments from dietary supplement manufacturers and some consumer groups argued that both types of claims should be permitted either because they are not implied disease claims or because implied disease claims are permissible. Conversely, most of the comments from health professional groups, groups devoted to specific diseases, pharmaceutical companies, and other consumer groups argued that neither type of claim should be permitted, because permitting implied disease claims to be made without prior review would jeopardize the public health by encouraging substitution of unproven remedies for proven ones. One comment argued that analysis of health maintenance claims is no different than analysis of any other structure/function claim: They are disease claims if they imply disease prevention or treatment. According to this comment, health maintenance claims are permissible unless they relate to endpoints that are understood to be disease markers, such as blood pressure and cholesterol. Comments from a former Commission member and from a consumer group argued that many health maintenance claims will be perceived as disease treatment or prevention claims, and urged that FDA follow the Commission's guidelines, under which the seriousness of the condition and the ability of the consumer to evaluate it are key factors in deciding whether a disease claim has been made. One comment argued that FDA may not prohibit a claim that a dietary supplement "maintains normal function" even if it implies a disease claim because 403(r)(6)(A) of the act expressly authorizes such claims.

One comment said that the proposed rule would frustrate the "orphan drug" process. The comment contended that if dietary supplement labeling may claim to promote or maintain "healthy" endpoints that are related to signs and symptoms of specific diseases, then incentives to conduct research on orphan drugs would be undermined. The comment explained that dietary supplements do not require the same financial investment as drugs do (because drugs must be approved as safe and effective for their intended uses and meet quality controls), and could undercut sales of a more heavily regulated and more expensive approved drug. The comment said that a dietary supplement manufacturer's ability to make a disease prevention claim by characterizing the product as promoting good health "cannot become a license to sell an active ingredient in a product

that is functionally a drug but is labeled as a dietary supplement.”

FDA has carefully considered these comments and has concluded that the distinction drawn in the proposal between maintaining normal function and treatment or prevention of abnormal function is supported by the statute and the Commission report. FDA does not agree that health maintenance claims must always be treated as implied disease claims. Section 403(r)(6)(A) of the act demonstrates that Congress intended to treat as structure/function claims some claims concerning maintenance of normal structure or function, because it expressly permits statements that “characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function.”

FDA also believes that many claims concerning the maintenance of “normal” or “healthy” structure or function do not imply disease prevention in the context of dietary supplement labeling, unless other statements or pictures in the labeling imply prevention of a specific disease or class of diseases. There may be cases, however, in which a statement of health maintenance can be understood only as a claim of prevention of a specific disease, in which case it will be considered a disease claim. Thus, any reference to “maintaining a tumor-free state” would be a disease claim. Similarly, a claim to “maintain normal bone density in post-menopausal women” is a disease claim because post-menopausal women characteristically develop osteoporosis, a disease whose principal sign is decreased bone mass.

FDA has added a sentence to § 101.93(g)(2) clarifying that the criteria in that paragraph are not intended to preclude structure/function claims that refer to the maintenance of healthy structure or function, unless they imply disease treatment or prevention.

For the reasons described elsewhere in this document, however, FDA does not believe that DSHEA permits claims concerning treatment or prevention of abnormal function, where such abnormal function implies a specific disease or class of diseases. Accordingly, FDA believes that the statutory scheme is consistent with treating many health maintenance statements as structure/function claims, while treating as health claims or new drug claims statements that imply disease treatment or prevention by reference to an effect on abnormal structure or function.

The Commission report also supports the distinction drawn by FDA between maintaining healthy function and

preventing or treating abnormal function. The report’s Guidance states:

4. Statements that mention a body system, organ, or function affected by the supplement using terms such as “stimulate,” “maintain,” “support,” “regulate,” or “promote” can be appropriate when the statements do not suggest disease prevention or treatment or use for a serious health condition that is beyond the ability of the consumer to evaluate.

5. Statements should not be made that products “restore” normal or “correct” abnormal function when the abnormality implies the presence of disease. An example might be a claim to “restore” normal blood pressure when the abnormality implies hypertension.

(Report at pp. 38 and 39.)

FDA agrees that if a health maintenance claim implies disease treatment or prevention, it would not be acceptable. (In FDA’s view, a claim promoting “use for a serious health condition that is beyond the ability of the consumer to evaluate” is simply one form of implied disease claim.) FDA believes that many health maintenance claims are acceptable. In some cases, a health maintenance claim could use terms that are so closely identified with a specific disease or that so clearly refer to a particular at-risk population that FDA would consider the claim to be an implied disease prevention claim, e.g., “maintains healthy lungs in smokers” would imply prevention of tobacco-related lung cancer and chronic lung disease. “Maintains healthy lung function,” alone, however, would be an acceptable structure/function claim.

In response to the comment contending that dietary supplements undercut sales of orphan drugs by making health promotion claims for active ingredients already approved as orphan drugs, FDA notes that section 201(ff)(3) of the act excludes from the definition of “dietary supplement” articles that have been approved as drugs or for which substantial clinical investigations conducted under an investigational new drug application (IND) have been made public, before they were marketed as dietary supplements or foods.

(45.) Many comments responded to FDA’s specific request for comment on whether it is appropriate to treat “maintains healthy cholesterol levels” as a permissible structure/function claim, while treating “lowers cholesterol” as a disease claim. A few comments supported the distinction drawn in the proposed rule. Many did not, however. One comment from a major trade association claimed that the distinction between lowering and maintaining cholesterol levels is ambiguous, asking “What is a healthy

cholesterol level, but a lower cholesterol level?” Another comment from a food industry group contended that “cholesterol” itself is a sign or symptom, and thus that both types of claims refer to a sign or symptom of disease. Several comments argued that lowering cholesterol is inextricably linked to cardiovascular disease. Some comments argued that the distinction between maintaining normal cholesterol and lowering cholesterol is arbitrary because both have as their purpose preventing heart disease, and consumers link cholesterol levels with disease prevention. Other comments, however, argued that cholesterol claims do not imply disease prevention. A comment from an organization devoted to prevention and treatment of heart disease argued that if any cholesterol claims were to be permitted, a claim like “promotes cholesterol clearance” would be a more accurate structure/function statement than “maintains healthy cholesterol” and less likely to imply disease prevention. Two comments contended that changing a claim from “lowers cholesterol” to “maintains healthy cholesterol levels” does not change the effect of the product or its use. Some comments argued that “lowers cholesterol” claims should be permitted for cholesterol levels that are not “abnormal” or are below hypercholesterolemia.

FDA does not agree that claims concerning maintenance of normal cholesterol levels necessarily constitute implied disease claims. Although an elevated cholesterol level is a sign of hypercholesterolemia and an important risk factor for heart disease, a cholesterol level within the normal range is not a sign or risk factor for disease. Moreover, maintaining cholesterol levels within the normal range is essential to the structure and function of the body for reasons other than prevention of heart disease. Although many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease, normal cholesterol levels play a positive role in maintaining a healthy body. Cholesterol is a necessary constituent of cell membranes and of myelin, the sheath that coats nerves. Cholesterol is also required for the synthesis of steroid hormones, which are essential for life. Finally, cholesterol is required for the production of bile in the liver, making possible absorption of dietary fat and fat soluble vitamins. Thus, a claim that a dietary supplement helps maintain cholesterol levels that are already within the normal range does not necessarily imply disease

treatment. FDA also believes that Congress intended to permit dietary supplements to carry claims of this type under section 403(r)(6)(A) of the act.

The agency has concluded, however, that references to "healthy" cholesterol may be misleading to consumers because the phrase "healthy cholesterol" is now frequently used to refer to high density lipoproteins (HDL), a specific cholesterol fraction believed to be beneficial. To avoid this confusion, FDA has concluded that an appropriate structure/function claim for maintaining cholesterol would be "helps to maintain cholesterol levels that are already within the normal range."

FDA continues to believe that "lowers cholesterol," however qualified, is an implied disease claim. As many comments argued, lowering cholesterol is inextricably linked in the public mind with treating elevated cholesterol and preventing heart disease. The agency also believes that "promotes cholesterol clearance" is an implied disease claim because it is directed at lowering cholesterol rather than maintaining levels already determined to be within a normal range. FDA will review all cholesterol claims to determine whether the labeling as a whole implies that the product is intended to lower elevated cholesterol levels. In such cases, FDA would consider the labeling to create an implied disease claim.

(46.) A comment from a former Surgeon General of the United States argued that, given the importance of preventing cardiovascular disease, dietary supplements should be permitted to make claims for cholesterol reduction, because "our citizens deserve the opportunity to know when safe and effective dietary supplements are available to lower cholesterol." A comment from the Nutrition Committee of the American Heart Association argued that current scientific evidence does not support added benefits of dietary supplementation with nutritive substances for prevention of cardiovascular disease in the general population, and expressed concern that dietary supplements also carry risks.

FDA agrees that prevention of heart disease is an extremely important public health goal. Lowering cholesterol with certain drugs has been conclusively shown to be effective in reducing mortality from coronary artery disease. Indeed, the evidence linking the lowering of elevated cholesterol with preventing heart disease is so strong that identifying and using effective therapies to lower cholesterol in patients with elevated cholesterol levels has become of compelling importance. With this in

mind, use of possibly ineffective therapies in persons with elevated cholesterol, which can delay or prevent effective treatment, poses significant public health risks. Although DSHEA requires that manufacturers who make structure/function claims have substantiation, manufacturers are not currently required to submit that substantiation to FDA for premarket review, nor does FDA have the resources to inspect and review the quality of the substantiation in most cases. For this reason, FDA does not believe that permitting "lowers cholesterol" claims on dietary supplements without prior review serves the public health.

(47.) A few comments argued that FDA may not prohibit "lowers cholesterol" claims because the agency had earlier issued an advisory letter permitting such claims if the claim stated that the product was useful in the context of a healthy diet. One of these comments contended that the agency may not change its advice or guidance because it has cited no studies in this rulemaking to support the view that "lowers cholesterol" implies disease treatment.

FDA does not agree that it may not change its position on whether particular cholesterol claims imply disease treatment. The record and analysis in this rulemaking, as well as FDA's experience in implementing DSHEA, provide an ample basis for the conclusions that the agency has reached on cholesterol claims.

G. Conditions Associated With Natural States (§ 101.93(g)(2)(iii))

The proposed rule stated that natural states such as aging, menopause, pregnancy, and the menstrual cycle, are not themselves diseases, but can be associated with abnormal conditions that are diseases. FDA proposed in § 101.93(g)(2)(iii) to treat as a disease claim a statement that a product had an effect on a condition associated with a natural state if the condition presented "a characteristic set of signs or symptoms recognizable to health care professionals or consumers" as an "abnormality." FDA provided as examples of such abnormal conditions the following: Toxemia of pregnancy; premenstrual syndrome; hot flashes; and presbyopia, decreased sexual function, and Alzheimer's disease associated with aging.

In the July 8, 1999, *Federal Register* notice announcing a public meeting and reopening the comment period, FDA asked for additional comment on this provision of the proposed rule. The agency sought specific comment on the

following three questions: (1) If FDA were to treat some conditions associated with natural states as diseases (e.g., toxemia of pregnancy and Alzheimer's disease) but not others (e.g., hot flashes, common symptoms associated with the menstrual cycle, and decreased sexual function associated with aging), what would be an appropriate principle for distinguishing the two groups? (2) For example, would it be appropriate to consider the severity of the health consequences if the condition were to go without effective treatment? (3) If so, how should "severity" be defined?

(48.) Although some comments from disease-specific organizations and health professionals supported this provision, most of the comments strongly objected to classifying common conditions associated with natural states as diseases. None of the objecting comments argued that toxemia of pregnancy or Alzheimer's disease are not diseases. Almost all of these comments, however, contended that PMS, hot flashes, and various conditions associated with aging, such as decreased sexual function, are so common that they should be considered neither abnormal nor diseases. Some comments argued that any condition suffered by more than 50 percent of the population should be considered normal and not a disease, and gave as an example benign prostatic hypertrophy. Other comments cited prevalence rates for conditions such as PMS and hot flashes, and contended that the cited rates were too high for these conditions to be considered abnormal. A large number of comments asserted that the proposed rule would treat pregnancy, menopause, and aging as diseases. A few comments argued that if menopause, aging, and pregnancy are not diseases, then signs and symptoms associated with these states cannot be diseases. One comment argued that conditions related to natural states are not diseases but "health-related conditions" and that DSHEA permits statements about health-related conditions.

In response to the questions in the July 8, 1999, *Federal Register* notice, many comments argued that the severity of the condition associated with a natural state was not an appropriate principle for distinguishing diseases from nondiseases. These comments generally argued that the severity of the symptoms (rather than the severity of the consequences of going without effective treatment) was not an adequate basis to distinguish diseases from nondiseases. One comment from a food industry group argued that this was an inappropriate principle because "all

natural states can have severe consequences if left unattended." This comment suggested that conditions that were "universal" should not be treated as diseases. This comment and one other also suggested that the distinguishing principle was whether the cause of the condition was "pathological."

FDA has reconsidered proposed § 101.93(g)(2)(iii), and has concluded that it is not appropriate, under DSHEA, to treat certain common, nonserious conditions associated with natural states as diseases. There are a wide variety of conditions representing impaired function of an organ or system that are associated with particular stages of life or normal physiologic processes. These stages and processes include adolescence, the menstrual cycle, pregnancy, menopause, and aging. (FDA notes that, contrary to the comments, the proposed rule would not have classified these stages or processes themselves as diseases; it classified only certain abnormal conditions associated with these stages or processes as diseases.) The conditions associated with these stages or processes can vary from common, relatively mild abnormalities, for which medical attention is not required, to serious conditions that can cause significant or permanent harm if not effectively treated.

For example, pregnancy is associated with common and mild abnormalities such as morning sickness and leg edema that cause no permanent harm if left untreated, as well as with such serious conditions as hyperemesis gravidarum, toxemia of pregnancy, and acute psychosis of pregnancy, which can be life-threatening if not effectively treated. The menstrual cycle is commonly associated with mild mood changes, edema, and cramping that do not cause significant or permanent harm if left untreated, but also, more rarely, with serious cyclical depression that can result in significant harm if not effectively treated. Aging is almost invariably associated with characteristic skin and scalp changes, such as wrinkles and hair loss, which do not need medical attention. It is also, however, associated with serious diseases that will result in significant, often irreversible damage, many of which can be effectively treated. These diseases include osteoporosis, glaucoma, and arteriosclerotic diseases of coronary, cerebral, and peripheral vessels. Adolescence is commonly associated with mild acne, which does not cause significant or permanent harm if not treated, and, rarely, with cystic acne, which can produce severe

physical and psychological scars if not effectively treated.

Whether all of these conditions represent diseases is, in part, a matter of definition and, in part, depends on the consequences of the conditions if not effectively treated, and on how commonly they occur, i.e., whether they may be considered "normal." Although most people consider the more serious or infrequent conditions referred to above to be diseases, views vary with respect to the common, milder conditions. FDA has reconsidered the position it took in the proposed rule and agrees with the comments that treating as diseases the common, mild symptoms associated with normal life stages or processes would not be consistent with the intent of DSHEA.

FDA does not believe that the frequency with which a condition associated with a natural state occurs is, by itself, sufficient to distinguish diseases from nondiseases. The severity of the consequences of disease, as well as the consequences of ineffective treatment, must also be considered. As noted above, whether common, minor conditions associated with natural states are diseases is a matter of debate, but FDA has decided not to treat them as diseases because the agency believes this approach is consistent with the intent of DSHEA. FDA does not, however, believe that DSHEA was intended to permit unreviewed claims about serious conditions that could cause significant or permanent harm, particularly where effective treatment is available. FDA also does not agree that "all natural states can have severe consequences if left unattended." FDA has listed a large number of conditions associated with natural states that commonly do not have serious consequences even if not effectively treated. FDA also does not agree that it is helpful in this context to distinguish between diseases and nondiseases by asking which have a "pathological" basis. The term "pathological" is itself defined by reference to disease, namely, "caused by or involving disease; morbid" (Ref. 7).

Accordingly, for purposes of this rule, mild conditions commonly associated with particular stages of life or normal physiological processes will not be considered diseases. Therefore, § 101.93(g)(2)(iii) now states that a statement will be considered a disease claim if it claims that the product "has an effect on an abnormal condition associated with a natural state or process, if the abnormal condition is uncommon or can cause significant or permanent harm." Ordinarily, FDA would follow the suggestion in the

comments that conditions associated with a stage of life or a normal physiological process be considered common if they occur in more than one-half of those experiencing that stage or process.

The following are examples of conditions about which structure/function claims could be made under § 101.93(g)(2)(iii): (1) Morning sickness associated with pregnancy; (2) leg edema associated with pregnancy; (3) mild mood changes, cramps, and edema associated with the menstrual cycle; (4) hot flashes; (5) wrinkles; (6) other signs of aging on the skin, e.g., liver spots, spider veins; (7) presbyopia (inability to change focus from near to far and vice versa) associated with aging; (8) mild memory problems associated with aging; (9) hair loss associated with aging; and (10) noncystic acne. The following are examples of conditions that would remain disease claims: (1) Toxemia of pregnancy; (2) hyperemesis gravidarum; (3) acute psychosis of pregnancy; (4) osteoporosis; (5) Alzheimer's disease, and other senile dementias; (6) glaucoma; (7) arteriosclerotic diseases of coronary, cerebral or peripheral blood vessels; (8) cystic acne; and (9) severe depression associated with the menstrual cycle.

FDA has not included benign prostatic hypertrophy (BPH) on either of these lists, because the agency does not believe that BPH should be considered a consequence of aging. Like many other diseases, e.g., diabetes, prostate cancer, and heart disease, the incidence of BPH is much higher among older men. This does not mean that BPH or prostate cancer is caused by the aging process. Even if BPH were considered a direct consequence of aging, however, claims to treat or prevent it would still be treated as disease claims because failure to obtain effective treatment can cause significant or permanent harm.

FDA notes that it does not base the exclusion of the mild common conditions associated with natural states from § 101.93(g)(2)(iii) on the argument advanced by one of the comments that these are "health-related conditions" and that DSHEA permits structure/function claims about health-related conditions. FDA believes that a "health-related condition" is a state of health leading to disease. As FDA has said previously, "diseases" and "health-related conditions" are "so closely related that no bright-line distinction is practicable" (58 FR 2478, 2481 January 6, 1993). There is nothing in DSHEA, its legislative history, or in the definition of "disease or health-related condition" that would suggest that common conditions associated with natural states

are "health-related conditions" within the meaning of section 403(r)(1)(B) of the act. Further, FDA does not agree that section 403(r)(6) of the act authorizes structure/function claims about "health-related conditions." Had Congress intended to authorize structure/function claims about "health-related conditions" it could easily have used that terminology, but did not.

(49.) Some comments concerned specific claims under proposed § 101.93(g)(2)(iii). One comment sought concurrence that the following are acceptable structure/function claims: "supports a normal, healthy attitude during PMS" and "supportive for menopausal women." Another comment argued that a statement that a product provides nutrients that diminish the normal symptomatology of premenstrual syndrome or menopause is a permissible structure/function claim. Another comment asked whether "helps to maintain normal urine flow in men over 50 years old" is a permissible structure/function claim. One comment urged that only products proven safe when used as directed should be permitted for sale for enlarged prostate and that such products should recommend that a man see his physician. Another comment argued that the claim "for men over 50 years old," which FDA had proposed as an acceptable structure/function claim, is vague and ambiguous and is of no use to consumers.

FDA agrees that "supports a normal, healthy attitude during PMS" and "supportive for menopausal women" are appropriate structure/function claims. "Supports a normal, healthy attitude during PMS" is acceptable because PMS is generally a common, mild condition associated with a normal physiologic process. "Supportive for menopausal women" is acceptable because it is a general statement that does not refer to symptoms of any conditions at all. Claims about diminishing the normal symptomatology of premenstrual syndrome or menopause would also be acceptable structure/function claims, if they did not suggest, for example, prevention or treatment of osteoporosis, or another disease associated with these states. "Helps to maintain normal urine flow in men over 50 years old," however, is an implied disease claim because, as many comments pointed out, the average or "normal" state in men over 50 years old is diminishing urine flow, in most cases due to BPH, so that the apparent "maintenance" really represents a claim of improvement (treatment).

H. Generally (§ 101.93(g)(2)(iv))

Under proposed § 101.93(g)(2)(iv), FDA stated that a statement would be considered a disease claim if it claimed explicitly or implicitly to have an effect on disease through one or more of the following factors: (1) The name of the product (e.g., "Carpaltum" (carpal tunnel syndrome), "Raynaudin" (Raynaud's phenomenon), "Hepatacure" (liver problems)). Names that did not imply an effect on a disease, such as "Cardiohealth" and "Heart Tabs," would not constitute disease claims; (2) statements about the formulation of the product, including a claim that the product contained an ingredient that has been regulated by FDA predominantly as a drug and is well known to consumers for its use in preventing or treating a disease (e.g., aspirin, digoxin, or laetrile); (3) citation of a publication or other reference, if the citation refers to a disease use. For example, labeling for a vitamin E product that included a citation to an article entitled "Serial Coronary Angiographic Evidence That Antioxidant Vitamin Intake Reduces Progression of Coronary Artery Atherosclerosis," would create a disease claim under this criterion; (4) use of the term "disease" or "diseased;" or (5) otherwise suggesting an effect on disease by use of pictures, vignettes, symbols, or other means (e.g., electrocardiogram tracings, pictures of organs that suggest prevention or treatment of a disease state, or the prescription symbol (Rx)). The proposed rule stated that a picture of a body would not constitute a disease claim under this criterion.

(50.) A few comments stated that the phrase "has an effect on" in proposed § 101.93(g)(2)(iv) is vague and could be interpreted by the agency to mean almost anything. Some of these comments argued that disease claims should include only those that use the specific terms "diagnose," "prevent," "treat," "mitigate," or "cure."

FDA does not agree that the phrase "has an effect on" is inappropriately vague. FDA believes that it is necessary to use a phrase that encompasses synonyms for the terms "diagnose," "prevent," "treat," "mitigate," or "cure." If disease claims were limited to those that used the specific terms in the statute, it would be possible to make obvious and explicit disease claims simply by using terms that are similar in meaning to the statutory terms, e.g., "relieves arthritis pain" rather than "treats arthritis pain," or "eliminates the risk of cancer" rather than "prevents cancer."

I. Product Name (§ 101.93(g)(2)(iv)(A))

(51.) One comment observed that there is an inconsistency between the statement in the proposed rule that "Heart Tabs" does not imply an effect on a disease and § 101.14(a)(1), which states that:

Health claim means any claim made on the label or in the labeling of a food, including a dietary supplement, that expressly or by implication, including "third party" references, written statements (e.g., a brand name including a term such as "heart"), symbols (e.g., a heart symbol) characterizes the relationship of any substance to a disease or health-related condition * * * and requested clarification.

FDA agrees, in part, and disagrees, in part, with the comment. FDA does not agree that § 101.93(g)(2)(iv)(A) and § 101.14(a)(1) are inconsistent. Section 101.14(a)(1) was issued in 1993 to implement the health claims provisions of NLEA. In § 101.14(a)(1), use of the term "heart" in a brand name and use of the heart symbol in labeling are offered as examples of health claims, if in the context of the labeling as a whole, the word or symbol suggests that there is a relationship between the product and a disease or health-related condition. Thus, according to the preamble to that final rule (58 FR 2478 at 2486), the heart symbol might appropriately appear in the labeling of a food product if, in context, it did not suggest a relationship to heart disease, e.g. in conjunction with "Hey, Fudge Lovers." If, however, the heart symbol appeared alone on a food, without further explanation from context, consumers might conclude that the food was beneficial for reducing the risk of developing cardiovascular disease (*id.*).

Following the issuance of § 101.14(a)(1), Congress enacted DSHEA. DSHEA created a special regulatory regime for dietary supplements. That regime, while closely related to the regime for food, was not identical to the food regime. Section 403(r)(6) of the act specifies certain types of structure/function claims and general well-being claims that may be made for dietary supplements without first obtaining new drug approval or health claim authorization. The types of claims listed in section 403(r)(6) of the act are similar, but not identical to the claims permitted for foods under section 201(g)(1)(C) of the act. Under *Nutrilab v. Schweiker*, 713 F.2d 335 (7th Cir. 1983), conventional food claims are limited to structure/function effects that derive from the taste, aroma, or nutritive value of the food. Dietary supplement claims are not subject to that limitation. Had Congress intended the scope of the permitted claims to be identical, it

could simply have declared that dietary supplements are "foods." In light of Congress' intent to expand the types of claims authorized for dietary supplements in DSHEA, FDA interprets § 101.14(a)(1) as permitting dietary supplements to have brand names that include the word "heart" or other organs, if, in the context of the labeling as a whole, the name does not imply disease treatment or prevention.

FDA does agree, however, that under § 101.14(a)(1), a dietary supplement name that included the word "heart" could be a health claim, depending on the context. Thus, a dietary supplement could be called "HeartTabs" if its claim was "to maintain healthy circulation," or some other role related to the structure or function of the heart that did not imply treatment or prevention of disease. If, however, the product name was not qualified by any further claim in the labeling, the product could be considered, under § 101.14(a)(1), to be intended for treatment or prevention of cardiovascular disease.

FDA also believes that the heart symbol has become so widely associated with prevention of heart disease that its use in the labeling of a dietary supplement would be ordinarily considered an implied heart disease prevention claim. Consistent with the examples provided in the January 6, 1993, *Federal Register* document on health claims (58 FR 2486), however, there may be unusual cases in which, in context, the use of a heart symbol does not imply heart disease prevention.

(52.) Several comments agreed with proposed § 101.93(g)(2)(iv)(A) that product names that imply an effect on disease, including implying cure or treatment of a disease, should not be allowed. The comments, however, requested that the agency provide further guidance as to what types of product names are acceptable and what types are not. Some comments questioned whether product names such as "CarpalHealth," "HepatoHealth," "HepataCare," "CircuCure," or "Soothing Sleep" would be acceptable under proposed § 101.93(g)(2)(iv)(A). Other comments disagreed with the agency's examples and stated that it is difficult to distinguish the reasoning behind some of the examples cited. For example, a few comments stated that both "Cardiohealth" and "Heart Tabs" imply that the product prevents heart disease.

Two principles formed the basis for the distinctions in the proposed rule between product names that were considered structure/function claims and those that were considered disease claims. First, the name should not

contain the name, or a recognizable portion of the name, of a disease. Second, the name should not use terms such as "cure," "treat," "correct," "prevent" or other terms that suggest treatment or prevention of a disease. Thus, "CarpalHealth" and "CircuCure" would be considered disease claims. In some cases, to determine whether a product name implies an effect on disease, the agency will need to consider the context in which a term is presented in the labeling as a whole. Thus, "Soothing Sleep" could be considered a claim to treat insomnia, unless the labeling made clear that the product was intended only for occasional sleeplessness. "HepataCare" and "HepataHealth" could also be considered disease claims because "Hepata" could be read as a reference to hepatitis, unless the labeling made clear that the product was intended for general liver health and not intended to treat or prevent hepatitis.

The agency notes that in the near future, FDA will issue for public comment a draft guidance to provide additional clarification and examples of claims that would and would not be considered disease claims under the final rule. FDA will include in the draft guidance examples of product names.

(53.) Another comment stated that proposed § 101.93(g)(2)(iv)(A) would prohibit the use of the name of the "dispensing institution" if it had the word "Cancer" in it because the agency would interpret the labeling as implying an effect on disease, when in fact the product was listing the institution where the product was dispensed, e.g., ABC Cancer Institute. Other comments were concerned that the proposed rule would prohibit the use of their company trade name, which includes the use of the word "prescription" and its abbreviation "Rx."

The agency reiterates that it will view the name in the context of the entire labeling to determine whether a disease claim is being made. However, a manufacturer may not circumvent the requirements of the act, DSHEA, or this final rule by using the name of an institution or the manufacturer to imply a disease claim.

The agency agrees that the use of the word "prescription" or its abbreviation "Rx" in the name of the product should not automatically be interpreted as a disease claim. Although these terms imply that the product is a prescription drug, some prescription drugs are intended for nondisease conditions. Therefore, if nothing else in the labeling suggests a disease use, the agency will not consider the use of "prescription" or "Rx" to be an implied disease claim.

The agency notes, however, that the use of these terms on dietary supplement products may deceive consumers into thinking that they are purchasing a prescription drug without a prescription. Thus, use of the terms "prescription" or "Rx" is misleading and will misbrand the product under section 403(a)(1) of the act if, in the context of the labeling as a whole, the terms imply that the product is a prescription drug.

(54.) A few comments cited in a proposed rule published in the *Federal Register* of March 27, 1974 (39 FR 11298), in which FDA stated that it would challenge brand names only in situations where clarifying language is incapable of rectifying FDA's concern with the brand name and that excision of a brand name should be a last resort and should be pursued only when all other methods of qualifying the name have failed.

The agency notes that the proposed rule cited in this comment was never finalized and was withdrawn on December 30, 1991 (56 FR 67440), as part of an FDA initiative to reduce the backlog of outstanding proposed rules that have never been finalized. The policies outlined in the March 27, 1974, *Federal Register* notice are not in effect.

(55.) Several comments sought a statement from FDA that if a product brand name becomes synonymous over time with use for prevention or treatment of a disease, it will still be permitted. As an example, the comments claimed that Kleenex has become synonymous with treatment of nasal congestion, but did not provide support for this assertion.

FDA does not believe that Kleenex is synonymous with treatment of nasal congestion and, absent any supportive data, has no reason to believe that consumers believe them to be synonymous. The agency would agree that Kleenex has become synonymous with "tissue," and that both are used in conjunction with nasal congestion. Neither tissue nor Kleenex, however, treat, prevent, or otherwise affect nasal congestion in any way. Because the agency was not presented with any specific examples of, nor is it aware of any, names of products that are not intended to treat disease but that have become synonymous with disease treatment or prevention, it does not have reason to believe that there is a real basis for concern.

J. Product Formulation (§ 101.93(g)(2)(iv)(B))

(56.) Several comments questioned whether the inclusion of a dietary ingredient in the ingredient list of a

dietary supplement would be interpreted as a disease claim under proposed § 101.93(g)(2)(iv)(B). They argued that to provide truthful labeling, this information must be included. Another comment stated that the proposal fails to distinguish between true claims and false claims. Several comments further argued that ingredient information may be of value to consumers to alert them to potential adverse effects or drug interactions. One comment urged that the presence of a constituent that is naturally occurring in a plant and is also regulated as a drug does not automatically classify the substance as a drug. The comment asserted that 45 percent of drugs are derived from plants, which, according to the comment, would classify a number of dietary ingredients as drugs.

Listing a dietary ingredient in the ingredient list of a dietary supplement will not be considered to imply an effect on disease unless the ingredient is one that has been regulated primarily by FDA as a drug and is well-known to consumers for its use or claimed use in preventing or treating a disease. (In the proposed rule, the agency gave as examples aspirin, digoxin, and laetrile.) Very few dietary ingredients meet this test. The agency agrees that a certain percentage of drug products are derived from plants. However, only a handful of these drugs are well-known to consumers under the name of the plant or natural plant ingredient from which they were derived. Instead, they are known to consumers under a brand name or generic name, e.g., aspirin. Thus, FDA does not believe that listing dietary ingredients that happen to be related to well-known drugs will fall under this provision, except in unusual circumstances. In those cases where a manufacturer does add a drug ingredient that is well-known to treat or prevent disease to its product and label its presence, however, FDA may consider it a disease claim. The fact that the labeling is truthful does not necessarily mean that it falls within the scope of claims authorized by section 403(r)(6) of the act. For example, the agency believes that there are many dietary ingredients that could be shown to treat or prevent diseases, and for which it could thus be truthful to state that the product treats or prevents a specific disease. Under the act, however, if a manufacturer wants to label its product to treat or prevent disease, it must do so under the drug approval provisions or the health claim provisions of the act. It may not do so under section 403(r)(6) of the act. In drafting section 403(r)(6) of the act to

exclude disease claims, Congress made a judgment that the public health will be served by requiring premarket review of such claims.

FDA agrees that it is important to inform consumers about potential adverse effects or drug interactions for specific dietary supplement ingredients. In fact, dietary supplement labeling, like the labeling of other FDA-regulated products, is required to include all facts that are material in light of consequences that may result from use of the product or representations made about it (sections 403(a)(1) and 201(n) of the act). This provision is not intended in any way to preclude truthful adverse event or drug interaction information from appearing in a dietary supplement's labeling.

(57.) A dietary supplement manufacturer asked FDA to clarify the effect of § 101.93(4)(ii) on a dietary ingredient found in common food(s), whose biological activity is first characterized in a food context, but which is subsequently approved as a drug. The comment asked whether, if indole-3-carbinol, a compound discovered in broccoli and other vegetables, were to be approved as a breast cancer drug, claims to the effect that a vegetable-based dietary supplement product contains indole-3-carbinol would be permitted as structure/function claims under the proposed rule. The comment claimed that the proposed rule would classify such claims as disease claims even if the biological activity of this dietary ingredient were first identified in the food context.

Where an ingredient has been approved as a drug, section 201(ff)(3) of the act prohibits marketing of the ingredient as a dietary supplement unless the ingredient itself was previously marketed as a food (including a dietary supplement), or unless a food containing the ingredient was previously marketed for the presence of the ingredient. In the example provided in the comment, the isolated ingredient indole-3-carbinol could not be marketed as a dietary supplement, unless a food containing the ingredient had been marketed for the presence of the ingredient before the drug was approved or was the subject of substantial investigations that had been made public. However, to avoid a conflict between this provision and section 201(ff)(3) of the act in a situation where the ingredient was marketed as a food first, FDA has revised § 101.93(g)(2)(iv)(B) to exclude claims about an ingredient that is an article included in the definition of "dietary

supplement" under section 201(ff)(3) of the act.

(58.) One comment misunderstood § 101.93(g)(2)(iv)(B) and believed that this provision only applies to the listing of OTC drug ingredients recognized by consumers.

This provision is not limited to the listing of OTC drug ingredients. For purposes of § 101.93(g)(2)(iv)(B), the agency may consider as a disease claim a claim that the product contains an ingredient that has been regulated by FDA as a drug, whether marketed over-the-counter or by prescription, and that is well known for its use in preventing or treating a disease.

K. Citation of Publication Titles (§ 101.93(g)(2)(iv)(C))

(59.) Many comments objected to this proposed criterion or sought clarification. Many comments said that the proposed criterion undermines DSHEA by prohibiting the use of most journals, is not required by DSHEA, or is contrary to section 403B of the act (21 U.S.C. 343-2), which, the comment said, exempts scientific publications from labeling rules and is intended to allow consumers to be more informed by reading scientific studies. Other comments said that Congress intended to encourage the dissemination of scientific research and truthful, non-misleading information, so FDA should not prohibit titles of scientific studies. Some comments stated that the issue should not be whether a publication's title refers to a disease use, but rather whether, on balance, the entire presentation, including the product label, package insert, and other labeling, represents a disease claim. These comments supported the use of complete citations to scientific literature, including the titles of scientific articles. Some comments suggested that the proposal contradicted earlier FDA positions. One comment referred to the September-October 1998 issue of *FDA Consumer* which, the comment stated, suggested that consumers contact companies to obtain scientific articles that the company might have to substantiate a claim. Another comment said the proposal was contrary to FDA policy to recognize and accept valid science. Several comments questioned how to provide substantiation of labeling claims, in compliance with 403(r)(6)(B) of the act, if the supporting articles cannot be cited. One comment stated that there will be more fraud and deception in the marketplace because companies will not cite scientific support for their statements. Several comments stated that the proposed rule will restrict

access by consumers and the medical community to important new research results and discourage companies from investing in research. A dietary supplement manufacturer suggested revising the provision to permit companies to cite "bonafide" textbooks and peer-reviewed scientific journals that mention a disease in the title. Another dietary supplement manufacturer suggested revising this provision to permit citation of a publication or reference if the citation "is necessary to present a balanced discussion of the documented mechanism by which a nutrient or dietary ingredient acts to maintain the structure or function of the body."

FDA agrees that in enacting DSHEA, Congress intended to encourage the dissemination of scientific research and truthful, non-misleading information. FDA also agrees that consumers can benefit from reviewing the scientific support used to substantiate a statement made for a dietary supplement under section 403(r)(6) of the act. In keeping with these goals, FDA has modified § 101.93(g)(2)(iv)(C) to narrow the circumstances under which citation to a scientific reference will be considered a disease claim. Based on Congress' explicit prohibition in section 403(r)(6) of the act of claims to affect disease, however, FDA does not believe that Congress intended to permit scientific references to be used in a way that constitutes an implied disease claim. Consequently, § 101.93(g)(2)(iv)(C) has been revised to state that citation of a title referring to a disease will be treated as a disease claim, if, in the context of the labeling as a whole, the citation implies treatment or prevention of a disease, e.g., through placement on the immediate product label or packaging, inappropriate prominence, or lack of relationship to the product's express claims.

The agency continues to believe that placing a citation to a scientific reference that mentions a disease in the title on the immediate product label or packaging should be considered a disease claim for that product, because of the unusual and unnecessary prominence of such placement. For citations to scientific references that refer to a disease use in the title and that are included in other types of labeling (i.e., other than the product label or packaging) the agency will consider the context in which the citation is presented. FDA agrees with the comments that the totality of all available labeling should be considered to determine the context. One element that the agency will look at is the prominence of the citation in the

labeling. If, for example, the citation is simply listed in the bibliography section of the labeling among other titles, it will generally not suggest an implied disease claim. On the other hand, highlighting, bolding, using large type size, or prominent placement of a citation that refers to a disease use in the title could suggest that the product has an effect on disease. The agency will also consider whether the cited article provides legitimate support for a 403(r)(6) of the act statement that appears in the labeling of the dietary supplement. Enhancing the bibliography with citations to scientific references that refer to a disease in the title and that have no reasonable relation to the statement made will be considered a disease claim. Similarly, the agency will consider whether citations are to bona fide research.

FDA also agrees that it is important to provide a balanced discussion of the scientific literature regarding the claim. FDA encourages manufacturers to cite references that provide a balanced discussion of the evidence supporting a structure/function claim.

The agency believes that the final rule strikes a reasonable balance between encouraging the dietary supplement industry to inform consumers about the substantiation for their claims and preventing abuses of section 403(r)(6) of the act.

(60.) Several comments challenged the basis for the proposed restriction of scientific references. One comment from industry said the proposed restriction on titles is outside DSHEA because the act refers to statements. The comment said titles could be prohibited if they were misleading, but said the rule should not contain a blanket prohibition.

The comment is apparently referring to section 403(r)(6) of the act, which prescribes the terms under which a "statement" may be made for a dietary supplement. FDA believes that the comment's reading is too literal, however. A "statement" does not have to be a declaratory sentence but rather is fairly read to include other kinds of statements, such as citations of scientific authority. In keeping with DSHEA's purpose to broaden the scope of labeling claims that may be made for dietary supplements without subjecting them to regulation as drugs, FDA believes that Congress intended "statement" to refer to any claim made that recommends or suggests a particular use of a dietary supplement. In addition to being under inclusive, a narrower interpretation would not benefit the dietary supplement industry because it would limit the scope of

claims authorized under section 403(r)(6) of the act.

(61.) A few comments stated that the agency did not provide any support for the assumption that citations are disease claims rather than substantiation for a claim.

FDA believes that a citation of a title that refers to a specific disease can serve both as a disease claim and as substantiation for a claim. A citation of a publication title that links the product to a particular disease could lead consumers to believe that the product can be used to diagnose, prevent, mitigate, treat, or cure a disease, even if the title also provides substantiation for the product claims.

As stated above, citation of a scientific reference will not be treated as a disease claim if, in the context of the labeling as a whole, the reference lacks prominence and if it is appropriate support for the product claim.

(62.) One comment sought clarification of the effect of this provision on multi-ingredient products. The comment asked whether a disease claim for the entire product would be created if the labeling cited an article about only one ingredient of a multi-ingredient product.

Generally, if a citation is presented in the product labeling in such a way as to imply that a specific ingredient can treat or prevent disease, the product, as a whole, will be considered to be intended to treat or prevent disease.

(63.) A few comments requested FDA to clarify how proposed § 101.93(g)(2)(iv)(C) would operate. The comments questioned whether they would have to delete a citation from a list or redact the reference to a disease from the title of the article. One comment asked whether an article that contains a reference to a disease can be cited if the title is not used in the citation. The comments further questioned whether they can provide the entire article, with the title on it, if requested by a consumer. Some comments asked FDA to clarify that a label may cite a title that appears in a publication whose name includes a disease (such as the publication titled *Cancer*) or to clarify how scientific studies may be cited. One comment requested that the agency issue further guidance to clarify what is and is not covered by § 101.93(g)(2)(iv)(C).

FDA does not expect a manufacturer to redact portions of the citation or delete a citation from a list of references or bibliography if it is appropriate to include the reference to substantiate a claim. As described above, if the citation to a scientific reference refers to a disease, the agency will consider the

context in which the citation is presented, including its prominence in the labeling and whether there is a reasonable relationship between the reference and the express claim. In most cases, the unredacted reference title can be included in the product labeling without subjecting the product to regulation as a drug, as long as the prominence of the reference does not suggest that it is being used to imply disease treatment or prevention. Under revised § 101.93(g)(2)(iv)(C), the only reason a publication title would be considered a disease claim regardless of prominence would be if the reference is not reasonably related to substantiating the product's express claim. In that case, FDA believes that the reference would be a disease claim, even if the name of the disease is redacted, because the only purpose of including the reference would be to suggest use of the product for treatment or prevention of the disease discussed in the reference.

With regard to citation of titles from journals whose official names include the name of a disease, the same considerations of appropriate prominence and reasonable relationship to the product's express claims apply. FDA expects that accepted conventions of scientific citation will be used for all citations that appear in labeling.

Finally, if specific information about an unlabeled use of a product is requested by a consumer, and the request is not solicited by the manufacturer, providing articles that are responsive to the request will not be considered a disease claim.

FDA will issue further guidance on § 101.93(g)(2)(iv)(C), if necessary.

(64.) Several comments sought modifications to proposed § 101.93(g)(2)(iv)(C). One comment suggested revising the provision to permit companies to cite articles or references that use "intermediate terms" (which the comment said were terms or phrases that have disease-related endpoints) on the label or labeling.

Whether a citation that refers to a disease-related endpoint will be considered a disease claim under the rule will depend on the context in which the disease-related endpoint is referred to and whether the reference implies that the product has an effect on disease. For example, the title of an article that states that a product was shown to maintain cholesterol levels that were already within the normal range, with no reference to a disease, would be considered a structure/function statement about maintenance rather than a disease claim. However, if the title of the article states that the product was shown to lower elevated

cholesterol levels, this implies that the product can be used to have an effect on the disease states hypercholesterolemia and heart disease, because heart disease is associated with high cholesterol levels.

(65.) A trade association suggested that the title should not be considered to be a disease claim unless it uses the terms "treat," "cure," "mitigate," "prevent," or "diagnose."

As stated elsewhere in this document, FDA believes that a disease claim can be made explicitly or implicitly using terms other than those listed in the comment. For example, depending on how it was used in a product's labeling, a scientific reference entitled "Using Ingredient X For Diabetes" could constitute a claim that the product can diagnose, mitigate, treat, cure, or prevent diabetes, without using any of these specific terms.

(66.) A few comments argued that citation of articles that refer to a disease use should be permitted because consumers have access to these articles in connection with the sale of dietary supplements under section 403B(a) of the act.

As stated above, FDA has revised the proposed rule's treatment of citations to scientific articles. Under the final rule, such citations will not always be considered disease claims. FDA does not agree, however, that section 403B of the act applies to the citation of titles in product labeling. Although section 403B of the act exempts certain publications from the labeling provisions of the act, section 403B(a)(2) states that the exemption applies only when, among other requirements, the publication is "used in connection with the sale of a dietary supplement to consumers when it * * * does not promote a particular manufacturer or brand of a dietary supplement." If the reference or the title of the reference was disseminated by a particular manufacturer of the dietary supplement discussed in the reference, the agency would conclude that it was being used to promote that manufacturer's brand of the dietary supplement. Therefore, the exemption in section 403B of the act would not apply.

Furthermore, to qualify for the exemption in section 403B of the act, a publication must be "an article, a chapter in a book, or an official abstract * * * reprinted in its entirety" and must be "displayed or presented, or * * * displayed or presented with other such items on the same subject matter, so as to present a balanced view of the available scientific information of a dietary supplement." A citation to an

article alone could not meet these requirements.

L. Use of Disease or Diseased (§ 101.93(g)(2)(iv)(D))

(67.) Many comments agreed with proposed § 101.93(g)(2)(iv)(D), stating that the terms "disease" or "diseased" should classify a statement as a disease claim. Several comments urged that a statement referring in a general way to the concept of "health promotion and disease prevention" not cause the statement to be considered a disease claim, as long as no specific disease was mentioned. One comment asked that the agency permit general discussions of the concept of disease prevention, citing the following example from the U.S. Public Health Service Healthy People 2000 initiative: "Better dietary and exercise patterns can contribute significantly to reducing conditions like heart disease, stroke, diabetes, and cancer, and could prevent 300,000 deaths."

FDA agrees that general statements about health promotion and disease prevention may be acceptable, as long as the statements do not imply that a specific product can diagnose, mitigate, cure, treat or prevent disease. Accordingly, FDA has revised § 101.93(g)(2)(iv)(D) to permit general statements about disease prevention that do not refer explicitly or implicitly to a specific disease or class of diseases or to the specific product or ingredient. For example, the statement "a good diet promotes good health and prevents the onset of disease" would not be considered a disease claim. On the other hand, the claim "Promotes good health and prevents the onset of disease" would refer implicitly to the product and would constitute a disease prevention claim. FDA also believes that the particular statement offered by one of the commenters would constitute a disease claim. The example cites four specific diseases. If that statement were included in the labeling for a dietary supplement, a consumer would reasonably assume that the statement applies to the product and that taking that dietary supplement contributes to preventing the diseases listed. If, however, the statement said "better dietary and exercise patterns can contribute to disease prevention and better health," FDA would not consider it a disease claim.

M. Pictures, Vignettes, and Symbols (§ 101.93(g)(2)(iv)(E))

(68.) Many comments agreed that certain pictures, vignettes, and symbols can explicitly or implicitly convey that the product has an effect on disease. A few comments agreed that a diseased

organ should be considered a disease claim. They argued, however, that a picture of a healthy heart, healthy artery, or other healthy organ should be permitted because such pictures do not in and of themselves depict a disease. A few comments stated that a healthy electrocardiogram (EKG) tracing should not be considered a disease claim. One comment requested that the agency clarify whether a picture of an organ is permitted if the claims are appropriate and within the scope of permitted structure/function claims. The comment offered as an example a statement that a product maintains cardiovascular health accompanied by a picture of a heart and circulatory system.

FDA agrees that in most cases, a picture of a healthy organ would not be considered a disease claim, if, in the context of the labeling as a whole, it did not imply treatment or prevention of disease. As described in response to comment 51 of section II.I of this document, however, there may be symbols for organs, like the heart symbol, that have become so widely recognized as symbols for disease treatment or prevention, their use in labeling would constitute an implied disease claim. FDA also believes that a picture of a healthy EKG tracing is an implied disease claim. Because most consumers cannot distinguish a healthy EKG tracing from an unhealthy one, both types may be viewed as references to diagnosis or treatment of unhealthy heart conditions.

N. Membership in Product Class (§ 101.93(g)(2)(v))

Some product class names are so strongly associated with use to treat or prevent a specific disease or class of diseases that claiming membership in the product class implies disease treatment or prevention. Under proposed § 101.93(g)(2)(v), a statement would have been considered a disease claim if it claimed that the product belonged in a class of products recognizable to health care professionals or consumers as intended for use to diagnose, mitigate, treat, cure, or prevent a disease. The preamble provided the following examples of class names that would imply disease treatment or prevention: Claims that the product was an "antibiotic," a "laxative," an "analgesic," an "antiviral," a "diuretic," an "antimicrobial," an "antiseptic," an "antidepressant," or a "vaccine." These examples were not intended to constitute an exclusive list of product class names that convey disease claims. Under the proposed rule, claiming that a product was in a class that is not

recognizable to health care professionals or consumers as intended for use to diagnose, mitigate, treat, cure or prevent disease would not have constituted a disease claim under this criterion. The preamble provided as examples of acceptable structure/function claims: Claims that the product was an "energizer," a "rejuvenative," a "revitalizer," or an "adaptogen." In light of the agency's decision that claims for relief of "occasional constipation" should not be considered disease claims, the term "laxative" will not be considered a disease claim under the final rule, as long as the remainder of the labeling makes clear that the product is not intended to treat chronic constipation.

(69.) Most of the comments on proposed § 101.93(g)(2)(v) were generally supportive, but some wanted to ensure that the provision would be applied in specific ways. One comment urged that "appetite suppressant" be treated as a disease claim, while another comment urged that "tonic" be treated as a structure/function claim.

FDA does not agree that "appetite suppressant" should be considered a disease claim. As discussed elsewhere in this document, although obesity is a disease, overweight is not. An appetite suppressant may be intended for ordinary weight loss, rather than as a treatment for obesity. Therefore, "appetite suppressant" would only be considered a disease claim in a context where it implies use for obesity. FDA agrees that "tonic" is not a disease claim. "Tonic" is commonly understood as a general term for anything that refreshes, and, by itself, would not be considered to constitute a disease claim.

(70.) Some comments stated that various class names should be allowed when they describe the mechanism by which a supplement has its effect, or when they are present in a product and it is truthful and not misleading to name them. One comment offered as examples of class names that might be used to describe a product's mechanism of action: A statement that a product that is soothing to the stomach achieves its effects as a result of its "carminative (antispasmodic) properties" or as a result of its "anti-inflammatory effect on the gastrointestinal tract." This comment stated that it is not membership in a given class of compounds that should make a product a drug, but rather the intended use of the product. One comment asked whether this criterion precludes a statement that daily consumption of vitamins and minerals may prevent the onset of disease or other physical ailments.

Nothing in this provision would preclude a manufacturer from truthfully declaring the ingredients contained in a product. In fact, FDA regulations require the ingredients in a dietary supplement to be listed on its label. (See § 101.4(a)(1) and (g) (21 CFR 101.4(a)(1) and (g)), and § 101.36). The rationale for § 101.93(g)(2)(v) is that certain product class names (not particular ingredients) are so strongly associated with use to diagnose, treat, mitigate, cure, or prevent disease that claiming membership in the class would constitute a disease claim. FDA does not believe that claiming membership in a product class is necessary in order to provide an accurate list of the ingredients present in a product.

FDA agrees that dietary supplements may carry statements that characterize "the documented mechanism of action by which a nutrient or dietary ingredient acts to maintain * * * structure or function," but only to the extent that such a statement does "not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases" (section 403(r)(6) of the act). In the examples provided in the comment, FDA is unaware of evidence establishing that the claims actually describe "documented" mechanisms by which the products "maintain" a calm stomach. Nevertheless, assuming that these statements met the other requirements of section 403(r)(6)(A) of the act, FDA would not consider the term "antispasmodic" to constitute a disease claim because the agency does not believe that it is closely associated with treatment or prevention of gastrointestinal disease. The term "anti-inflammatory" is, however, strongly associated with treatment of certain serious gastrointestinal diseases, and would constitute a disease claim.

FDA agrees with the statement that it is not membership in a given class of compounds that makes a product a drug, but rather the intended use of the product. This criterion sets forth FDA's conclusion that *claiming* membership in certain product classes that are strongly associated with use to treat or prevent disease is evidence that the product is intended to treat or prevent disease.

Although this provision does not itself treat as a disease claim a statement by a vitamin manufacturer that the product prevents the onset of a disease, such a statement would be considered a disease claim under § 101.93(g)(2)(I), which covers statements that a product has an effect on a specific disease or class of diseases. In addition, a general statement that a product prevents the onset of disease would be considered a disease claim under

§ 101.93(g)(2)(iv)(D), as noted in the discussion of that provision. Claiming membership in the class of vitamins or minerals would not constitute a disease claim under this criterion.

(71.) A food manufacturers' trade association and an individual manufacturer opposed the provision, arguing that it goes beyond the intent of DSHEA and would prohibit the use of any term associated with a drug product.

FDA does not agree that this provision goes beyond the intent of DSHEA nor that it would prohibit the use of any term associated with a drug product. DSHEA precludes statements under section 403(r)(6) of the act from claiming to treat or prevent disease. This provision constitutes FDA's conclusion that some drug class names (but not all terms associated with drug products) are so strongly associated with disease prevention or treatment that claiming membership in the class constitutes a claim that the product, like other members of the class, treats or prevents disease.

(72.) One pharmaceutical company argued that proposed § 101.93(g)(2)(v) would violate DSHEA, because DSHEA specifically defines as a dietary supplement an article that is approved as a new drug under section 505 of the act, if it was, prior to approval, marketed as a dietary supplement.

FDA agrees that the dietary supplement definition includes the provision cited by the comment (section 201(ff)(3)(A) of the act), but believes that the definition and § 101.93(g)(2)(v) are not inconsistent. Section 101.93(g)(2)(v) would treat as a disease claim a labeling statement that the supplement is a member of a product class when that class is so recognizable for its disease treatment or prevention use that the labeling statement would be understood as a disease claim for the supplement. The criterion would not treat inclusion of an ingredient in a dietary supplement as a disease claim merely because the ingredient had been approved under section 505 of the act nor would it preclude listing the ingredient in the Supplement Facts panel or ingredient list.

O. Substitute for Disease Therapy
(§ 101.93(g)(2)(vi))

Under proposed § 101.93(g)(2)(vi), a statement would have been considered a disease claim if it explicitly or implicitly claimed that the product was a substitute for another product that is a therapy for a disease. FDA offered "Herbal Prozac" as an example of such a claim. A claim that did not identify a specific drug, drug action, or therapy

(e.g., "use as part of your weight loss plan") would not constitute a disease claim under this criterion.

(73.) There was general support for the provision, particularly for considering terms that make a direct connection with an approved drug, like "Herbal Prozac" and "Herbal Phen-fen," disease claims. Several organizations noted that associating dietary supplements with regulated drug products is deceptive and dangerous because it can signal to consumers that because the product is "herbal" it is safer. Several medical associations, however, objected to the interpretation that "use as part of your weight loss plan," is nonspecific and would be acceptable. They maintained that the term implies treatment of a disease, obesity. A comment from a manufacturer also strongly objected to the statement in the proposal that "Use as part of your weight loss plan" would be an acceptable structure/function claim. The comment contended that the legislative history of the act shows that Congress intended weight loss claims to be treated as disease claims. Finally, the comment argued that even if FDA decides to permit weight loss claims as structure/function claims, the legislative history of the act and case law require that FDA classify products containing "antinutrients" as drugs.

FDA agrees with these comments that obesity is a disease, and that obesity claims are not acceptable structure/function claims. Being overweight, i.e., being more than one's ideal weight but less than obese, however, is not a disease. FDA believes that it is commonly understood that "weight loss plans" relate to a broad range of overweight statuses. Therefore, weight loss plans are not so narrowly associated with disease treatment that a reference to use as part of a weight loss plan should be considered a disease claim.

FDA does not agree that either the legislative history of the act or the case law interpreting section 201(g) of the act or DSHEA require a determination that FDA classify as drugs products making weight loss claims. The legislative history of section 201(g)(1)(C) of the act shows that Congress added the structure/function definition of "drug" in part to capture obesity claims that were not covered by section 201(g)(1)(B) because obesity was not, at that time, considered a disease. FDA believes that the legislative history in fact supports FDA's view that weight loss claims are properly considered structure/function claims. Although obesity claims are now covered by section 201(g)(1)(B) of the act because obesity is now considered a

disease, section 201(g)(1)(C) was added to cover conditions, like overweight, that are not considered diseases, but that affect the structure or function of the body. Structure/function claims under section 403(r)(6) of the act are closely related to structure/function claims under section 201(g)(1)(C) of the act and therefore should encompass weight loss claims.

FDA also does not agree that cases cited by the comment compel the conclusion that weight loss products must be regulated as drugs. In *Nutrilab v. Schweiker*, 713 F.2d 335 (7th Cir. 1983), *American Health Products Co. v. Hayes*, 574 F. Supp. 1498 (S.D.N.Y. 1982), *aff'd*, 744 F.2d 912 (2d Cir. 1984), and *United States of America v. Undetermined Quantities Of "CAL-BAN 3000"*, 776 F. Supp. 249 (E.D.N.C. 1991), the courts held that certain weight loss products were drugs under section 201(g)(1)(C) of the act because they were labeled to affect the structure or function of the body, and did not qualify for the "food" exception to section 201(g)(1)(C). At the time these cases were decided, the only issue was whether these products were "foods" or "drugs." Since then, however, DSHEA created a new statutory category of products, dietary supplements. Section 403(r)(6) of the act, which was added by DSHEA, permits structure/function claims to be made for dietary supplements without subjecting them to regulation as drugs, even if they could not qualify for the "food" exception in section 201(g)(1)(C) of the act. Therefore, these cases do not establish that dietary supplements making weight loss claims must be regulated as drugs. To the contrary, because the products were held to be drugs under section 201(g)(1)(C) of the act rather than section 201(g)(1)(B), these cases support treatment of weight loss claims for dietary supplements as structure/function claims authorized under section 403(r)(6) of the act.

Finally, FDA does not agree that, under *United States v. Ten Cartons, More or Less, of an Article * * * Ener-B Vitamin B-12*, 72 F.3d 285 (2d Cir. 1995), dietary supplements making weight loss claims must necessarily be regulated as drugs. The court in *Ener-B* held that a dietary supplement that makes a structure/function claim may nevertheless be regulated as a drug, under certain circumstances. In that case, the court found that FDA could regulate a product as a drug, based on its method of intake (nasal administration). Nothing in that case suggests that FDA must regulate dietary supplements making weight loss claims as drugs.

(74.) Several comments reiterated that general statements about the nature of a product or its mechanism of action should not be disease claims, or should be structure/function claims as long as they are truthful and not misleading. One comment objected to the provision as duplicative of proposed § 101.93(g)(2)(v). Another comment sought to delete the provision, arguing that dietary supplement manufacturers have the right to communicate to consumers that their products have fewer side effects than drugs.

FDA does not believe that this provision precludes general statements about the function or mechanism of action of a dietary supplement. It is not necessary to claim that the product is a substitute for a drug or therapy to describe its function or its mechanism of action. Nor is § 101.93(g)(2)(vi) duplicative of § 101.93(g)(2)(v). Claiming that a product is a substitute for a specific drug or therapy, e.g., "Herbal Prozac," is a different means of communicating that a dietary supplement is intended to treat a disease than claiming that the product belongs to a class of drugs associated with treatment or prevention of that disease, e.g., "antidepressant."

FDA does not agree that section 403(r)(6) of the act permits a dietary supplement manufacturer to claim that its product has fewer side effects than a drug, if the drug is intended to treat or prevent disease, because the clear implication is that the dietary supplement is intended for treatment or prevention of the same disease. If, however, the drug is not intended to treat or prevent disease, a dietary supplement manufacturer is free to make truthful, non-misleading comparisons between the drug and the dietary supplement.

P. Augmentation of Therapy or Drug for Disease (§ 101.93(g)(2)(vii))

Under proposed § 101.93(g)(2)(vii), a statement would have been considered a disease claim if it explicitly or implicitly claimed that the product augmented a particular therapy or drug action. The preamble offered the following example of a disease claim under this criterion: "Use as part of your diet when taking insulin to help maintain a healthy blood sugar level." A claim that did not identify a specific drug, drug action, or therapy would not constitute a disease claim under this criterion. The preamble gave the following example of an acceptable structure/function claim: "use as a part of your weight loss plan."

(75.) Several comments supported this provision. A few comments requested

that FDA withdraw the provision, arguing that dietary supplements are often useful in providing nutritional support to complement drug therapy or medical treatment and that the agency should encourage such information to be communicated to consumers. One comment stated that as long as the statement makes it clear that the product is being recommended for its nutritional impact on structure or function "as part of the therapy and not as the therapy itself," FDA should permit the statement. According to the comment, "use as part of your diet when taking insulin to help maintain a healthy blood sugar level" should be acceptable because the product is being recommended for its nutritional impact on structure or function as part of the therapy and not as the therapy itself. Another comment asked whether removing the words "when taking insulin" from the statement would make it an acceptable structure/function claim.

The agency agrees that dietary supplements may be useful in providing nutritional support. Associating such a statement with an express or implied claim that the dietary supplement augments a therapy or drug action, however, implies that the dietary supplement has a role in treating or preventing the disease for which the drug or other therapy is used.

The agency does not agree that the proposed claim involving insulin is an acceptable structure/function claim. Persons who take insulin have a disease, namely, diabetes. By referring to the use of the dietary supplement in conjunction with and for the same purpose ("to maintain a healthy blood sugar level") as a drug (insulin), which is used to for a disease (diabetes), the statement implies that the dietary supplement will help treat diabetes.

A general statement that a dietary supplement provides nutritional support would be an acceptable structure/function claim, provided that the statement does not suggest that the supplement is intended to augment or have the same purpose as a specific drug, drug action, or therapy for a disease. In the example, if the statement were changed to "use as part of your diet to help maintain a healthy blood sugar level," the claim would be considered acceptable. Deleting the reference to the drug, insulin, would remove the implication that the dietary supplement is used to augment the insulin to treat, mitigate, prevent, or cure diabetes.

On its own initiative, FDA is modifying § 101.93(g)(2)(vii) to limit its applicability to claims for augmentation

of drugs or therapies that are intended to diagnose, mitigate, treat, cure, or prevent disease.

(76.) Another comment noted that the agency did not address the use of synonyms for "augment," such as "strengthen," "reduce," "improve," "modify," "inhibit," "protect," or "defend."

Use of these terms may be appropriate in some contexts, i.e., when the statements do not suggest disease prevention or treatment use. If, however, the use of these terms implies that the dietary supplement augments a particular therapy or drug action or otherwise suggests an effect on disease, the agency will consider the statement a disease claim.

(77.) A trade association maintained that under the proposal, bread, crackers, and other baked goods used in conjunction with prescription drugs and/or other therapy would not be considered a food, but a drug, under certain circumstances.

Section 101.93 is intended to provide regulatory criteria for statements made for dietary supplements. Under section 201(ff)(2)(B) of the act, a dietary supplement does not include a product represented for use as a conventional food or as a sole item of a meal or the diet. If statements made for breads, crackers, and other baked goods characterize the relationship between a substance in the food and a disease or health-related condition, they must comply with the health claims provisions for foods under section 403(r)(1)(B) and (r)(3) through (r)(4) of the act.

Q. Role in Body's Response to Disease or Disease Vector (§ 101.93(g)(2)(viii))

Under proposed § 101.93(g)(2)(viii), a statement would have been considered a disease claim if it explicitly or implicitly claimed a role in the body's response to a disease or to a vector of disease. The preamble to the proposal defined a vector of disease as an organism or object that is able to transport or transmit to humans an agent, such as a virus or bacterium, that is capable of causing disease in man. The preamble offered as examples of disease claims under this criterion claims that a product "supports the body's antiviral capabilities" or "supports the body's ability to resist infection." A more general reference to an effect on a body system that did not imply prevention or treatment of a disease state would not have constituted a disease claim under this criterion. FDA provided as an example of an acceptable structure/function claim

under this criterion "supports the immune system."

(78.) Two comments from health associations supported this provision. One comment from a manufacturer argued that it should be deleted because a number of nutrients and dietary supplements "have a role in the body's response to disease." One comment argued that the body has natural defenses to disease, that these are normal functions of the body, and that therefore, statements such as "enhances disease resistance" should be allowable as structure/function claims. Comments from a consumer organization and a member of the President's Commission on Dietary Supplement Labels asserted that the provision made too many claims allowable. These comments stated that as long as a claim includes a disease-fighting function of the body, e.g., "supports the immune system," it should be considered a disease claim, regardless of other functions that might be involved.

FDA agrees that nutrients and dietary supplements may play a role in the body's response to disease. This does not mean, however, that disease prevention claims are acceptable structure/function claims. The act requires dietary supplement manufacturers who wish to make disease prevention claims to do so by obtaining authorization for a health claim or by obtaining new drug approval. Although FDA agrees that claims that a product fights disease, or enhances disease-fighting functions of the body, are disease claims, FDA does not agree that claims such as "supports the immune system" are specific enough to imply prevention of disease.

(79.) Several comments argued that there was no significant difference between "supports the immune system" (identified as a structure/function claim in the proposal) and "supports the body's antiviral capabilities" (identified as a disease claim in the proposal). One view was that both should be considered structure/function claims. Conversely, other comments contended that "supports the immune system" is a disease claim, because it could be interpreted as a claim for treatment or prevention of human immunodeficiency virus (HIV) disease. Another comment recommended that "supports the body's antiviral capabilities" be allowable as a structure/function claim, stating that the broader "supports the immune system" statement was vague and useless to consumers because the immune system has many functions.

The distinction between the two claims is one of specificity. An intact immune system has several functions.

In addition to their role in the defense against pathogens, certain components of the immune system, namely white blood cells, have other important functions. For example, white blood cells play an essential role in the phagocytosis and disposal of aging red blood cells or otherwise damaged cells. A statement of support for the immune system, by itself, conveys no specific reference to disease treatment or prevention. The claim that vitamin A is necessary to maintaining a healthy immune response does not imply that a specific disease or class of diseases will be prevented. In contrast, a claim that a product "supports the body's antiviral capabilities" represents a claim of treatment or prevention of a specific class of diseases, those caused by viruses (e.g., colds, hepatitis, or HIV infection).

R. Treatment/Prevention of Adverse Events (§ 101.93(g)(2)(ix))

Under proposed § 101.93(g)(2)(ix), a statement would have been considered a disease claim if it explicitly or implicitly claimed to treat, prevent, or mitigate adverse events associated with a therapy for a disease (e.g., "reduces nausea associated with chemotherapy," "helps avoid diarrhea associated with antibiotic use," and "to aid patients with reduced or compromised immune function, such as patients undergoing chemotherapy"). A claim that did not mention a therapy for disease (e.g., "helps maintain healthy intestinal flora") would not have constituted a disease claim under this criterion.

(80.) Comments from two large health organizations supported this provision, while two large business organizations and several other comments criticized it. Those opposing the provision argued that the proposal incorrectly categorized adverse reactions as diseases. Opposing comments also contended that dietary supplements may be useful as an adjunct to therapy by counterbalancing the effects of a drug in depleting a nutrient or interfering with the metabolism of a nutrient, and that this should be considered a structure/function role.

FDA believes that some of these comments may have misconstrued the provision. The criterion is not intended to capture every adverse event claim, but only claims about adverse events that satisfy the definition of disease. In the proposed rule, this limitation was conveyed by the phrase "and manifested by a characteristic set of signs or symptoms." Because the final rule uses a different definition of disease, § 101.93(g)(2)(ix) has been revised to state that claims about

adverse events are disease claims only "if the adverse events constitute diseases." FDA believes that a claim that a product is useful because it counterbalances the effects of a drug in depleting a nutrient or interfering with the metabolism of a nutrient would be acceptable as a structure/function statement. Such a claim would not suggest treatment of an adverse reaction that meets the definition of disease. However, as discussed above, if the claim expressly or impliedly suggests that the supplement is intended to augment a specific drug, drug action, or therapy for a disease, or serve the same purpose as a specific drug or therapy for a disease, then the statement may be considered a disease claim.

(81.) A dietary supplement manufacturer requested that FDA clarify why a statement that refers to a drug but not a disease, such as "helps individuals using antibiotics to maintain normal intestinal flora" is a disease claim, but a general statement, such as "helps maintain intestinal flora" is a permissible structure/function claim.

Although the statement "helps individuals using antibiotics to maintain normal intestinal flora" does not explicitly refer to a disease, there is an implicit claim that use of the dietary supplement while taking antibiotics will prevent or mitigate a disease. Persons using certain antibiotics are at risk of developing overgrowth in the gut of a pathogenic organism because along with fighting the target organisms in the body the antibiotic can suppress normal intestinal flora that are used to prevent infection in the intestinal tract. A firm that markets its product to address this concern, with claims that the product can be used to maintain normal intestinal flora while taking antibiotics, is making an implied disease prevention claim. Conversely, the statement "helps maintain intestinal flora" alone, without any reference to a disease, drug, drug action, or therapy, does not imply an effect on disease and would be considered a structure/function claim about general health maintenance.

S. Otherwise Affects Disease (§ 101.93(g)(2)(x))

Under proposed § 101.93(g)(2)(x), a statement would have been considered a disease claim if it suggested an effect on a disease or class of diseases in a manner other than those specifically enumerated in the first nine criteria.

(82.) A food manufacturers' trade association commented that this provision is of no regulatory importance, whereas a dietary supplement trade association and

several other comments considered it an over-reaching "catch-all" provision that would allow FDA to treat any claim as a disease claim. These comments provided examples of a number of claims that they believed would be disease claims under this provision, e.g. "provides nutritional support for women during premenstruation by promoting proper fluid balances and breast health," and "ginger supports the cardiovascular system by inhibiting leukotriene and thromboxane synthesis, substances associated with platelet aggregation."

FDA believes that this provision is necessary to allow for implied disease claims that may not fit into the nine enumerated criteria. The nine criteria are examples, and not an exhaustive list, of types of claims that the agency believes would constitute disease claims, based on past experience. Rather than attempting to evaluate or categorize statements that have not yet been presented to FDA, § 101.93(g)(2)(x) recognizes the possibility that other types of statements may also imply disease treatment or prevention. FDA does not believe that the provision will cause the agency to classify any structure/function statement as a disease claim. To regulate a statement as a disease claim under this provision, the agency would have to show that the statement implied an effect on disease. The two examples quoted in the comments do not appear to the agency to constitute disease claims.

T. Specific Claims Not Mentioned in the Proposed Rule

(83.) One comment contended that a dietary supplement called "pain free" or "pain product" that is labeled "to support and maintain joints," should not be regulated as an internal analgesic drug product under the OTC drug review because it is intended to maintain or support "normal well-being and pain levels." According to this comment, however, products sold as "pain relief" or "otherwise indicated to relieve temporary occurrences of arthritis pain" could be regulated as drug products under the OTC review, because the tentative final monograph for internal analgesics requires that such products be labeled for the "temporary relief of minor aches and pains" (53 FR 46204). At the same time, this comment argued that pain, in and of itself, is not a disease and therefore that pain claims should not be regulated as disease claims unless accompanied by an explicit reference to a specific disease.

FDA agrees in part and disagrees in part with this comment. FDA agrees that some minor pain relief claims may be

appropriate structure/function claims for dietary supplements. A claim that a product is intended to treat minor pain, without reference of any other conditions, symptoms, or parts of the body that would imply disease treatment or prevention, would be an appropriate structure/function claim, because minor pain, by itself, can be caused by a variety of conditions, not all of them disease-related.

FDA does not agree, however that general well-being or health maintenance claims would encompass such pain claims. Pain is not a normal state, nor are there "normal pain levels." The claim is thus clearly one of pain treatment or prevention. FDA also does not agree that section 403(r)(6) of the act authorizes a product whose name promises freedom from or relief of pain ("pain-free" or "pain product") and whose labeling includes claims related to maintenance or support of joints. While the latter claims alone are appropriate structure/function statements, in conjunction with a name that includes the term "pain," the product is clearly making a claim related to treatment or prevention of joint pain. As explained elsewhere in this document, joint pain is a characteristic symptom of arthritis, and joint pain claims are therefore disease claims. Acceptable structure/function claims could be made, however, for pain associated with nondisease states, e.g., muscle pain following exercise.

(84.) One comment listed several claims and sought concurrence that they were acceptable structure/function claims: "Boosts stamina, helps increase muscle size, and helps enhance muscle tone"; "deters bacteria from adhering to the wall of the bladder and urinary tract"; and "dietary support during the cold and flu season." Another comment asked whether "promotes general well-being during the cold and flu season" is a permissible claim.

FDA agrees that "boosts stamina, helps increase muscle size, and helps enhance muscle tone" are acceptable structure/function claims, because they do not refer to any disease. However, the agency notes that a claim to increase muscle size implies an effect that may subject the product regulation as an anabolic steroid under the Controlled Substances Act (see 21 U.S.C. 802(41)). "Deters bacteria from adhering to the wall of the bladder and urinary tract" is not an acceptable structure/function claim because it implies prevention of bacterial infections of the bladder and urinary tract. The claims "dietary support during the cold and flu season" and "promotes general well-being during the cold and flu season" are

disease claims because they imply that the product will prevent colds and flu or will mitigate the symptoms of those diseases.

(85.) One comment asked that the FDA clarify that dietary supplements can bear "smoking-alternative" claims if they avoid references to nicotine, nicotine withdrawal symptoms, and tobacco-related disease. The comment sought concurrence that the following types of claims were permitted: "Smoking alternative," "temporarily reduces your desire to smoke," "to be used as a dietary adjunct in conjunction with your smoking cessation plan;" and "mimics the oral sensations of cigarette smoke."

FDA agrees that certain smoking alternative claims may be acceptable structure/function claims, if they do not imply treatment of nicotine addiction, relief of nicotine withdrawal symptoms, or prevention or mitigation of tobacco-related illnesses. "Smoking alternative," "temporarily reduces your desire to smoke" and "mimics the oral sensations of cigarette smoke" may be acceptable (for products that otherwise meet the definition of a dietary supplement), if the context does not imply treatment of nicotine addiction, e.g., by suggesting that the product can be used in smoking cessation, or prevention or mitigation of tobacco-related diseases. For example, such claims would not be disease claims if the context made clear that they were for short-term use in situations where smoke is prohibited or socially unacceptable. "To be used as a dietary adjunct in conjunction with your smoking cessation plan," however, is a disease claim because it is a claim that the product aids in smoking cessation, thereby implying that the product is useful in treating nicotine addiction. As noted earlier, a claim that the product is useful in counterbalancing the effects of a drug in depleting a nutrient or interfering with the metabolism of a nutrient would be acceptable as a structure/function statement.

(86.) One comment offered as acceptable structure/function claims a long list of OTC drug claims provided for in the monographs for antacids, antifatulents (antigas), antiemetics, nighttime sleep-aids, stimulants (alertness aids), daytime sedatives, aphrodisiacs, products for relief of symptoms of benign prostatic hypertrophy, anticholinergics (products that, at low doses, depress salivary and bronchial secretions), and products for certain uses. Two comments sought clarification that inclusion of a claim in an OTC monograph does not preclude its use as a structure/function claim.

FDA agrees that some of the claims on the comment's list of OTC drug claims may be acceptable structure/function claims, but believes that others on the list are disease claims. Of the claims listed in the comment from the "Antacids" monograph, "relief of sour stomach" and "upset stomach" are acceptable structure/function claims, because they refer to a nonspecific group of conditions that have a variety of causes, many of which are not disease-related. Thus, they are not characteristic of a specific disease or class of diseases. Although "relief of heartburn" and "relief of acid indigestion" without further qualification are not appropriate structure/function claims, the agency has concluded that "occasional heartburn" and "occasional acid indigestion" can also be considered nonspecific symptoms, arising as they do in overindulgence and other sporadic situations. These claims could be appropriate structure/function claims. In contrast, "recurrent" or "persistent" heartburn and acid indigestion can be hallmarks of significant illness, and are therefore disease claims.

All of the claims listed in the comment from the "Antiflatulents" (antigas) monograph are acceptable structure/function claims, because the symptoms in the claims are not sufficiently characteristic of specific diseases: "Alleviates the symptoms referred to as gas," "alleviates bloating," "alleviates pressure," "alleviates fullness," and "alleviates stuffed feeling." The claim listed in the comment from the "Antiemetics" monograph, "for the prevention and treatment of the nausea, vomiting, or dizziness associated with motion," is also a permitted structure/function claim.

Of the claims listed in the comment from the "Nighttime" sleep-aids monograph, "for the relief of occasional sleeplessness" is an acceptable structure/function claim, because occasional sleeplessness is not a characteristic symptom of a disease. "Helps you fall asleep if you have difficulty falling asleep," and "helps to reduce difficulty falling asleep" are disease claims because, unless the context makes clear that the product is only for occasional sleeplessness, they imply treatment of insomnia, a disease. The claim listed in the comment from the "Stimulants" (alertness aids) monograph, "helps restore mental alertness or wakefulness when experiencing fatigue or drowsiness," is an acceptable structure/function claim because occasional fatigue and drowsiness are not characteristic

symptoms of a specific disease or class of diseases. FDA notes, however, that chronic fatigue or daytime drowsiness can be symptoms of chronic fatigue syndrome and narcolepsy, respectively. Products labeled "to help restore mental alertness or wakefulness when experiencing fatigue or drowsiness" should not imply treatment of either of these diseases.

Of the claims listed in the comment from the "Daytime" sedatives monograph, almost all are acceptable structure/function claims. "Occasional simple nervous tension," "nervousness due to common every day overwork and fatigue," "a relaxed feeling," "calming down and relaxing," "gently soothe away the tension," "calmative," "resolving that irritability that ruins your day," "helps you relax," "restlessness," "nervous irritability," and "when you're under occasional stress, helps you work relaxed" are all acceptable structure/function claims, because all suggest occasional rather than long-term or chronic mood changes. Although occasional or acute symptoms can be characteristic of diseases in other settings, none of the occasional symptoms referred to here is characteristic of a specific disease. "Nervous tension headache" is a disease claim because tension headache meets the definition of a disease.

Of the claims listed in the comment from the "Aphrodisiacs" monograph, "arouses or increases sexual desire and improves sexual performance" is an acceptable structure/function claim because it does not imply treatment of a disease. "Helps restore sexual vigor, potency, and performance," "improves performance, staying power, and sexual potency," and "builds virility and sexual potency" are disease claims because they use the term "potency," which implies treatment of impotence, a disease. If, however, these claims made clear that they were intended solely for decreased sexual function associated with aging, they could be acceptable structure/function claims. The claim from the "Products for relief of symptoms of benign prostatic hypertrophy" monograph ("To relieve the symptoms of benign prostatic hypertrophy, e.g., urinary urgency and frequency, excessive urinating at night, and delayed urination") is a disease claim, because benign prostatic hypertrophy meets the definition of a disease.

The claim listed in the comment from the "Anticholinergics" monograph is a disease claim. "Relieve excessive secretions of the nose and eyes" refers to the characteristic signs or symptoms of hay fever. Of the claims listed in the

comment from the "Products for certain uses" monograph, "digestive aid," "stool softener," "weight control," and "menstrual" are, by themselves, acceptable structure/function claims if the labeling does not otherwise imply treatment or prevention of a disease. None mentions a characteristic symptom of a disease. "Laxative" is a not a disease claim, if the labeling makes clear that the intended use is for treatment of occasional rather than chronic constipation. "Nasal decongestant," "expectorant," and "bronchodilator" are disease claims. "Nasal decongestant" is a treatment for a characteristic symptom of colds, flu, and hay fever. "Expectorant" is a treatment for a characteristic symptom of colds, flu, and bronchitis. "Bronchodilator" is a treatment for bronchospasm, a characteristic symptom of asthma.

The claim from the "Products for the treatment and/or prevention of nocturnal leg muscle cramps" monograph ("treatment and/or prevention of nocturnal leg muscle cramps, i.e., a condition of localized pain in the lower extremities usually occurring in middle life and beyond with no regular pattern concerning time or severity") is an appropriate structure/function claim. Nocturnal leg cramps do not meet the definition of disease.

As is clear from this response, FDA agrees that inclusion of a claim in an OTC monograph does not preclude its use as a structure/function claim. FDA notes, however, that in light of the statutory requirement that dietary supplements bear all information that is material in light of consequences that may result from use of the product or representations made about it, dietary supplements that contain or are labeled as containing ingredients covered by an OTC monograph and that are being sold for the claims covered by the monograph may be misbranded to the extent that they omit material information required under the monograph. For example, if the OTC monograph required a label statement that products containing a particular ingredient should not be used by persons taking a prescription monoamine oxidase inhibitor, a dietary supplement containing that ingredient would be misbranded if its label did not include such statement.

U. Substantiation of Claims

(87.) Several comments requested that the final rule explicitly state that structure/function statements must be adequately substantiated and that FDA provide guidance on what constitutes adequate substantiation. One comment

maintained that adequate substantiation is critical to ensuring that consumers receive truthful and accurate information about the benefits of dietary supplements. Another comment argued that this final rule should focus on adequate substantiation of claims rather than on delineating the boundaries between structure/function claims and disease claims. Other comments maintained that substantiation is not as effective in preventing consumer fraud as preapproval of the claims because consumers will be using the products long before the label claims are investigated.

FDA agrees that the statutory requirement to substantiate claims is important. FDA does not agree, however, that it is necessary to state in the regulatory text of the final rule that structure/function claims must be adequately substantiated. Section 101.93(a)(3) requires a firm notifying FDA of a claim under section 403(r)(6) of the act to certify that the firm has substantiation that the claim is truthful and not misleading. FDA also does not agree that substantiation is an appropriate alternative to distinguishing structure/function claims from disease claims. The requirement that structure/function statements and other statements for dietary supplements under section 403(r)(6) of the act be adequately substantiated is distinct from the requirement that such statements not claim to diagnose, treat, mitigate, cure, or prevent disease. Both of these requirements are imposed by the statute and must be complied with.

(88.) Several comments offered advice on what types of evidence should constitute adequate substantiation. A consumer health organization suggested that health claims and structure/function claims for dietary supplements be based on the totality of the publicly available scientific evidence, including results from well-designed studies conducted in a manner consistent with generally recognized scientific principles and procedures. The comment added that consumers would be better served if standards for support applied to both health claims and structure/function claims. Another consumer health organization suggested that substantiation be based on "significant scientific agreement."

Many of the comments suggested that the agency adopt FTC standards for substantiation. A comment from FTC explained that FTC typically applies a substantiation standard known as "competent and reliable scientific evidence" to claims about the safety and effectiveness of dietary supplements, after first looking at the overall context

to determine what the claim is. The comment further stated that FTC's approach to substantiation is consistent with the guidance provided by the President's Commission on Dietary Supplement Labels, and, because FDA concurred with the Commission's guidance on substantiation, the comment suggested that FDA refer to the Commission guidance in the final rule.

As stated above, the agency does not believe that this final rule is the appropriate venue to address the substantiation requirement. FDA does, however, agree that claims under section 403(r)(6) of the act should be supported by adequate scientific evidence and may provide additional guidance regarding substantiation for 403(r)(6) statements at a future date.

The Commission report included guidance on what quantity and quality of evidence should be used to substantiate claims made under 403(r)(6) of the act. It also contained guidance on the content of the substantiation files for such statements, including the 30-day notification letter to FDA, identification of the product's ingredients, evidence to substantiate the statements, evidence to substantiate safety, assurances that good manufacturing practices were followed, and the qualifications of the person(s) who reviewed the data on safety and efficacy. In a notice published in the *Federal Register* (63 FR 23624 at 23633), FDA stated that it agreed with the guidance of the Commission. FDA encourages manufacturers of dietary supplements making a 403(r)(6) of the act statement for a dietary supplement to follow this guidance.

(89.) A food manufacturer suggested that the agency require dietary supplement manufacturers making structure/function claims to disclose in labeling any and all scientific studies supporting the claim. In addition, the comment advocated requiring that these studies be performed using the marketed formulation. The comment also urged FDA to determine how contrary studies should be addressed.

DSHEA does not require dietary supplement labeling that carries a statement under section 403(r)(6) of the act to include in the labeling "any and all scientific studies supporting the claim." Section 403(r)(6)(B) of the act requires only that the "manufacturer have substantiation that such statement is truthful and not misleading." Contrary studies should be considered when deciding whether to make and how to word a 403(r)(6) of the act statement to ensure that any statements made are truthful and not misleading.

Additionally, in response to a request for substantiation for the statement, the agency would expect manufacturers to provide a requester with contrary as well as supporting studies.

There is no specific statutory requirement that the studies substantiating the statement be performed using the actual marketed formulation. However, many ingredients and factors influencing the formulation can affect the safety and effectiveness of the dietary supplement. These variations from the marketed product should be considered before using a study to substantiate a statement made for a particular product.

V. Enforcement Issues

(90.) One comment said that the proposal shifts the burden of proof to manufacturers to show that their files match and support the claims made for their products.

The regulations issued by this final rule do not address or affect the burden of proof during enforcement actions. However, section 403(r)(6)(B) of the act clearly states that manufacturers must have substantiation to show that the statements that they make under section 403(r)(6) of the act are truthful and not misleading. This indicates that manufacturers must be prepared to demonstrate to the court that they have support for each claim.

(91.) One comment predicted widespread noncompliance with the rule because of its complexity and limited FDA resources.

FDA disagrees with the comment. FDA believes that most of the rule is straightforward, and the comments received on the proposed rule indicate that dietary supplement manufacturers understood the provisions of the rule. Moreover, as noted in the Analysis of Impact in section VI.E of this document, most of the claims of which FDA has been notified are consistent with the final rule. Thus, based on what has been provided to FDA, most manufacturers would appear to be already in compliance with this final rule. If it becomes apparent that there are provisions that are being violated because of true confusion about their applicability, FDA will issue clarifying guidance. FDA agrees that its enforcement resources are limited, and is issuing this rule in part to avoid inefficient use of those resources on case-by-case enforcement. FDA believes that the dietary supplement industry will make good faith efforts to comply with this rule, once it becomes effective.

W. Other Comments

(92.) One comment said FDA should conduct an educational campaign to enhance public awareness of the differences between structure/function claims and disease claims and the meaning of individual claims.

FDA intends to conduct various outreach activities on dietary supplement matters.

(93.) One comment said FDA should amend the tentative final monograph on OTC laxatives to be consistent with the rule. The comment explained that the tentative final monograph should permit the words "help maintain regularity" on OTC labeling.

The agency disagrees with the comment. The fact that "helps maintain regularity" is an acceptable structure/function claim does not mean that it satisfies the requirements for inclusion in an OTC monograph, including the requirement of a finding of general recognition of safety and effectiveness.

(94.) Several comments addressed manufacturing or related issues. One comment said FDA should investigate effects of dissolution on product potency and efficacy, while other comments advocated using United States Pharmacopeia standards for all dietary supplements on matters pertaining to dissolution, disintegration, purity, and potency. One comment added that poor product quality would present a health threat to consumers and result in economic fraud.

Another comment said FDA should concentrate on standardization and quality control instead of regulating labeling statements, but offered no specific suggestions. Some comments, however, made specific recommendations. One comment said that product labels should contain lot numbers and expiration dates and that manufacturers should conduct stability tests to determine accurate expiration dates. Another comment said the public should be protected against poor manufacturing standards for herbal products. Other comments simply stated that there is substantial potential for public harm because there are: Multiple sources of dietary supplement ingredients; multiple suppliers; a lack of regulatory production standards, or questions concerning product safety, efficacy, and manufacturing quality; vigorous product promotion; and a sizeable market. One comment simply asked for good manufacturing practice regulations for dietary supplements.

Manufacturing issues are outside the scope of this rule. FDA intends to issue a separate proposed rule on current good manufacturing practice (CGMP) for

dietary supplements, and that proposed CGMP rule may address some of the issues raised by the comments.

III. Legal Authority

A. Scope of Section 403(r)(6) of the Act

1. Relationship Between Sections 403(r)(6) and 201(g)(1)(C) of the Act

(95.) Several comments stated that the proposal mistakenly suggests that there is only one type of structure/function claim that may be used for dietary supplements. Some of these comments said that if a structure/function claim does not trigger drug status for the product and is not a health claim, then such a claim may be made in labeling for a dietary supplement so long as it is truthful and not misleading. These comments asserted that such a claim is not subject to the notice, labeling, or disclaimer requirements in section 403(r)(6) of the act. As an example, the comments said the claim that "calcium helps build strong bones" is not a health claim because it does not characterize a relationship between the substance and a disease, damage, or dysfunction of the body. The comments added that FDA recognized this in the final rule that it published in the *Federal Register* on September 23, 1997 (62 FR 49859, 49860, 49863, and 49864), when it stated in the preamble that claims that cranberry juice cocktail helps maintain urinary tract health or that calcium builds strong bones and teeth are not health claims because no disease is mentioned explicitly or implicitly. Some comments added that FDA cannot say that only those claims falling under section 406(r)(6) of the act are structure/function claims because such a result would be contrary to the act and would mean that the proposed rule must be withdrawn.

FDA agrees with these comments in part and disagrees in part. The agency agrees that statements such as "calcium helps build strong bones" are not health claims because they do not characterize the relationship between a substance and a disease or health-related condition. Rather, such statements are structure/function claims authorized by section 403(r)(6) of the act.

FDA does not agree with the comment's statement that dietary supplements may bear structure/function claims without complying with the notice, disclaimer, and other requirements of section 403(r)(6) of the act. Section 403(r)(6) of the act, by its terms, applies to dietary supplements. The other possible source of authority to make structure/function claims on dietary supplements is section 201(g)(1)(C) of the act, which provides

that "articles (other than food) intended to affect the structure or any function of the body of man or other animals" are drugs. Under this provision, foods may make claims to affect the structure or function of the body without being regulated as drugs. By its terms, however, section 201(g)(1)(C) of the act exempts a dietary supplement that bears a structure/function claim from drug regulation only if it is also a food. The last sentence of section 201(ff) of the act provides, "Except for purposes of section 201(g), a dietary supplement shall be deemed to be a food within the meaning of this Act." The clear import of this language is that dietary supplements are not foods under section 201(g) of the act and therefore cannot qualify for the "(other than food)" exception to the drug definition in section 201(g)(1)(C). As a result, dietary supplements that use structure/function claims may do so only under section 403(r)(6) of the act and are therefore subject to the disclaimer, notification, and other requirements in that section and in FDA's implementing regulation.

The agency acknowledges that it took a contrary position in the September 1997 final rule preamble referred to in the comment. In that preamble, FDA said that a dietary supplement could bear a structure/function claim under the "(other than food)" exception to the definition of "drug" in section 201(g)(1)(C) of the act, provided that the claim was truthful, non-misleading, and derived from nutritive value (see 62 FR 49859 at 49860, 49863, and 49864). However, the agency has now reconsidered in light of the plain language of section 201(ff) of the act and is revoking its statements on this subject in the September 1997 preamble (i.e., the statements at 62 FR 49859 at 49860, 49863, and 49864 concerning structure/function claims for dietary supplements under section 201(g)(1)(C)). It should be noted, however, that the agency is not revoking its statements in that preamble concerning structure/function claims for conventional foods under section 201(g)(1)(C) of the act. As explained in the September 1997 preamble (62 FR 49859 at 49860), conventional foods may make structure/function claims under section 201(g)(1)(C) of the act as long as such claims are truthful, non-misleading, and derive from the nutritive value of the food.

For a limited transition period, FDA does not intend to take enforcement action against firms who have relied on the agency's September 1997 final rule preamble statements to make a structure/function claim for a dietary supplement under section 201(g)(1)(C) of the act. To allow a reasonable time for

the necessary label changes, the transition period will last until the applicable compliance date for the rest of the rule; i.e., small businesses will have 18 months from publication to comply, and other firms will have 12 months. As of the applicable compliance date, firms that have been making structure/function claims under section 201(g)(1)(C) of the act must either remove the claim or comply with the requirements of section 403(r)(6) of the act and § 101.93, including notifying FDA of the claim and relabeling to add the required disclaimer. New structure/function claims are not subject to this transition period; any firm that makes a structure/function claim in the labeling of a dietary supplement after the effective date of this rule must comply with section 403(r)(6) of the act and § 101.93.

(96.) One comment objected to a sentence in the introductory paragraph in the preamble to the proposed rule. The sentence stated that, before DSHEA, certain claims could have rendered a product a "drug" under the act. The comment argued that even before DSHEA, dietary supplements could make structure/function claims and not be considered drugs. The comment said that section 201(g)(1)(C) of the act expressly excluded food from the definition of drug and that dietary supplements fell within the "food" exception. The comment characterized DSHEA as limiting and restricting "what had been the unconditional right of dietary supplement marketers to make structure/function claims."

The agency agrees that before DSHEA, dietary supplements that were also foods could make structure/function claims under section 201(g)(1)(C) of the act without being considered drugs. However, the passage of DSHEA changed the regulatory framework for structure/function claims on dietary supplements by adding sections 201(ff) and 403(r)(6) to the act. As explained in the response to the preceding set of comments, section 201(ff) of the act provides that dietary supplements are not considered food for purposes of section 201(g). Therefore, dietary supplements may no longer make structure/function claims under the "food" exception to the drug definition in section 201(g)(1)(C) of the act. FDA therefore agrees with the comment that in one respect, DSHEA limited the ability of dietary supplement marketers to make structure/function claims.

The sentence in the introductory paragraph of the preamble to the proposed rule correctly stated that "certain claims"—structure/function claims for dietary supplements that

were not also foods—could have rendered the product a drug before the passage of DSHEA (63 FR 23624). Post-DSHEA, however, dietary supplements may make structure/function claims under section 403(r)(6) of the act regardless of whether they are also foods. Thus, although in one way DSHEA did limit the ability of dietary supplement marketers to make structure/function claims, it also significantly expanded the opportunity to make structure/function claims in another way by removing the limitation that dietary supplements must be foods to make structure/function claims. Under section 403(r)(6) of the act, claims may be made for nondisease effects of a dietary supplement on the structure or function of the body, regardless of whether those effects are nutritive, as long as the product is intended to supplement the diet as provided in section 201(ff)(1) of the act. 2. Structure/Function Claims for Conventional Foods

(97.) Several comments sought consistency in the treatment of conventional foods and dietary supplements with respect to structure/function claims and health claims. Some of these comments contended that this rule would permit dietary supplements to carry claims that would be health claims if made for a conventional food. One comment stated that differential treatment of foods and dietary supplements was inconsistent with the Commission's recommendations. This comment suggested that differential treatment would cause consumers to perceive dietary supplements as better sources for safeguarding health than conventional foods. One comment expressed the view that the rule should apply to claims for conventional foods as well as dietary supplements and requested FDA to clarify the rule's scope. Other comments said that any structure/function claims that may be made for dietary supplements may also be made for conventional foods. The comments explained that the history of the act shows that claims that food affect the structure or function of the body do not result in the food being classified as a drug, citing the district court and appellate decisions in *American Health Products Co. v. Hayes*, 574 F. Supp. 1498, 1501 (S.D.N.Y. 1983), *aff'd*, 744 F.2d 912 (2d Cir. 1984). Another comment stated that established case law shows that an article may be a food if it is used primarily for taste, aroma, or nutritional value, but that nutritional value is not required in all instances. One comment further noted that FDA, when it

implemented the labeling requirements for DSHEA (62 FR 49859, 49860, and 49861) said that it was committed to "as much parity between dietary supplements and conventional foods as is possible within the statute" and that FDA has recognized that a dietary supplement may lawfully be in conventional food form, but must be represented as a dietary supplement (citing 62 FR 49826 at 49837, September 23, 1997).

Given this background, the comments argued that FDA cannot take the position that a structure/function claim may be made for a conventional food only if the effect derives from the food's nutritional value. One comment added that the act does not distinguish foods based on their nutritional value and that DSHEA considers structure/function claims for all dietary ingredients to be "statements of nutritional support." The comment said FDA, therefore, should recognize that structure/function claims that can be made for dietary ingredients when those ingredients are in dietary supplements can also be made when those ingredients are in conventional food, but added that the disclaimer statement and notification to FDA, as required by section 403(r)(6)(C) of the act, apply only to dietary supplements and not to conventional food. One comment said that requiring structure/function claims for conventional foods to be derived from the food's nutritional value would create a marketing disparity and put conventional foods at a competitive disadvantage.

This rule applies to claims for dietary supplements only. Its purpose is to implement section 403(r)(6) of the act, which applies to dietary supplements only. Therefore, a detailed discussion of the regulatory framework applicable to structure/function claims for conventional foods, which are made under section 201(g)(1)(C) of the act, is beyond the scope of the rule. FDA advises, however, that for consistency, the agency is likely to interpret the dividing line between structure/function claims and disease claims in a similar manner for conventional foods as for dietary supplements. The agency also notes that as discussed in the response to comment 1 in section II.A of this document, FDA reaffirms the statements about structure/function claims for conventional foods in the September 23, 1997 (62 FR 49859), final rule entitled "Food Labeling: Nutrient Content Claims, Health Claims, and Statements of Nutritional Support for Dietary Supplements." As explained in that rule (62 FR 49859 at 49860, 49861, and 49864), the fact that structure/function claims for conventional foods

are limited to effects derived from nutritional value, while structure/function claims for dietary supplements are not, is a result of differences in the language of the exemption for foods in section 201(g)(1)(C) of the act, as interpreted by the courts (see *Nutrilab, Inc. v. Schweiker*, 713 F.2d 335, 338 (7th Cir. 1983)), and the language of section 403(r)(6) of the act.

(98.) One comment suggested revising the definition of "disease or health-related condition" in proposed § 101.14(a)(6) to include a reference to § 101.93, and also recommended revising the definition of "health claim" at § 101.14(a)(1) to be consistent with § 101.93. Currently, § 101.14(a)(1) reads as follows:

Health claim means any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication, including "third party" references, written statements (e.g., a brand name including a term such as "heart"), symbols (e.g., a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition. Implied health claims include those statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition.

The comment would revise the definition to read as follows:

Health claim means any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication, including "third party" references, written statements (e.g., a brand name that includes or implies a disease, such as "Raynaud's"), symbols, or vignettes, characterizes the relationship of any substance to a disease or health-related condition (e.g., disease-indicating electrocardiogram tracings, pictures of organs that suggest prevention or treatment of a disease state, the prescription symbol, or any reference to prescription use). Implied health claims include those statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition.

As stated in response to comment 51 of section II.I of this document, FDA does not believe that §§ 101.14(a)(1) and 101.93(g) are inconsistent. As a result of the special regime for dietary supplements under DSHEA, there may be some differences in the treatment of dietary supplements and conventional foods under § 101.14(a)(1).

3. Relationship Between Structure/Function Claims and Health Claims

(99.) One comment stated that the proposed rule "improperly distinguishes between other health-

related claims and structure/function claims." Relying in part on the introduction to section 403(r)(6) of the act ("For purposes of paragraph (r)(1)(B) * * *"), the comment asserted that structure/function claims are a subset of the claims authorized by section 403(r)(1)(B) of the act (health claims). Consequently, because claims under section 403(r)(1)(B) of the act may characterize the relationship of a nutrient to a disease, the comment stated that FDA cannot preclude structure/function claims from making any contextual references to diseases.

FDA disagrees with this comment. Structure/function claims are not a subset of health claims because, clearly, there are claims about the effect of a product on the structure or function of the body that are not also health claims. To be a health claim, a claim must refer to the relationship between a food substance and a disease or health-related condition. FDA interprets "health-related condition" to mean a state of health leading to disease. Claims such as "calcium builds strong bones" are not health claims because they do not refer explicitly or implicitly to any disease or health-related condition. Therefore, the comment is based on an invalid premise.

(100.) One comment requested that FDA revise § 101.93(f) to state that the requirements of section 403(r)(6) of the act, e.g., use of the disclaimer and substantiation, apply only to structure/function claims that fall within the definition of a "health claim" in § 101.14(a)(1) and (a)(5). According to this comment, the introduction to section 403(r)(6) of the act ("For purposes of paragraph (r)(1)(B) * * *") establishes that structure/function claims that do not fall within the definition of health claims are not subject to section 403(r)(6), and may be made without complying with any of its requirements.

FDA does not agree and, in fact, believes that the opposite is true. As explained elsewhere in this document and in the proposed rule, structure/function claims that fall within the definition of health claims, or that otherwise constitute disease claims, do not fall within the scope of claims authorized under section 403(r)(6) of the act, but other structure/function claims do fall within the scope of section 403(r)(6) and are subject to its requirements. Adopting the interpretation advocated by the comment would bring about illogical results for dietary supplement labeling claims in two ways. First, structure/function claims that are also health claims would not be subject to the

health claims prior authorization requirements, but instead could be made simply by meeting the requirements of section 403(r)(6) of the act and FDA's implementing regulations. The language in section 403(r)(6) of the act excluding claims to affect disease from the coverage of that section demonstrates that Congress made a public health judgment that claims promoting dietary supplements for disease uses should continue to require premarket authorization. It would not make sense for Congress to exclude labeling claims pertaining to disease uses in one part of section 403(r)(6) of the act, while permitting such claims in another paragraph of the same section. Moreover, the interpretation advocated by the comment would lead to confusing and contradictory labeling. A dietary supplement that bears a health claim—a claim that, by definition, is a claim that a substance in the supplement in some way has an effect on a disease—would also have to bear a contradictory disclaimer that it is not intended to treat, mitigate, or prevent any disease. Second, structure/function claims that are not also health claims would not be authorized under section 403(r)(6) of the act at all. In fact, a structure/function claim on a dietary supplement would subject it to drug regulation because, as explained in the response to comment 1 in section II.A of this document, section 403(r)(6) of the act is the only provision that authorizes the use of structure/function claims on dietary supplements.

The introductory language in section 403(r)(6) ("For purposes of [section 403(r)(1)(B) * * *]) does not support the interpretation advocated in the comment. If Congress had wanted to subject only structure/function claims that are also health claims to section 403(r)(6) of the act, it could have done so much more directly by using language such as "A statement for a dietary supplement may be made if * * * and the statement is a statement of the type governed by paragraph (r)(1)(B)." The ambiguity of the "For purposes of (r)(1)(B)" language is well demonstrated by the diametrically opposed interpretations adopted by this comment and the preceding comment. FDA interprets this language as a caution that the category of claims covered by section 403(r)(6) of the act is not to be interpreted as coextensive with health claims, the category covered by section 403(r)(1)(B) of the act. Congress may have been concerned that the health claims category would swallow the category of claims under section 403(r)(6) of the act because all claims

under section 403(r)(6) could be characterized as referring to a "health-related condition" if that term were defined broadly as "a state of health." The result would have been that all structure/function claims, as claims about the relationship between a substance and a health-related condition, would also have been health claims and would have required premarket authorization. By including the introductory language, Congress effectively forestalled such an interpretation.

(101.) Another comment said the proposed rule does not distinguish between structure/function statements that assert health claims and those that do not, and said the failure to make this distinction would mean that more products would be subject to the rule than necessary.

FDA does not agree that the rule fails to distinguish between structure/function claims that do and do not assert health claims. On the contrary, the rule makes clear that only structure/function claims that do not assert health claims may be made under section 403(r)(6) of the act. To the extent that the comment may be suggesting that structure/function claims that are also health claims should be exempt from the health claims authorization requirements, the agency disagrees for the reasons given in the response to the previous comment.

B. Miscellaneous Legal Issues

(102.) Two comments said the proposed rule violated the Administrative Procedure Act because it was arbitrary and capricious, on two grounds. One comment asserted that FDA failed to consider an important aspect of the problem of distinguishing between drug claims and dietary supplement claims: The application of the "general well-being" provision of section 403(r)(6) of the act. The comment argued that FDA should have considered whether claims relating to normal body functions might qualify as "general well-being" claims under section 403(r)(6) of the act before deciding to regulate them as disease claims. The comment also argued that FDA's explanation of the need for the proposed rule ran counter to the evidence before the agency, in that the agency's actions on notifications of claims under section 403(r)(6) of the act did not support a need for further regulation.

The "general well-being" provision of section 403(r)(6) of the act authorizes statements in dietary supplement labeling that describe "general well-being from consumption of a nutrient or

dietary ingredient" (section 403(r)(6)(A) of the act). FDA did not consider whether statements were authorized under this provision in developing the proposed rule because the purpose of the rule was to implement the structure/function provisions of section 403(r)(6)(A) of the act, not other provisions. However, consideration of this provision as applied to normal body functions would not have led to a different result. The criteria in the rule were developed to identify claims that refer directly or indirectly to an effect on disease and do not encompass claims that refer only to general well-being. Claims relating to normal body functions are authorized under the rule.

The comment's argument about the use of FDA's actions on notifications of claims under section 403(r)(6) of the act to justify the rule is addressed in comment 4 of section II.A of this document.

(103.) One comment claimed that the proposal does not require FDA to show any evidence of a manufacturer's intent to find that a dietary supplement claim constitutes an illegal drug claim. The comment argued that proposed § 101.93(g)(2)(ii), (g)(2)(iii), (g)(2)(viii), and (g)(2)(x) run afoul of the recent appellate decision in *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155 (4th Cir. 1998), contending that "a product is not a drug merely because a consumer uses it as one" and that "there must be proof as to the manufacturer's intent." The comment also cited *National Nutritional Foods Ass'n v. Mathews*, 557 F.2d 325 (2d Cir. 1977), to support its position that a manufacturer's intent, as determined from labeling or advertising, is the primary factor in determining whether a product is intended to treat a disease.

Although FDA disagrees with the *Brown & Williamson* decision and is awaiting the outcome of Supreme Court review, this rule does not depend on the resolution of the legal issues in that case. The focus of the rule is on express and implied claims made by the vendor in labeling. None of the provisions of the rule, including those mentioned in the comment, rely on consumer use as a standard for determining whether the product is intended to treat or prevent disease.

The rule is consistent with the decision in *National Nutritional Foods Ass'n v. Mathews*, in which the court said, "FDA is not bound by the manufacturer's subjective claims of intent but can find actual therapeutic intent on the basis of objective evidence. Such intent also may be derived or inferred from labeling, promotional material, advertising, and 'any other

relevant source'" (557 F.2d at 334 (citations omitted)). See also § 201.128 (listing evidence FDA will consider in determining the intended use of a drug).

(104.) One comment said that the proposal must be withdrawn because, contrary to section 403(r)(6) of the act, it gives manufacturers the burden to prove that a claim is not a drug claim when, in fact, FDA has the burden, by a preponderance of relevant evidence, to establish that a dietary supplement is misbranded. The comment cited two court opinions, *United States v. 29 Cartons * * * an Article of Food (Oakmont)*, 987 F.2d 33 (1st Cir. 1993) and *United States v. An Article of Food * * * Viponte Ltd. Black Currant Oil*, 984 F.2d 814 (7th Cir. 1993), for the proposition that, before DSHEA was enacted, courts had invalidated an FDA enforcement theory that shifted the burden of proof to manufacturers.

FDA disagrees with this comment. Although the comment is correct that FDA has the burden of proving that a dietary supplement—or, in fact, any food—is misbranded, the rule does not give manufacturers the burden of proving that a claim is not a drug claim. The rule does not shift the burden of proof in an enforcement action but rather sets forth criteria for what claims are disease claims that may subject a product marketed as a dietary supplement to regulation as a drug.

The two cases cited in the comment are inapposite. They concern FDA's efforts to regulate certain dietary ingredients as food additives and do not have any relevance to claims issues.

(105.) One comment said that the proposed rule is inconsistent with the act and congressional intent, arguing that, by enacting DSHEA, Congress had taken steps to reverse FDA's "overly restrictive" approach towards claims and had commanded the agency to expand, rather than restrict, the amount of health information permitted on dietary supplement labels and labeling. According to the comment, the proposal "directly and substantially violates the overall statutory scheme and the expressed legislative intent" and FDA "has no authority to proceed with the rulemaking without a grant of authority from Congress in light of the Act's language and Congressional intent."

The agency disagrees with this comment and believes that the rule is consistent with the act and congressional intent. Although Congress, in enacting DSHEA, did expand the scope of information in dietary supplement labeling by providing for claims to affect the structure or function of the body and the other types of claims authorized by

section 403(r)(6) of the act, Congress also explicitly limited statements under section 403(r)(6) to those that do not claim to "diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases." This rule does not create new restrictions but merely implements the provisions of section 403(r)(6) of the act. FDA has authority to issue implementing regulations under section 701(a) of the act, which authorizes the agency to issue regulations for the efficient enforcement of the act.

(106.) One comment declared that FDA has no legal basis to include a broad variety of implied claims.

FDA disagrees with this comment. The agency has regulated implied claims in labeling for many years, in many contexts. (See, e.g., 21 CFR 104.5(b) and (d) (prohibiting certain implied claims relating to compliance with nutritional quality guidelines); 21 CFR 101.13(a) (classifying implied claims to characterize the level of a nutrient in food as nutrient content claims subject to the same requirements as express claims); 21 CFR 101.95 (prescribing conditions under which implied claims of freshness may be made for foods); 21 CFR 201.10(c)(3) (prohibiting use in ingredient statement of fanciful drug or ingredient names that falsely imply that the drug or ingredient has some unique effectiveness or composition); 21 CFR 201.302(c) (prohibiting implied claims that drugs for internal use that contain mineral oil are for administration to infants). The agency has also regulated implied claims in prescription drug advertising. (See, e.g., § 202.1(a)(3) (21 CFR 202.1(a)(3)) (prohibiting use in advertising of fanciful product or ingredient names that falsely imply that the drug or ingredient has some unique effectiveness or composition); § 202.1(e)(6)(v) (prohibiting implied claims that a study represents more widespread experience with the drug than it actually does).) More specifically, the agency has repeatedly taken the position that implied disease claims in labeling subject a product to regulation as a drug. In the animal drug context, § 500.52 (21 CFR 500.52) provides that the use of certain terms in the labeling of products intended for use in or on animals implies that the product is capable of a therapeutic effect and causes the product to be a drug within the meaning of section 201(g) of the act. In the human drug context, § 201.56(c) (21 CFR 201.56(c)) prohibits "implied claims or suggestions of drug use" in prescription drug labeling unless the product has been shown to be safe and effective for the implied or suggested use. (See also § 310.530 (21

CFR 310.530) (use of the word "hormone" in labeling is an implied drug claim.) Moreover, courts have upheld FDA's authority to regulate implied drug claims. (See, e.g., *United States v. Storage Spaces Designated Nos. "8" and "49"*, 777 F.2d 1363, 1366 & n. 5 (9th Cir. 1985), cert. denied, 479 U.S. 1086 (1987); *Pasadena Research Labs., Inc. v. United States*, 169 F.2d 375, 383 (9th Cir.), cert. denied, 335 U.S. 853 (1948); *United States v. Six Dozen Bottles* * * * "*Dr. Peter's Kuriko*", 158 F.2d 667, 669 (7th Cir. 1947); *United States v. John J. Fulton Co.*, 33 F.2d 506, 507 (9th Cir. 1929); *Bradley v. United States*, 264 F. 79, 81-82 (5th Cir. 1920); *United States v. Kasz Enterprises, Inc.*, 855 F. Supp. 534, 539, 543-44 (D.R.I. 1994), modified on other grounds, 862 F. Supp. 717 (D.R.I. 1994); *United States v. 43 1/2 Gross Rubber Prophylactics*, 65 F. Supp. 534, 535 (D. Minn. 1946), aff'd sub nom. *Gellman v. United States*, 159 F.2d 881 (8th Cir. 1947).)

(107.) Many comments argued that the proposed rule ignored the Supreme Court decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

FDA disagrees with these comments. The comments did not explain how the rule was contrary to or even affected by the decision. *Daubert* involved the admissibility of scientific evidence in a judicial proceeding under the Federal Rules of Evidence. This rulemaking does not present issues regarding the admissibility of evidence in any proceeding, judicial or administrative, nor does it address expert testimony (which was at issue in *Daubert*). Thus, FDA does not agree that the rule "ignores" or is contrary to the *Daubert* decision.

C. Constitutional Issues

1. First Amendment

(108.) Several comments focused on the First Amendment. One comment argued that the rule violates the First Amendment because it is more restrictive than is necessary to advance FDA's interests. The comment conceded that the government may regulate or prohibit commercial speech if the speech is inherently false, deceptive, or misleading, but argued that the government can only restrict commercial speech that is not false, deceptive, or misleading if the government shows that the restriction directly and materially advances a substantial state interest in a manner that is no more extensive than necessary to serve that interest (citing *Ibanez v. Florida Dept. Of Bus. & Prof'l Regulation*, 512 U.S. 136, 142 (1994);

Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 566 (1980)). The comment argued that not all structure/function claims prohibited under the proposed rule are inherently false or misleading and that if FDA does not review the evidence for a claim, the claim does not become false or misleading. Although the comment admitted that FDA has a substantial interest in regulating the safety, efficacy, and labeling of dietary supplements in order to protect the public health, the comment claimed that the regulation was more extensive than necessary. The comment argued that a disclaimer is "the constitutionally mandated method of regulating commercial speech."

Other comments said the proposed rule violates the First Amendment because, using the analysis in *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980), it is not narrowly tailored to meet FDA's interests and does not directly and materially advance the agency's interests. In general, these comments offered various reasons why the proposed rule did not survive scrutiny under *Central Hudson*. For example, under *Central Hudson*, the government may regulate commercial speech that concerns unlawful activity or is misleading if, among other things, the government asserts a substantial interest in support of its regulation. In brief, the comments said FDA failed to assert a substantial interest or construed the government's interest to be Congress' interest in increasing the amount of information to consumers. Others said that, contrary to *Central Hudson*, the proposed rule was not narrowly tailored and suppressed more speech than necessary to protect a possible government interest in protecting consumers from fraud and protecting public health and either suggested alternatives or said FDA should consider less restrictive alternatives. Some comments said the proposal also did not advance the asserted government interest because it blurred, instead of clarified, the line between drug and dietary supplement claims.

One comment also asserted that there is no substantial government interest involved, because FDA has not shown a concern for consumer safety or a danger to public health; according to this comment, the proposed rule was a response to confusion by manufacturers and consumers about what claims are permitted.

Some comments also argued that FDA has not shown that the claims are misleading or that the commercial speech covered by the proposed rule is

inherently misleading. One comment asserted that, if statements were untruthful or misleading, DSHEA would have prohibited them.

Another comment said the proposal "trenches on" the First Amendment because consumers have the right to receive, and manufacturers have the right to express, non-misleading information. The comment cited *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998) for this proposition. Another comment cited the *Washington Legal Foundation* decision to argue that the proposed rule would "impermissibly curtail" the flow of information to consumers. The comment suggested that less restrictive alternatives, such as "allowing implicit, but not explicit, claims," establishing "categories of diseases that clearly denoted drug claims" or identifying terms that connote "treatment," "cure," or "mitigation" exist.

A few comments simply claimed that the proposal violates the First Amendment because it would decrease the amount of scientific information on labels and labeling or because it represents a "prior restraint" on health claims. Other comments objected to particular provisions of the proposed rule on First Amendment grounds, notably proposed § 101.93(g)(2)(iv)(C), which provided that citation of the title of a scientific reference in dietary supplement labeling would be a disease claim if the title referred to a disease use of the product. Several comments said that this provision of the proposed rule would violate the First Amendment as an unlawful restraint on commercial speech. Others characterized the proposed provision as simply a restriction on freedom of speech, whether the restriction was on the right of companies to provide the information or on the right of consumers to receive the information. One comment said that references to publication titles could be prohibited if they were misleading, but that the rule should not contain a blanket prohibition. Some comments added that the agency should reconsider its position on this provision in light of *Washington Legal Foundation v. Friedman*.

Finally, a comment said that the proposal was contrary to the decision of the U.S. Court of Appeals for the District of Columbia Circuit in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999). According to the comment, the court of appeals' First Amendment ruling in *Pearson* requires the agency to permit health claims that do not satisfy the "significant scientific agreement" standard as long as the claim can be

rendered non-misleading by requiring a disclaimer. According to the comment, the court's decision also requires FDA to further define the "significant scientific agreement" standard for authorizing dietary supplement health claims. The comment said that the proposed rule was premature in light of the need to amend the health claims regulations to conform to the *Pearson* decision. The comment also argued that, in light of *Pearson*, FDA may not issue a final rule that prohibits disease claims but rather must choose the less restrictive alternative of permitting such claims provided that they are accompanied with disclaimers.

FDA does not believe that the rule violates the First Amendment. The rule does not prohibit any speech; rather, it clarifies the circumstances under which FDA will consider a certain type of speech—labeling claims—to be evidence of intended use as a drug, absent health claim authorization. Thus, the rule does not regulate speech as such, but rather as evidence of intended use. The use of speech as evidence of a company's intended use for its products is constitutional because "[t]he First Amendment * * * does not prohibit the evidentiary use of speech * * * to prove motive or intent" (*Wisconsin v. Mitchell*, 508 U.S. 476, 489 (1993)). (See also *Village of Hoffman Estates v. Flipside*, 455 U.S. 489, 495–96 (1982) (upholding village ordinance treating the proximity of drug-oriented literature as evidence that items were marketed for use with illegal drugs). Because it is the intent and not the speech that triggers a regulatory burden on the speaker, there is no First Amendment violation. (See *Wisconsin v. Mitchell*, 508 U.S. at 489; *United States v. Articles of Drug * * * B-Complex Cholinol Capsules*, 362 F.2d 923, 927 (3d Cir. 1966) (no impingement on free speech for FDA to use statements made by a lecturer employed by a manufacturer as evidence of the manufacturer's intent that its products be used for therapeutic purposes).)

Even if the rule were viewed as a direct restriction on speech, it would not violate the First Amendment. The marketing in interstate commerce of a drug that has not been determined by FDA to be safe and effective is illegal (see section 301(a) and (d) of the act (21 U.S.C. 331(a) and (d)) and 505 of the act. Thus, labeling claims that promote a dietary supplement for disease uses promote the product for use as an unapproved new drug, which is illegal. Speech promoting an illegal activity may be restricted without violating the First Amendment (*Central Hudson*, 447 U.S. at 563–564). In *Pittsburgh Press Co.*

v. Pittsburgh Comm'n on Human Relations, 413 U.S. 376 (1973), the Supreme Court held that an advertisement could be prohibited where it indicated that the advertiser was likely to have an illegal intent while engaging in the proposed transaction (*id.* at 389). There, as here, "the restriction * * * is incidental to a valid limitation on economic activity" (*id.*).

Nor does the rule create an unconstitutional prior restraint. FDA does not believe that the regulations in § 101.93(f) and (g) are properly analyzed as a prior restraint at all. As explained previously, the regulations do not restrict speech but rather treat it as evidence of a product's intended use. Using speech to infer intent does not violate the First Amendment (*Wisconsin v. Mitchell*, 508 U.S. 476, 489 (1993)). Thus, the regulations do not prevent speech from happening, but, as evidence of intended use, they determine the consequences that result from certain types of speech. (See *Village of Hoffman Estates v. Flipside*, 455 U.S. at 495–96 (rejecting head shop's "exorbitant" claim that village ordinance treating the proximity of drug-oriented literature as evidence of intended use was a prior restraint).)

Although the regulations cannot themselves be considered as a direct prior restraint, it is true that claims classified as disease claims under the regulations are subject to prior authorization requirements that could be considered prior restraints—namely, the prior authorization requirement for dietary supplement health claims and the new drug approval requirements that are triggered in the absence of health claim authorization. In both cases, a disease claim cannot be made until FDA has evaluated the safety of the product and the evidence supporting the claim. However, labeling claims are commercial speech, and the Supreme Court has indicated that the prior restraint doctrine may not apply to commercial speech. (See *Central Hudson*, 447 U.S. at 571 n.13 ("[C]ommercial speech is such a sturdy brand of expression that traditional prior restraint doctrine may not apply to it."; *Virginia State Bd. of Pharmacy v. Va. Citizens Consumer Council*, 425 U.S. 748, 771–72 n.24 (1976) (greater objectivity and hardness of commercial speech may make prior restraint doctrine inapplicable). Commercial speech is "sturdy" because of its profit motive. "[S]ince advertising is the *sine qua non* of commercial profits, there is little likelihood of its being chilled by proper regulation and forgone entirely" (*Virginia State Bd. of Pharmacy*, 425 U.S. at 771–72 n.24). The same is true

of labeling. The Supreme Court has expressed approval of prior review requirements in commercial speech cases. (See *Shapero v. Kentucky Bar Ass'n*, 486 U.S. 466, 476 (1988) (lawyer may be required to file solicitation letter with State in advance, to give it "ample opportunity to supervise mailings and penalize actual abuses"); *Central Hudson*, 447 U.S. at 571 n.13 (State may require "a system of previewing advertising campaigns").)

If the prior authorization requirement for dietary supplement health claims and the approval requirement for new drugs were to be considered prior restraints, they would be constitutional prior restraints. The only court of appeals to address the issue in the health claims context ruled that the health claims authorization process is not an unconstitutional prior restraint. In a recent case challenging the NLEA and FDA's health claim regulations for dietary supplements, the U.S. Court of Appeals for the Second Circuit held that the prior restraint doctrine did apply, but it went on to uphold the statute and regulations based on consideration of the *Central Hudson* factors. *Nutritional Health Alliance v. Shalala*, 144 F.3d 220, 227-28 (2d Cir.), cert. denied, 119 S. Ct. 589 (1998). In *Nutritional Health Alliance*, the Second Circuit held that the health claims authorization process is "sufficiently narrowly tailored" and has adequate procedural safeguards—including a deadline for final agency action, a decision making standard to constrain the agency's discretion, and provision for development of a record for judicial review—to render it constitutionally valid (144 F.3d at 228; see § 101.70 (procedures for petitioning for a health claim)). In upholding the regulatory scheme, the court also stressed that matters of public health and safety were involved (144 F.3d at 228). The same considerations that the court in *Nutritional Health Alliance* relied on also operate in the new drug approval context: Matters of public health and safety are involved, and the act and implementing regulations provide many procedural safeguards, including a deadline, a decision making standard, and the development of a record for judicial review (see section 505(c)(1), (d), and (h) of the act and; 21 CFR 314.200.) Moreover, as far as FDA is aware, the constitutionality of the new drug approval process has never been challenged on First Amendment grounds. Therefore, FDA does not believe that the prior restraint argument in the comments has merit.

Many of the comments assumed that the test for restrictions on commercial speech set forth by the Supreme Court

in *Central Hudson* applies. FDA believes that it is not necessary to reach the *Central Hudson* test because the rule is constitutional under *Wisconsin v. Mitchell*, *Pittsburgh Press*, and *Village of Hoffman Estates*; however, the rule also easily passes muster under the four-part test in *Central Hudson*. Under that test, the first question is whether the commercial speech at issue is false, misleading, or concerns unlawful activity, because such speech is beyond the First Amendment's protection and may be prohibited. If the speech is truthful, non-misleading, and concerns lawful activity, the government may nonetheless regulate it if the government interest asserted to justify the regulation is substantial; the regulation directly advances the asserted governmental interest; and the regulation is no more extensive than necessary to serve the government interest (*Central Hudson*, 447 U.S. at 566). The Supreme Court has explained that the last element of the test is not a "least restrictive means" requirement, but rather requires narrow tailoring—"a fit that is not necessarily perfect, but reasonable" between means and ends (*Board of Trustees of the State Univ. of N.Y. v. Fox*, 109 S. Ct. 3028, 3032-35 (1989)). In subsequent decisions, the Court has also clarified that "misleading" in the first element of the test refers to speech that is inherently or actually misleading. Thus, if the speech to be regulated is not inherently or actually misleading, the remainder of the test applies. (See *In re R.M.J.*, 455 U.S. 191, 203 (1982).)

As previously discussed, FDA believes that claims for disease uses that have not been found to be safe and effective are speech related to an unlawful activity, and therefore there is no need to reach the remaining elements of the *Central Hudson* test. The agency also considers such claims inherently misleading because, when accompanied by a disclaimer that directly contradicts the claim by stating that the product is not intended to have an effect on disease, they are inherently likely to confuse consumers rather than provide them with useable information. Speech that is "more likely to deceive the public than to inform it" is not protected by the First Amendment (*Central Hudson*, 447 U.S. at 563). If not inherently misleading, claims for disease uses that have not been found to be safe and effective are at least potentially misleading because of the confusion caused by the disclaimer. Such claims also may lead consumers to believe that the product has benefits in

treating or preventing disease, even if that is not the case.

Even if the remaining elements of the *Central Hudson* test are reached, the rule and the statutory provisions that it implements are constitutional. As previously noted, this rule restricts no speech directly. Rather, it determines what types of speech in dietary supplement labeling will trigger other statutory provisions and regulations that may be considered restrictions on speech. To the extent that this rule, the statute, and the drug and health claim regulations restrict speech by requiring either health claim authorization or new drug approval before a business may make a disease claim for a dietary supplement, that restriction directly advances the substantial government interest in protecting and promoting the public health by helping to ensure that products intended to have an effect on a disease are safe and effective for that intended use. That interest is an interest both in preventing direct harm from such products—i.e., protecting the public from adverse events that such products might cause—and in preventing the indirect harm to health that is caused when an ill person foregoes medical care in favor of ineffective self-treatment.

Requiring prior FDA review and authorization of disease claims ensures that such claims will be evaluated by a public health agency that has scientific and medical expertise so that only products that are safe and effective will be permitted to be sold for therapeutic purposes. As a government agency with no financial stake in either permitting or denying claims, FDA is in a position to evaluate the strength of the safety and efficacy evidence objectively.

The rule and the other components of the regulatory framework for drugs and health claims also advance the related substantial government interest in protecting consumers from fraud. If products are marketed for disease uses only after they have been demonstrated to be safe and effective for such uses, consumers will not suffer economic harm from spending money on worthless remedies.

Moreover, the rule is not more extensive than necessary. The agency does not believe that the alternatives mentioned in the comments, or any other alternative, would adequately further its substantial interest in protecting and promoting public health by ensuring the safety and efficacy of products intended to have an effect on disease. For example, allowing implicit disease claims, but not explicit ones, would merely allow companies to do indirectly what they cannot do

directly—to market products for disease uses without demonstrating their safety and efficacy. Likewise, identifying specific terms that connote treatment, cure, or mitigation would not accomplish the goal of requiring proof of the safety and effectiveness of products marketed for disease uses. Merely regulating synonyms for those terms would leave unregulated those claims that achieve the same effect without using such a synonym, such as the claims “herbal Prozac” and “for cancer.” The suggestion in one comment that FDA establish “categories of diseases that clearly denote drug claims” is not a workable alternative either. Section 403(r)(6) of the act provides that the category of structure/function claims excludes claims to affect any category of disease, not just certain categories.

Permitting disease claims under section 403(r)(6) of the act as long as they are accompanied with a disclaimer, as suggested by the comment that cited the Pearson decision, would be an untenable alternative. If companies could avoid the time and expense of complying with the new drug provisions of the act merely by attaching a disclaimer to a disease treatment or prevention claim, the longstanding system of drug regulation in this country would be eviscerated, with serious public health consequences. Nothing in *Pearson* requires such a result. Indeed, the *Pearson* court recognized that its ruling did not apply to drugs (164 F.3d at 656 n. 6). Because the act classifies products on the basis of intended use, dietary supplements that make disease claims are drugs, unless the disease claim is also an authorized health claim for which the product qualifies (see section 201(g)(1) of the act).

The *Washington Legal Foundation* decision is not to the contrary. That case involved the dissemination of information on “off-label” (unapproved) uses for approved drugs and devices to physicians by means of scientific and educational symposia, reprints, and textbooks. The U.S. District Court for the District of Columbia held certain FDA guidance documents that described acceptable ways of disseminating such information unconstitutional under the *Central Hudson* test. While recognizing the substantial government interest in having off-label uses for drugs and devices found to be safe and effective by FDA, the court held that the guidance documents violated the First Amendment because it believed that they “restricted” speech in a manner that was more extensive than necessary to further that interest. (See 13 F. Supp.

2d at 73.) (Subsequent to the 1998 decision cited by the comments, the court rendered another decision adverse to FDA (*Washington Legal Foundation v. Henney*, 1999 WL 557679 (D.D.C. July 28, 1999)). That decision concerned the constitutionality of certain provisions of the FDA Modernization Act of 1997 involving the same subject matter as the guidance documents, and the court’s First Amendment rationale was similar to its rationale in the 1998 decision pertaining to the guidance documents.)

FDA disagrees with the district court decision in *Washington Legal Foundation* and has appealed. In any event, however, the outcome in *Washington Legal Foundation* does not determine the outcome here for several reasons. First, in *Washington Legal Foundation* the court found a less restrictive alternative that it concluded would more precisely address the government’s regulatory concerns: Requiring manufacturers who disseminate information about off-label uses to physicians through scientific reprints or educational symposia to disclose: (1) Their interest in drugs or devices that are the subject of such activities, and (2) the fact that the use discussed has not been approved by FDA. Here, as explained previously, there are no less restrictive alternatives to this rule that would further the government’s substantial public health interest. Second, in *Washington Legal Foundation* physicians were the intended audience of the commercial speech at issue. In contrast, consumers are the primary audience for dietary supplement labeling. Although the marketplace includes consumers of varying levels of sophistication, the average consumer does not possess the medical and scientific expertise necessary to evaluate claims about the effect of a product on disease. (See *American Home Products Corp. v. FTC*, 695 F.2d 681, 698 (3d Cir. 1983); *Association of Nat’l Advertisers, Inc. v. Lungren*, 44 F.3d 726, 733–34 (9th Cir. 1994), cert. denied, 516 U.S. 812 (1995).) Finally, in *Washington Legal Foundation*, it was undisputed that the products involved were drugs (or, in some cases, devices) to be used in treating or preventing disease. In contrast, the purpose of this rule is to distinguish between products that are intended to affect disease and products that are not.

The agency does not believe this rule is premature in light of the need to reassess the regulatory regime for health claims under *Pearson*. Since health claims and structure/function claims are regulated separately, there is no need to wait for any post-Pearson changes for

health claims to be complete before proceeding with this rulemaking on structure/function claims. Moreover, since the agency has decided not to amend the health claims regulations as part of this rulemaking, there is no potential conflict between the two.

The First Amendment issues raised in comments on § 101.93(g)(4)(iii) (proposed § 101.93(g)(2)(iv)(C)), concerning citations to scientific references in labeling, are not different from those raised by comments on the rule as a whole and are addressed in the preceding analysis. FDA also notes that, as discussed elsewhere in this document, § 101.93(g)(4)(iii) has been revised to narrow the circumstances under which the agency will consider citations to scientific references in labeling to be disease claims.

(109.) Another comment further asserted that the prohibition against implied disease claims violates the First Amendment because it does not advance the safety of dietary supplements. The comment acknowledged that some dietary supplements “may present serious safety risks,” but said “these risks will not be lessened by prohibiting truthful, non-misleading structure/function claims * * *.” The comment suggested that other provisions in DSHEA address the safety of dietary supplements and that FDA can bring an enforcement action if it has safety concerns.

FDA agrees with this comment in part and disagrees in part. The agency agrees that prohibiting truthful, non-misleading structure/function claims would not lessen the safety risks posed by some dietary supplements. The rule is aimed at the safety risks posed by unapproved drug claims and unauthorized health claims on dietary supplements. Unproven disease claims on a product marketed as a dietary supplement may induce consumers to treat themselves with the supplement instead of seeking treatments that are known to be effective. Such claims may also dissuade consumers from seeing a doctor. These are very real safety risks. To the extent that safety risks are caused by the composition of a dietary supplement rather than by claims made for it, the agency agrees that other provisions in DSHEA and the act are the appropriate remedy.

2. Equal Protection

(110.) One comment claimed the rule violates the equal protection clause of the Fourteenth Amendment because it supposedly gives more protection to the “labeling rights and speech” of pharmaceutical manufacturers than to dietary supplement manufacturers.

First, it should be noted that the equal protection clause of the Fourteenth Amendment applies only to the States, not to the Federal Government. However, the due process clause of the Fifth Amendment contains an equal protection component that is equivalent to the equal protection clause of the Fourteenth Amendment (*Schweiker v. Wilson*, 450 U.S. 221, 226 & n. 6 (1981)). Even if the comment is interpreted to refer to equal protection under the Fifth Amendment, FDA disagrees with it. First, the comment does not explain in what manner the rule gives more protection to the labeling rights and speech of pharmaceutical manufacturers than to those of dietary supplement manufacturers. Second, even if the rule does treat these two classes of manufacturers differently, treating different regulated groups differently does not in itself violate the equal protection clause. Unless a regulatory classification jeopardizes the exercise of a fundamental right or classifies upon inherently suspect grounds such as race or religion, it is subject to the least exacting form of equal protection review: Whether the classification it draws bears a rational relationship to a legitimate government interest. (See *Nordlinger v. Hahn*, 505 U.S. 1, 10 (1992).)

This rule neither jeopardizes the exercise of a fundamental right nor creates a suspect classification. The purpose of the rule is to clarify the statutory distinction between products that are intended for use in treating or preventing disease and products that are intended for use in affecting the structure or function of the body. Products intended to treat or prevent disease are subject to regulation as drugs, unless they qualify for an authorized health claim. Products intended to affect the structure or function of the body may be regulated as dietary supplements, subject to certain conditions. Products regulated as drugs must meet strict requirements for a premarket demonstration of safety and efficacy (see sections 201(p) and 505 of the act); these requirements do not apply to dietary supplements. The distinction that the statute and this rule draw between products that are intended to have an effect on disease and those that are intended only to affect the structure or function of the body is clearly rationally related to the legitimate government interest of ensuring that products intended to have an effect on a disease are safe and effective for that intended use.

3. Takings Under the Fifth Amendment

(111.) Several comments claimed that the proposal violates the Takings Clause

of the Fifth Amendment because it would prohibit the use of specific terms that now appear in product names, trademarks, trade names, symbols, and company logos, or would harm companies that use such terms in their corporate names. One comment said FDA must provide compensation for each taking, but that the proposal failed to do so.

FDA disagrees with these comments. The Takings Clause forbids the government from taking private property for public use without just compensation. However, FDA believes that no taking will occur as a result of this rule.

The first issue to be considered is whether the categories of names, words, and symbols identified in the comments on this issue are property within the meaning of the Takings Clause. The Constitution itself does not define what qualifies as property. Rather, "existing rules or understandings derived from an independent source," such as State or Federal law, define the interests that qualify for protection as property under the Fifth Amendment (*Lucas v. South Carolina Coastal Council*, 505 U.S. 1003, 1030 (1992)).

The categories of names, words, and symbols mentioned by the comments are intangible property interests. As discussed below, trademarks and trade names are property to the extent that they are associated with business goodwill. A trademark is a word, name, symbol, device, or combination thereof that a person uses, or intends to use and has applied to register, to identify and distinguish his or her goods from others on the market and to indicate their source (15 U.S.C. 1127). A trade name is the name a person uses to identify his or her business (15 U.S.C. 1127) and may include corporate, partnership, and other names. Symbols and logos, when used to identify a product or company, may be property insofar as they are trademarks or trade names. Likewise, product names may be property if they are protected by a trademark or trade name. For brevity, in the remainder of this discussion the categories of names, words, and symbols mentioned by the comments on the takings issue will be referred to collectively as "trademarks and trade names."

Trademarks and trade names are property, but only insofar as they are associated with the goodwill of an ongoing business. (See *American Steel Foundries v. Robertson*, 269 U.S. 372, 380 (1926).) They have no intrinsic value. The purpose of a trademark or trade name is to prevent confusion with the products of another manufacturer. (See *United Drug Co. v. Theodore*

Rectanus Co., 248 U.S. 90, 97 (1918).) Trademarks and trade names are given legal protection to prevent one manufacturer from passing off its goods as the goods of another and thus taking advantage of the latter's goodwill (*American Steel Foundries*, 269 U.S. at 380; *United Drug*, 248 U.S. at 97).

The Supreme Court has declined to prescribe a "set formula" for identifying takings and instead has characterized takings analysis as an "essentially ad hoc, factual" inquiry (*Penn Central Transp. Co. v. City of New York*, 438 U.S. 104, 124 (1978)). Nonetheless, the Court has identified three factors for consideration in assessing whether a regulatory taking has occurred: The character of the governmental action; the regulation's economic impact; and the extent to which the regulation interferes with reasonable investment-backed expectations (*Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1005 (1984)). The force of any one of these factors may be "so overwhelming * * * that it disposes of the taking question" (*Monsanto*, 467 U.S. at 1005). When examined in light of these three factors, the rule does not effect a compensable taking under the Fifth Amendment.

a. *The character of the government action.* With respect to the first factor, the character of the government action, courts are more likely to find a taking when the interference with property can be characterized as a physical invasion by government than when the interference is caused by a regulatory program that "adjust[s] the benefits and burdens of economic life to promote the common good" (*Penn Central*, 438 U.S. at 124). The Supreme Court has held that, when a governmental action is taken in order to protect the public interest in health, safety, and welfare, this factor weighs heavily against finding a taking. (See *Keystone Bituminous Coal Ass'n v. DeBenedictis*, 480 U.S. 470, 488 (1987).) Regulatory actions taken to protect the public health are rarely, if ever, held to constitute takings. (See *Porter v. DiBlasio*, 93 F.3d 301, 310 (7th Cir. 1996) (action taken to protect public health falls within class of property deprivations for which Fifth Amendment does not require compensation); *Jarboe-Lackey Feedlots, Inc. v. United States*, 7 Cl. Ct. 329 (1985) (seizure of adulterated meat not a taking).)

Although these regulations will restrict the use of certain terms, including terms that appear in some trademarks and trade names, this restriction does not rise to the level of a taking. Governmental restrictions on the uses individuals can make of their

property are "properly treated as part of the burden of common citizenship" (*Keystone*, 480 U.S. at 491 (citation omitted)). These burdens are "borne to secure 'the advantage of living and doing business in a civilized community'" (*Andrus v. Allard*, 444 U.S. 51, 67 (1979) (quoting *Pennsylvania Coal Co. v. Mahon*, 260 U.S. 393, 422 (1922) (Brandeis, J., dissenting)). Moreover, these regulations are not without benefit to manufacturers. (See *Keystone*, 480 U.S. at 491 ("While each of us is burdened somewhat by such restrictions, we, in turn, benefit greatly from the restrictions that are placed on others.")) The regulations will help ensure a level playing field in the dietary supplement market because no manufacturer will be able to make an implied disease claim without prior FDA review under the health claim or new drug standard. Previously, unreviewed implied disease claims on dietary supplements proliferated, in part because of uncertainty about the line between structure/function claims and disease claims.

These regulations are rationally related to, and substantially advance, FDA's legitimate interest in promoting and protecting the public health by ensuring the safety and efficacy of products promoted for use in treating or preventing disease. (See *Keystone*, 480 U.S. 470 at 485; *Monsanto*, 467 U.S. at 1007.) By clarifying that such products may not be marketed under the structure/function claim regime, FDA is seeking to ensure that they are regulated through the drug approval or health claims authorization process, as appropriate.

The effect of the regulations cannot be characterized as a taking of property. Dietary supplement companies will not be precluded from using terms that imply a disease claim in their trademarks and trade names. If they wish to continue using trademarks and trade names that imply a disease claim, they may do so, provided that they first meet the safety and efficacy standards and other regulatory requirements applicable to drugs or, in appropriate cases, provided that they obtain authorization to make a health claim. (As discussed below, only non-misleading trademarks and trade names may be used.)

Even if these regulations could be said to prevent a business from using a trademark or trade name on its dietary supplements, such a result still would not constitute a taking of the trademark or trade name. The purpose of giving trademarks and trade names legal protection is to prevent one

manufacturer from passing off its goods as the goods of another (*American Steel Foundries*, 269 U.S. at 380). This regulation will not allow one manufacturer to use another's trademark or trade name; rather, all manufacturers will be precluded from using trademarks and trade names that contain an implied disease claim unless they have obtained new drug approval or health claim authorization. Thus, manufacturers will not suffer any competitive injury.

Moreover, deprivation of a trademark alone is not a deprivation of property. Because the trademark is "merely a protection for the good will" (*Hanover Star Milling Co. v. Metcalf*, 240 U.S. 403, 414 (1916)), only if a regulation takes the owner's goodwill as well would the regulation be a taking. It is not apparent, however, that these regulations will deprive manufacturers of any goodwill. Manufacturers will be faced with a choice as to whether to change their trademark or trade name or to seek approval for their products as drugs. In some cases, they will also have a third option: Seeking authorization to make a health claim. If they are able to obtain drug approval for the intended use suggested by the trademark or trade name, they will not have to change the trademark or trade name, provided that the name is not confusingly similar to the name of another drug or otherwise misleading (see section 502(a)(1) of the act (21 U.S.C. 352(a)(1)); and § 201.10(c)(3) and (c)(5)). Similarly, if they are able to obtain authorization to make a health claim for the intended use suggested by the trademark or trade name, they will not have to change the trademark or trade name unless it is misleading. (See section 403(a)(1) of the act.) Even if a manufacturer chooses to change its trade name or trademark, it will not be deprived of the goodwill underlying them but only of that particular symbol of the goodwill. The manufacturer will still be able to transfer the goodwill associated with its products to another trade name or trademark.

Case law on the treatment of goodwill under the Takings Clause supports the view that no taking will occur as a result of these regulations. The general rule is that the owner of a place of business to which the government takes title is not entitled to compensation for loss of goodwill (*United States v. General Motors Corp.*, 323 U.S. 373, 379 (1945)). The reason for the rule is that the business may reopen at another location to which the goodwill may be transferred (*Kimball Laundry Co. v. United States*, 338 U.S. 1, 11-12 (1949)). Only where the government operates the

business, thereby depriving the owner of its "going-concern value," is there a compensable taking of goodwill. In *Kimball*, the Supreme Court held that the government owed compensation for the loss of goodwill associated with the temporary taking of a laundry during World War II. This action was held to be a taking of goodwill because the government not only physically took but also operated the laundry during the war (*Kimball*, 338 U.S. at 12-13). Thus, during the period that the government operated the laundry, there was no business to whose benefit the goodwill associated with the private laundry business could inure. Here, the government is not taking any trademark or trade name for its own use, nor is it shutting down the businesses that own them. Therefore, the goodwill symbolized by the trademark or trade name will remain with these businesses.

Finally, although trademarks and trade names can be property when they symbolize and protect the goodwill associated with a business, there can be no property interest in an illegal product. Dietary supplements that bear claims to treat or prevent disease are misbranded and are also unapproved new drugs (unless the claim is an authorized health claim). As such, they may not legally be sold in interstate commerce (see section 301 (a) and (d) of the act. There can be no taking of an illegal article. (See *Meserey v. United States*, 447 F. Supp. 548, 554 (D. Nev. 1977) ("Plaintiff has not been denied his property. He is denied the right to introduce his goods into commerce unless they are in compliance with the [Federal Food, Drug, and Cosmetic] Act.")) Moreover, it has always been illegal to market dietary supplements or other foods with disease claims, except that since 1990 the act has permitted authorized health claims. These regulations merely clarify the line between acceptable structure/function claims and prohibited disease claims. (See *Lucas*, 505 U.S. at 1030 ("The use of [property] for what are now expressly prohibited purposes was always unlawful, and * * * it was open to the State at any point to make the implication of those background principles of * * * law explicit" without paying compensation) (emphasis in original).) For this reason and the other reasons previously discussed, the first factor of the takings analysis indicates that these regulations effect no takings.

b. *The economic impact of the government action.* The second factor to consider is the economic impact of the government action. This impact is not to be considered piecemeal by dividing a property interest "into discrete

segments and attempt[ing] to determine whether rights in a particular segment have been entirely abrogated" (*Penn Central*, 438 U.S. at 130). The analysis involves looking not just at what has been lost, but at the nature and extent of the interference with rights in the property as a whole. (See *Penn Central*, 438 U.S. at 130-31; *Andrus v. Allard*, 444 U.S. at 65-66.) Thus, here the total impact of the regulations on property rights should be considered, rather than only whether a business can or cannot continue to use a particular trademark or trade name. It is clear that a regulation's economic impact may be great without rising to the level of a taking. (See *Pace Resources, Inc. v. Shrewsbury Township*, 808 F.2d 1023, 1031 (3d Cir.), cert. denied, 482 U.S. 906 (1987) (citing *Hadacheck v. Sebastian*, 239 U.S. 394 (1915) (reduction in value from \$800,000 to \$60,000); *Euclid v. Ambler Realty Co.*, 272 U.S. 365 (1926) (75 percent diminution in value).)

In assessing whether a regulation effects a taking, the Supreme Court has considered whether the regulation denies an owner the "economically viable" use of its property. (See, e.g., *Keystone*, 480 U.S. at 499.) Although it is undeniable that compliance with these regulations will cost money and may mean that certain trademarks and trade names must be altered, companies will not be denied the economically viable use of their property. As previously discussed, some firms may be able to obtain new drug approval or health claim authorization for those products that bear trademarks or trade names that include disease claims. If approved as new drugs or authorized to bear a health claim, in many cases these products could continue to bear the original trademark or trade name. This approach would, however, require the company involved to make significant expenditures of time and money to submit a new drug application (NDA) or health claim petition to FDA. The financial burden required to comply with such requirements is not a taking under these circumstances, however, just as it is not a taking to require other companies to comply with applicable requirements before marketing a new drug or a food bearing a health claim. Obtaining new drug approval or authorization to make a health claim may be costly, but it is not the kind of economic impact that leads to a taking. "Requiring money to be spent is not a taking of property" (*Atlas Corp. v. United States*, 895 F.2d 745, 756 (Fed. Cir.), cert. denied, 498 U.S. 811 (1990)).

As previously noted in the discussion of the first factor of the takings analysis, case law indicates that the regulations

will cause no loss of goodwill even in cases where a trademark or trade name must be changed because new drug approval or health claim authorization cannot be obtained. Even if the regulations do cause a loss of goodwill, however, FDA believes that the economic impact of that loss of goodwill is outweighed in the takings analysis by lack of reasonable investment-backed expectations in being able to make disease claims in trademarks and trade names.

c. *Interference with reasonable investment-backed expectations.* The final factor to consider is whether a company has a reasonable investment-backed expectation in continuing to use a trademark or trade name. To be reasonable, expectations must take into account the power of the state to regulate in the public interest (*Pace Resources*, 808 F.2d at 1033). Reasonable expectations must also take into account the regulatory environment, including the foreseeability of changes in the regulatory scheme. "In an industry that long has been the focus of great public concern and significant government regulation," *Monsanto*, 467 U.S. at 1008, the possibility is substantial that there will be modifications of the regulatory requirements. "Those who do business in the regulated field cannot object" if the regulatory scheme is "buttressed * * * to achieve the legislative end" (*Connolly v. Pension Benefit Guar. Corp.*, 475 U.S. 211, 227 (1986) (citation omitted)). The lack of a reasonable investment-backed expectation can outweigh the other takings factors and be determinative in whether a taking has occurred (*Monsanto*, 467 U.S. at 1005).

Companies that use trademarks or trade names that include disease claims lack a reasonable investment-backed expectation that they will be able to continue to use those trademarks and trade names. First, the Supreme Court has said that it is unreasonable to have high expectations in personal property (i.e., property other than land): "[I]n the case of personal property, by reason of the State's traditionally high degree of control over commercial dealings, [the property owner] ought to be aware of the possibility that new regulation might even render his property economically worthless * * *." (*Lucas v. South Carolina Coastal Council*, 505 U.S. at 1027-28). Second, the dietary supplement and drug industries are a "focus of great public concern and significant government regulation" (*Monsanto*, 467 U.S. at 1008). A product that bears a disease claim, whether that claim appears in a trademark, trade

name, or elsewhere, has been subject to regulation as a drug since 1906, except that since 1990 the act has permitted conventional foods and dietary supplements to bear authorized health claims without drug approval. Since 1938, drugs (with certain narrow exceptions) have been subject to a premarket approval requirement. Given this longstanding history of close regulation, it cannot be reasonable for a manufacturer or distributor to expect to be able to make disease claims without prior authorization from FDA.

Moreover, it has always been illegal to market dietary supplements or other foods with disease claims, except that since 1990 authorized health claims have been permitted. These regulations merely clarify the line between acceptable structure/function claims and prohibited disease claims. (See *Lucas*, 505 U.S. at 1030 ("The use of [property] for what are now expressly prohibited purposes was always unlawful, and * * * it was open to the State at any point to make the implication of those background principles of * * * law explicit.") Companies in the dietary supplement industry should have been aware that FDA was likely to issue such a clarification, not only because of the regulatory environment generally but also for several specific reasons. First, the passage of DSHEA, which added section 403(r)(6) to the act, created a likelihood that FDA would issue regulations "to achieve the legislative end" of permitting structure/function claims without premarket review, while continuing to prohibit disease claims lacking FDA authorization (see *Connolly*, 475 U.S. at 227 (citation omitted)). Second, the Commission on Dietary Supplement Labels specifically encouraged FDA to clarify the appropriate scope of structure/function statements (Ref. to Commission report, p. 38). Third, the rapidly expanding dietary supplement market and the proliferation of implied disease claims in labeling should have put the industry on notice that FDA might take action.

For all these reasons, there can be no reasonable investment-backed expectations with respect to trademarks and trade names that include disease claims. Thus, the third factor of the takings analysis weighs strongly against finding a taking of property that requires compensation under the Fifth Amendment. Moreover, the three factors, taken together, show that these regulations do not effect such a taking. Therefore, FDA concludes that the comments arguing the contrary are unpersuasive.

IV. Implementation Plan

The preamble to the proposed rule discussed FDA's tentative conclusions regarding the effective date of a final rule and the agency's implementation plan. In general, the preamble to the proposed rule stated that a final rule would become effective 30 days after the date of the final rule's publication in the **Federal Register**. Any product that is marketed for the first time after publication of the final rule, and any new claims made for an existing product for the first time after the publication of the final rule, will be expected to be in compliance beginning 30 days after publication of the final rule. However, small businesses that marketed a product as of the date of publication of a final rule would have had an additional 17 months to bring existing claims (i.e., claims already in the products' labeling on January 6, 2000 for those products into compliance, provided that the small business had notified FDA of the claim as required by section 403(r)(6) of the act and § 101.93(a) and that FDA had not objected to the claim. For all other products that were on the market as of the date of publication of a final rule, FDA would have allowed an additional 11 months beyond the effective date to bring existing claims for those products into compliance, provided that the firm had notified FDA of the claim as required by section 403(r)(6) of the act and § 101.93(a) and that FDA had not objected to the claim. Any product marketed for the first time after the date of publication of the final rule, and any new claim made for an existing product for the first time after publication of the final rule, would have been expected to be in compliance beginning 30 days after the date of publication of a final rule.

(112.) Two comments suggested extending the compliance period to 6 months after the date of publication of a final rule. The comments also advocated that there be no distinction between large and small businesses for compliance dates. The comments further suggested that FDA give businesses whose products were on the market as of the date of publication of a final rule 15 months (instead of 11 or 17 months) to comply. Another comment suggested that the final rule become effective 12 months, rather than 30 days, after its publication date.

FDA believes that the proposed compliance periods of 11 and 17 months following the effective date of the final rule are reasonable and fair, and that the distinction between large and small businesses is appropriate.

FDA has decided, however, that it will not treat manufacturers who have not notified the agency of their claims differently from other manufacturers. At least some of those manufacturers who did not submit 30-day notifications to the agency may have failed to do so believing that notification was not necessary under section 201(g)(1)(C) of the act. Therefore, all manufacturers will have 11 months after the effective date of the final rule to come into compliance, and small businesses will have 17 months after the effective date of the final rule. The agency believes that these compliance periods, uniformly applied, are sufficiently long that it is not necessary to extend the effective date to 6 months after publication in the **Federal Register**.

For a limited transition period, FDA does not intend to take enforcement action against firms who have relied on the agency's September 1997 preamble statements to make a structure/function claim for a dietary supplement under section 201(g)(1)(C) of the act. To allow a reasonable time for the necessary label changes, the transition period will last until the applicable compliance date for the rest of the rule; i.e., small businesses will have 18 months from publication to comply, and other firms will have 12 months. As of the applicable compliance date, firms that have been making structure/function claims under section 201(g)(1)(C) must either remove the claim or comply with the requirements of section 403(r)(6) of the act and § 101.93, including notifying FDA of the claim and relabeling to add the required disclaimer. New structure/function claims are not subject to this transition period; any firm that makes a structure/function claim in the labeling of a dietary supplement after the effective date of this rule must comply with section 403(r)(6) of the act and § 101.93.

V. Environmental Impact

The agency has determined under 21 CFR 25.30(h) and (k), 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.

VI. Analysis of Impacts

A. Background

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Order 12866 directs agencies

to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Regulatory Flexibility Act requires agencies to examine the economic impact of a rule on small entities. The Unfunded Mandates Reform Act requires agencies to prepare an assessment of anticipated costs and benefits before enacting any rule that may result in an expenditure in any one year by State, local and tribal governments, in the aggregate, or by the private sector, of \$100 million (adjusted annually for inflation).

FDA concludes that this final rule is consistent with the principles set forth in the Executive Order and in these two statutes. The agency has determined that the rule is a significant regulatory action as defined by the Executive Order, because it raises novel policy issues. FDA has further determined that the final rule may have a significant economic impact on a substantial number of small entities. This section constitutes the agency's final regulatory flexibility analysis as required under the Regulatory Flexibility Act. Because this rule imposes no mandates on government entities and will not result in private expenditures of \$100 million in any one year, the Unfunded Mandates Reform Act does not require the agency to prepare a cost-benefit analysis.

B. Benefits of the Labeling Requirements

The primary purpose of the rule is to provide a consistent standard for distinguishing between claims that may be made in labeling without prior review by FDA and claims that require prior authorization as health claims or prior review as drug claims. The larger goal is to ensure that information about non-disease-related effects of a dietary supplement on the body may be freely disseminated in labeling, while at the same time guaranteeing that claims for use of a dietary supplement to treat or prevent disease are not made without prior review to ensure that the supplement is safe and effective for that use.

Although dietary supplements can play a valuable role in consumer health, the agency recognizes that, when inappropriately labeled, they can pose unnecessary risks. Such risks arise when the product labeling: (1) Encourages consumers to self-treat for a serious disease without the benefit of a medical diagnosis, or to self-treat for a

serious disease by substituting a dietary product of uncertain value for a medical therapy that has been shown to be safe and effective; (2) encourages consumers to feel sufficiently protected from a serious disease (e.g., cancer) that they delay, or possibly forego, regular screening or early medical attention that may be critical to improved odds of patient survival; or (3) increases the risk of adverse reactions due to interactions with other chemical compounds (e.g., prescription medications) taken by the patient. As consumer spending on dietary supplements continues to rise, the need for an information standard that minimizes these risks becomes more acute.

The rule may also benefit consumers by encouraging manufacturers of dietary supplements to develop the safety and effectiveness data needed to support a health or drug claim. Where disease claims can be made without this demonstration of safety and effectiveness, product manufacturers have less incentive to develop the substantial documentation needed to receive this agency authorization. The availability of additional products with authorized health or drug claims would be extremely useful to the many consumers who have difficulty distinguishing among the variety of products now marketed for particular health concerns.

The dietary supplement industry has grown rapidly, with estimated sales in 1996 of \$10.4 billion for all dietary supplements, including \$4.9 billion for vitamins and \$3.0 billion for nonprescription herbal products (Ref. 8). FDA has limited information on the number of products and quantities sold, or on the age, gender, and disease status of persons currently using dietary supplements. However, a 1997 survey of 43,000 households, conducted by the Hartman and New Hope research organization, indicates that approximately 70 percent of all households reported using vitamins, minerals, or herbal supplements in the past 6 months (Ref. 9). Among survey respondents, those under age 30 accounted for only 8 percent of all households with a member using dietary supplements; ages 30 to 39 accounted for 21 percent, ages 40 to 49 accounted for 22 percent, ages 50 to 59 accounted for 18 percent, and ages 60 or older accounted for 30 percent (Ref. 10). Although the oldest group of survey respondents were, on the whole, less knowledgeable about individual products, they reported more regular product use and more use for specific conditions than younger respondents.

FDA anticipates, therefore, that the final rule will clarify the dividing line between acceptable structure/function claims and disease claims, and thereby reduce the number of inappropriate disease claims in dietary supplement labeling. The defined standard for structure/function claims under section 403(r)(6) of the act will help to avoid instances of inappropriate substitution of dietary products for timely disease screening or medical treatment, and of adverse interactions or contraindications of drug-supplement combinations. In addition, the rule may promote the development of data and information for the support of new health or drug claims. Although FDA cannot quantify these regulatory benefits, the agency expects that this standard will positively support the effective integration of dietary supplements into consumers' overall programs of wellness and self-care.

C. Costs of Compliance

The costs to industry are the direct costs of compliance, which are primarily the costs of the needed product relabeling; and the indirect costs of compliance, which include the potential loss of product sales due to the elimination of disease claims. The following section details the agency's calculation of the direct costs of compliance. FDA has been unable, however, to estimate the extent of the indirect costs of this rule. As explained below, the agency estimates that over 800 dietary supplement products will need to be relabeled due to this rule. The substitution of a valid structure/function claim for a disease claim may, in fact, lead to a decrease in the sale of certain products. The magnitude of this impact, however, is unknown, as most firms will replace the disease claim with a structure/function claim that appeals to many of the same consumers. It is also possible that some firms will avoid a potential drop in sales by developing the safety and effectiveness data needed to obtain either a new drug approval or authorization from FDA to make a health claim. The agency cannot quantify the probability of these occurrences, however, and no industry comment includes such data.

1. Proposed Rule

In the preamble to the proposed rule (63 FR 23624), FDA had projected that the direct costs of compliance would range from \$0.1 million to \$8.5 million. This figure largely reflected agency estimates of the average cost of relabeling a typical dietary supplement product multiplied by the number of dietary supplement products that would

need to be relabeled to conform with the proposed criteria for structure/function claims. The cost categories included administrative, analytical, and inventory disposal activities.

FDA acknowledged that estimates of the number of dietary supplement products were approximate, but projected that the proposed rule would cover about 29,000 products, with about 75,000 distinct labels, or stock keeping units (SKU's). The agency also explained that the rule would directly affect from 500 to 850 manufacturers of dietary supplement products.

To estimate the lower-bound costs of the proposed rule, FDA assumed that the 2,300 notifications initially received from dietary supplement manufacturers adequately represented the number of products with structure/function claims. The agency had already objected to 150 notifications because they contained obvious disease claims, but identified an additional 60 notifications containing one or more claims that might not have met the newly proposed criteria for structure/function claims. Consequently, FDA's lower-bound direct cost estimate included label changes for 60 dietary supplement products. The estimated administrative, redesign, and inventory losses associated with these 60 label changes totaled between \$91,400 and \$123,400.

FDA also presented an upper-bound \$8.5 million estimate of the direct costs of the proposed rule, based on the likelihood that many additional dietary supplements are marketed with structure/function claims. For this estimate, the agency concluded that about 30 percent, or 22,500, of the estimated universe of 75,000 dietary supplement labels contain structure-function claims. Assuming that the proportion of disease claims on all labels containing structure/function claims equals the proportion of disease claims in the 2,300 notifications containing structure/function claims, the agency calculated that up to 585 labels ($60/2,300 \times 22,500$) could need to be changed if the proposed rule became final. The higher costs of the upper-bound estimate resulted both from the substantially increased assumed number of affected labels and from the impact of the significantly shorter compliance period (30 days) for manufacturers that had not notified FDA of their structure/function claim by the publication date of the final rule.

2. Final Rule

A number of the comments submitted in response to the proposed rule specifically addressed FDA's analysis of compliance costs. As a result, the

agency has altered several of its cost assumptions. In addition, FDA has adjusted its analysis to reflect the modified provisions of the final rule. As described below, the agency estimates the total direct costs of the final rule to be about \$3.73 million, but presents sensitivity analysis to indicate that the costs could rise to as much as \$10.35 million under certain worst-case assumptions.

Although several industry comments suggested that FDA had underestimated the costs of relabeling, no comments objected to the specific elements that were considered, i.e., administrative, redesign, and inventory disposal activities. In response, FDA has retained this format for its analysis of the final rule. One comment claimed that FDA had underestimated the number of products that would be affected, but provided no evidence or basis for determining a more accurate count. Another comment stated that the agency's cost estimates were not well explained and that all assumptions were not disclosed. Consequently, FDA has revised its analysis to: (1) Simplify the cost-estimating methodology, (2) clearly present and describe each assumption, (3) fully explain the derivation of the estimated direct costs of compliance, and (4) conduct sensitivity analysis for the remaining areas of significant uncertainty.

a. Cost of designing new labels.

Dietary supplements will no longer be able to make claims whose status was previously unclear, but which now have been defined as disease claims. Firms may comply either by obtaining new drug approval, by receiving authorization from FDA to make a health claim, or by revising their product labeling to eliminate disease claims. Because the cost of submitting adequate documentation to obtain new drug approval or health claim authorization far exceeds the cost of modifying a label, this analysis assumes that the direct costs of the rule will be the costs of modifying labels with disease claims. As explained above, FDA recognizes that some firms may choose to obtain health claim authorization or new drug approval as an alternative means of compliance, or to improve the marketability of their products. The agency believes, however, that it is unlikely that the rule would be the determining factor in a large number of instances.

No public comments provided alternative estimates of the number of affected dietary supplement products. As noted above, FDA had estimated that the industry markets approximately 29,000 covered products with about

75,000 distinct labels. The agency has used this estimate for its analyses of dietary supplement rules over the past several years (e.g., 60 FR 67211 December 28, 1995) and has received no indication from industry that better estimates were available. Although the agency's preliminary analysis reported that an estimated 30 percent of the products (8,700) carry structure/function claims, more recent data from a random survey conducted for FDA by RTI of about 3,000 dietary supplement products indicates that this percentage may have been too low (Ref. 11). Although RTI notes that the surveyed sample is too small to support quantitative inferences for the population of dietary supplements, FDA finds the data to be the best available. The RTI report actually shows that 69 percent of the products in its sample have claims, but this percentage includes "diet supplementation" claims. When adjusted to exclude "diet supplementation" only 62 percent of the products in the RTI data base include relevant claims. Even this 62 percent figure is too high, however, because RTI over-sampled herbal products, which have a higher probability of claims and would not exceed 60 percent and has used this figure as its final estimate.

Of the first 2,300 notifications of structure/function claims reviewed by FDA, no more than 60, or 2.6 percent of the products with claims, would have needed labeling changes due to the criteria described in the proposed rule. Since that time, the total number of notifications with structure/function claims submitted to the agency has increased to about 5,200. A subsequent review of all of the submitted claims indicates that the final rule could require about 1.9 times as many label modifications as the proposed rule, owing largely to the revised criteria for cholesterol claims in the final rule. FDA estimates that the final rule may require revised labels for about 4.81 percent of the 17,400 dietary supplement products (29,000 x 60 percent currently estimated as marketed with structure/function claims (Refs. 15 and 16). (Excluding cholesterol claims would reduce this figure to 1.74 percent of the products with claims.)

The resulting label cost calculations are straightforward. First, the agency found that revised labels (for all claims including cholesterol) may be needed for approximately 837 products (17,400 products with claims x 4.81 percent). Because each product may contain roughly 2.6 distinct SKU's (75,000 SKU's ÷ 29,000 products), labels for an estimated 2,164 SKU's may need to be modified (837 products x 2.6 SKU's/

product). As described in its earlier analysis, based on an average of the estimates provided in comments to earlier rules, FDA determined that the average label redesign cost is about \$1,700 per dietary supplement SKU for a 12-month compliance period, and \$1,300 for an 18-month compliance period. No industry comment questioned the reasonableness of these unit cost estimates.

The final rule sets compliance periods of 1 year for large firms (revenues above \$20 million) and 18 months for small firms (revenues below \$20 million), except that new claims (i.e., claims not made before the publication of the final rule) must be in compliance as of the effective date. Such claims will not necessitate relabeling, however. FDA does not know the size of the firms that will need to make label changes. RTI (Ref. 12) reports that 95 percent of the firms in the industry are small, but that the 5 percent that are large account for 80 percent of industry sales. The RTI product data base also indicates that approximately 25 percent of the sample products were manufactured by just 5 percent of the companies. Thus, FDA has assumed that approximately one-quarter of the affected products will come from large firms and three-quarters from small firms. Consequently, the total estimated label redesign costs equal about \$3.03 million (i.e., \$1,700 x 0.25 x 2,164 SKU's + \$1,300 x 0.75 x 2,164 SKU's).

b. Administrative costs. One industry comment contended that FDA had not adequately explained the basis for its company-specific administrative costs, estimated at \$425 and \$320 respectively, for 12-month and 18-month compliance periods. These figures were derived from data presented in a 1991 RTI report on the cost of FDA's food labeling regulations (Ref. 13). They included costs associated with interpreting a regulation, determining the manner of compliance and managing the compliance method. RTI had estimated that, on average, small firms would bear administrative costs of \$850 to comply with the new food labeling rules for a 1-year compliance period, and \$650 for a 2-year compliance period. For its analysis of the proposed rule, FDA reduced this figure by fifty percent, based on the smaller administrative effort that would be needed to comply with the proposed rule, compared to the conventional food labeling regulations evaluated by RTI in 1991. The regulations that were the subject of the 1991 RTI evaluation involved a broader range of administrative options and tasks, such as nutritional testing and

product reformulation. (The \$320 estimate for the 18-month compliance period was determined by interpolating between the estimates for 12 and 24 months.) The agency has raised these costs by about 27 percent to \$540 and \$407, respectively, to account for salary inflation since 1991 (Ref. 14).

FDA had initially estimated that 500 to 850 firms manufacture dietary supplements. The recent RTI study, however, has identified 1,050 manufacturers (Ref. 12). This higher number probably overestimates the size of the industry covered by this rule, because it includes homeopathic products, which are drugs by statutory definition, and "functional foods" and sports nutrition products, which may be either conventional foods or dietary supplements depending on how they are marketed and used. For this final analysis, FDA has assumed that 1,000 companies manufacture the dietary supplement products covered by this rule. Although only a small fraction of these establishments will need to implement changes in labeling due to this rule, the agency anticipates most firms will review the final rule to assess whether their labeling will be affected.

The administrative costs of the final rule would likely be higher for those firms that will need to revise labels and lower for those firms that do not. Nevertheless, FDA assumes that, on average, all large dietary supplement manufacturers would incur costs of \$540 and all small dietary supplement manufacturers would incur costs of \$407. As noted above, RTI found that about 95 percent of the firms in this industry are small. Thus, the agency calculated administrative costs to equal about \$413,000 (i.e., 950 small firms x \$407 + 50 large firms x \$540). FDA notes that these estimates may overstate the incremental administrative costs of this final rule, because dietary supplement firms must already comply with DSHEA and this rule is meant to clarify the meaning of that act, rather than to add new requirements. Nevertheless, the agency's sensitivity analysis, presented below, doubles the above cost estimates.

c. Costs of inventory losses. The final cost component involves the value of lost inventory. FDA's preliminary analysis relied on information from an earlier nutrition labeling rule that affected the entire dietary supplement industry. That information indicated that inventory disposal costs for the entire industry would be about \$8 million for an 18-month compliance period and \$15 million for a 12-month compliance period. As explained above, FDA estimated that about 2.89 percent

of the dietary supplement products will require new labels as a result of this rule (837 + 29,000) and that about three quarters of the affected products are manufactured by small firms. Thus, total inventory disposal costs are calculated at \$281,000 (i.e., \$8 million x 2.89 percent x 0.75 + \$15 million x 2.89 percent x 0.25).

d. Total direct compliance costs. As described above, FDA has assumed the direct compliance costs of this rule to be the costs associated with relabeling those dietary supplements whose labeling claims are considered disease claims under the newly defined criteria. Redesign costs are estimated at \$3.03 million, administrative costs at \$413,000, and inventory disposal costs at \$281,000. In sum, therefore, the total estimated direct compliance costs equal almost \$3.73 million.

In addition, there may be costs associated with the discussion in the final rule concerning structure/function claims made under section 201(g)(1)(C) of the act. (See response to comment 95 in section III.A.1 of this document.) The agency believes that some firms have been making structure/function claims for dietary supplements without including a disclaimer statement or notifying FDA, based on FDA's statements in a 1997 preamble (62 FR 49859 at 49860, 49863, and 49864). Because the agency has not repudiated these statements, any firm that has relied on them to make a claim for a dietary supplement will need to add the disclaimer to all applicable labels, as well as to notify FDA, according to the requirements of this section 403(r)(6) of the act and § 101.93. Because firms making such claims have not identified themselves to FDA, the agency does not have a reliable database on which to base a cost estimate of the number of firms and products that may incur costs to comply with this new provision.

The costs to industry of the final rule are substantially different from the costs of the proposed rule, because of two important changes to the proposed requirements. First, the final rule requires more product labels to be changed, because it includes more specific parameters for acceptable structure/function claims about cholesterol. This change increases the direct compliance costs of the final rule. Second, the proposed rule required needed label modifications to be completed within 30 days after publication of the final rule, for those products without a properly submitted claim notification. Roughly 70 percent of all products with claims may have fallen into this group (1–5,200 products without notifications + 17,400 products

with claims). Because relabeling costs are reported to double for each halving of the compliance period, compliance costs would have been eight times greater for those products. For the final rule, all large firms will be expected to comply within 12 months, and all small firms within 18 months, regardless of whether the firm has notified FDA of the structure/function claims on its products. This change significantly reduces the direct compliance costs of the final rule.

e. Sensitivity analysis. Due to uncertainty with respect to several factors in the agency's direct cost model, FDA has prepared a sensitivity analysis of other possible cost scenarios. First, FDA tripled the percentage of product notifications assumed to be out of compliance with the new criteria for structure/function claims. This change results in almost tripling the total direct compliance costs of the regulation, raising the estimate from about 3.73 million to about 10.35 to about \$5.93 million. Second, FDA doubled its estimate of administrative costs. This change raises the initial cost estimate to about \$4.14 million. Changing both assumptions simultaneously raises the total estimated costs to about \$11 million. Finally, under the initial scenario, if all of the needed label changes were assumed to affect only small businesses, the total cost estimate rises to about \$3.46 million. This sensitivity analysis indicates that the total direct costs of this rule would not impose a major burden on this industry even if the most uncertain cost factors are doubled or tripled from FDA's best estimates.

D. Other Industry Comments

Several comments insisted that FDA had not conducted a comprehensive cost-benefit analysis of the proposed rule, as required under Executive Order 12866. These comments stated that FDA's economic analysis ignored both the potential savings in consumer health care expenditures that would be lost by restricting important labeling information, as well as the likely negative effect of the proposal on the growth of the dietary supplement industry. One industry comment, for example, declared that a substantive cost-benefit analysis "must identify the potential health benefits that are lost as a consequence of reduced consumer access to useful information about the health-related properties of dietary supplements and ingredients." It noted that FDA's analysis "fails to consider the public health benefits associated with ingesting dietary supplements as

well as the losses to public health that could result from consumers failing to take appropriate dietary supplements due to uninformative structure/function claims." That comment also maintains that "FDA's failure to assess and consider such benefits (and costs) stands in contrast with the specific finding of DSHEA that 'appropriate use of safe nutritional supplements will limit the incidence of chronic diseases, and reduce long-term health care expenditures.'" The comment also points out that FDA has performed such analyses in other rulemakings, e.g., tobacco, nutrition labeling, and ephedra regulations.

FDA disagrees. Although Executive Order 12866 directs agencies to assess the costs and benefits of economically significant rules, the quantification of these expected costs and benefits is required only "to the extent feasible" (58 FR 51735 at 51741, October 14, 1993). As described above, FDA believes that its final rule strikes the appropriate balance with respect to health-related claims in dietary supplement labeling. The rule classifies certain claims as acceptable structure/function claims that may be made without prior FDA review. Although the provision of structure/function information to consumers may reduce health care expenditures, no health organization, industry association, or any other interested public or private group has presented information or data that would allow the agency to develop a quantifiable estimate of the health care benefits. The rule classifies other claims as disease claims that are subject to existing requirements for new drug approval or health claim authorization before a product may be marketed with the claim. FDA believes that classifying claims into a category that requires FDA review of safety and efficacy evidence, where appropriate, will similarly reduce long-term health care expenditures. Again, however, the agency has no means of quantifying the probable health outcomes of this aspect of the rule and therefore has no means of quantifying its impact on health care expenditures. Because this analysis discusses the types of benefits and costs reasonably expected, and quantifies those that can be "feasibly" quantified, the agency has, in fact, complied with the direction of Executive Order 12866.

FDA has attempted to quantify the benefits of some of its previous regulations. The agency's estimated benefits of the tobacco rule relied on a widely established risk assessment published by the American Cancer Society. Estimated benefits of the proposed ephedra rule were based on

incidents identified in the agency's adverse event database. Estimated benefits of the nutrition labeling rule were derived from epidemiological studies of the consequences of dietary fat. In each case, the agency believed that it had a reasonably reliable data base upon which to base conclusions, and each risk assessment dealt with the risks of a single substance (tobacco, ephedra, and dietary fat). In contrast, this structure/function rule governs structure/function claims in the labeling for all dietary supplements. Although the agency could conceivably analyze a few of the claims covered by the rule, adequate data on the benefits and risks of most of these products are not available. Consequently, the agency believes that this rule will improve the nation's health, but concludes that it cannot feasibly quantify the effects of the rule on the nation's health expenditures.

One industry comment suggested that the regulatory system could impede firms from conducting research to substantiate structure/function claims, if DSHEA is construed so narrowly that it excludes meaningful health-related benefits. This comment noted, however, that the absence of an enforceable legal standard for substantiation would discriminate against companies that do research to support their claims and would deter science-based companies from entering the market. Similarly, a patient organization and several pharmaceutical companies expressed concern that the rule would permit some products to escape regulation as drugs and therefore diminish incentives for the costly clinical research conducted by pharmaceutical companies and academic scientists.

As stated previously in the document, FDA is not aware of any evidence that would indicate that the establishment of criteria for distinguishing structure/function claims from disease claims will adversely affect the conduct of scientific research. In fact, FDA believes that the final rule accords with the intent of DSHEA in promoting the enhancements to consumer health expected from the broad dissemination of structure/function information, while reducing the risks to consumer health associated with the promotion of disease treatment and/or prevention uses for products whose safety and efficacy have not been demonstrated.

E. Regulatory Alternatives

FDA has considered several major alternatives to the proposed rule as part of the rulemaking process. These include: (1) Taking no new regulatory action; (2) treating a statement about a

dietary supplement as a disease claim only if the statement included an express reference to a specific disease; and (3) treating a statement about a dietary supplement as a disease claim if the statement mentions an abnormality of the structure or function of the body, even if the abnormality was not characterized by a set of signs or symptoms recognized as the disease. These alternatives are fully discussed in the preamble to the proposed rule (63 FR 23624 at 23630) and alternative (2) is also discussed extensively in section II.E of this document. In brief, FDA finds that the public comment does not include evidence or arguments sufficient to persuade the agency to support these alternatives.

Within the broad framework of the final rule, FDA weighed other policy changes that could affect the compliance costs. One option would have set the compliance period for all firms at 6 months and another at 12 months from the publication date of the final rule. Other options would have extended the compliance period beyond 18 months for small businesses, or completely exempted small businesses from the rule. Finally, the proposed rule would have permitted firms 12 or 18 months to comply, depending on whether they were large or small firms; but only if they had submitted timely notifications of their structure/function claims to FDA and FDA had not objected to the claims. Other firms had only a 30-day compliance period.

Based on its model of food labeling costs, FDA assumes that compliance costs double for each halving of the compliance period (Ref. 13). Thus, the first option, which set a 6-month compliance date for all firms, results in average relabeling costs twice as high as that of the 12-month compliance period. FDA decided that this additional burden was not warranted. The option of a 12-month compliance period for small as well as large firms was rejected because of the additional burden to small firms, which may find it more difficult to effect rapid shifts in labeling procedures. The final rule provides small firms with an additional 6 months to introduce these labeling changes. Extending the compliance date for small firms beyond 18 months was rejected, because the agency did not believe that the delayed consumer benefits would be balanced by the relatively modest additional cost saving. Exempting all small firms was not acceptable, because most firms covered by this rule are small. The final option, which was to include the compliance periods specified in the proposed rule, required label changes within 30 days for

products bearing claims of which FDA had not been notified or claims to which FDA had already objected. This option was rejected because it could have increased costs per label for many small firms by a factor of eight.

F. Small Business Impacts

As stated above, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities, unless the rule is not expected to have a significant economic impact on a substantial number of small entities. With this final rule, FDA is defining the types of statements that can be made concerning the effect of a dietary supplement on the structure or function of the body. It also establishes criteria for determining when a statement represents a claim to diagnose, cure, mitigate, treat, or prevent disease and thus is not acceptable as a structure/function claim. The regulation was prepared in response to the dietary supplement industry's request for clarification from FDA with respect to the distinction between structure/function and disease claims, and to guidance in the Commission report suggesting that FDA provide such clarification to industry.

For its analysis of the proposed rule, FDA had estimated that between 500 and 850 firms were involved in dietary supplement manufacturing. A more recent industry survey reports that 1,050 companies manufacture dietary supplements; although as explained above, some of these companies may

manufacture products not covered by this rule. FDA has projected the industry size for this rule at about 1,000 firms. The Small Business Administration (SBA) has determined that dietary supplement manufacturers with fewer than 500 employees are small businesses. Because most data sources characterize firms in this industry by sales revenues rather than employment size, and because company revenues of less than \$20 million correlate reasonably well with a 500 employee threshold, FDA has received approval from the SBA to use a less-than-\$20 million sales revenue standard to represent small dietary supplement manufacturers. Table 1 displays the reported size distribution of the dietary supplement manufacturing industry.

As described above, FDA assumes that all small manufacturers of dietary supplements will incur administrative costs of about \$407 per firm. In addition, a number of small manufacturers of dietary supplements will need to alter some product labels, at an average redesign cost of about \$1,300 per SKU, and an average inventory cost of about \$107 per SKU. FDA further analyzed the dietary supplement product data base described in the October 1999 RTI report (Ref. 11) to determine how these products may be distributed among small businesses. As noted earlier, FDA estimates that about 628 of the 837 products (75 percent) needing revised labels due to this rule are manufactured by small firms. If these 628 products were randomly distributed among the 950 small

businesses, less than 0.1 percent of the small firms (1 firm) would be likely to have more than 4 of these products and only about 3 percent (30 firms) to have more than 2 of these products.

A small firm that needs to redesign labels for three products (about eight SKU's) due to the rule will incur estimated one-time direct compliance costs of about \$11,650. A small firm that needs to redesign labels for 4 products (about 10 SKU's) would incur costs of about \$14,950, or roughly 1.2 percent of average company revenue. Thus, the assumption that these products are randomly distributed among small firms indicates that very few small businesses would be likely to incur relabeling costs that are greater than 1 percent of average small company revenue. It is possible, however, that some firms will have a disproportionate number of labels to be revised. In the RTI database of 3,000 randomly selected products, only 3 companies (all large) have more than 24 products. Although the data base sample show a number of small companies with up to 24 products, it is very unlikely that all of these product labels would need to be changed due to this rule. If a small company needed to revise 10 products, however, its direct costs of compliance would be about \$37,000. Moreover, although FDA cannot quantify the likelihood, some small firms could lose product sales due to the necessary removal of a disease claim from a product label. Thus, FDA finds that this rule may have a significant economic impact on a substantial number of small companies.

TABLE 1.—ESTIMATED NUMBER OF DIETARY SUPPLEMENT MANUFACTURERS AND REVENUES, BY SIZE CATEGORY¹

Size Category	Number of Companies	Revenues (\$ in billions)	Percentage of Market
>\$100 million	16	3.32	55%
\$20 to \$100 million	38	1.54	25%
<\$20 million	996	1.19	20%
Total	1,050	6.05	100%

¹ Research Triangle Institute, "Economic Characterization of the Dietary Supplement Industry," March 1999, pp. 5-15.

VII. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Commission on Dietary Supplement Labels, *Report to the President, Congress,*

and the Secretary of the Department of Health and Human Services, November 1997.

2. *Dorland's Illustrated Medical Dictionary*, 28th ed., W. B. Saunders Co., Philadelphia, p. 478, 1994.

3. *Stedman's Medical Dictionary*, 26th ed., Williams & Wilkins, Baltimore, p. 492, 1995.

4. *The Encyclopedia Americana*, International Edition, Grolier Inc., Danbury, p. 168, 1985.

5. *Black's Law Dictionary*, 6th ed., West Publishing Co., St. Paul, p. 467, 1990.

6. *The Merck Manual*, 17th ed., Merck Research Laboratories, Whitehouse Station, NJ, p. 416, 1999.

7. *Webster's Encyclopedic Unabridged Dictionary*, p. 1057, 1989.

8. *Economic Characterization of the Dietary Supplement Industry*, prepared for DHHS/FDA/CFSSAN by Research Triangle Institute, Center for Economics Research under Contract No. 223-96-2290: Task Order 3, Final Report, p. 5-2, March 1999.

9. Herb and Supplement Usage Nears 70 Percent, Natural Foods Merchandiser, www.nfm-online.com/nfm_backs/Feb_98/herbusage.html.

10. Wyngate, P., Consumers Not Supplement Brand Savvy, Natural Foods Merchandiser, www.nfm-online.com/nfm_backs/Mar_98/brandsavvy.html.

11. *Dietary Supplement Sales Information*, prepared for DHHS/FDA/CFSSAN by Research Triangle Institute, Center for Economics Research Under Contract No. 223-96-2290:

Task Order 4, Final Report, pp. 5-8, October 1999.

12. Research Triangle Institute, *Economic Characterization of the Dietary Supplement Industry*, p. 5-15.

13. Research Triangle Institute, "Compliance Costs of Food Labeling Regulations," prepared for CFSAN/FDA by RTI under Contract No. 223-87-2097, final report, pp. 5-3, 5-4, January 1991.

14. U.S. Department of Labor, Bureau of Labor Statistics, BLS.

15. Memorandum from R. J. Moore, FDA, to file, calculation of notifications made pursuant to 21 U.S.C. 343(r)(6).

16. Memorandum from J. Lienesch, FDA, to file, calculation of relabeling cost estimate for final rule on statements made for dietary supplements concerning the effect of the production on the structure or function of the body, December 22, 1999.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371.

2. Section 101.93 is amended by revising the section heading and by adding paragraphs (f) and (g) to read as follows:

§ 101.93 Certain types of statements for dietary supplements.

* * * * *

(f) *Permitted structure/function statements.* Dietary supplement labels or labeling may, subject to the requirements in paragraphs (a) through (e) of this section, bear statements that describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans or that characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such

structure or function, provided that such statements are not disease claims under paragraph (g) of this section. If the label or labeling of a product marketed as a dietary supplement bears a disease claim as defined in paragraph (g) of this section, the product will be subject to regulation as a drug unless the claim is an authorized health claim for which the product qualifies.

(g) *Disease claims.* (1) For purposes of 21 U.S.C. 343(r)(6), a "disease" is damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition.

(2) FDA will find that a statement about a product claims to diagnose, mitigate, treat, cure, or prevent disease (other than a classical nutrient deficiency disease) under 21 U.S.C. 343(r)(6) if it meets one or more of the criteria listed below. These criteria are not intended to classify as disease claims statements that refer to the ability of a product to maintain healthy structure or function, unless the statement implies disease prevention or treatment. In determining whether a statement is a disease claim under these criteria, FDA will consider the context in which the claim is presented. A statement claims to diagnose, mitigate, treat, cure, or prevent disease if it claims, explicitly or implicitly, that the product:

(i) Has an effect on a specific disease or class of diseases;

(ii) Has an effect on the characteristic signs or symptoms of a specific disease or class of diseases, using scientific or lay terminology;

(iii) Has an effect on an abnormal condition associated with a natural state or process, if the abnormal condition is uncommon or can cause significant or permanent harm;

(iv) Has an effect on a disease or diseases through one or more of the following factors:

(A) The name of the product;

(B) A statement about the formulation of the product, including a claim that the product contains an ingredient (other than an ingredient that is an article included in the definition of "dietary supplement" under 21 U.S.C. 321(ff)(3)) that has been regulated by FDA as a drug and is well known to consumers for its use or claimed use in preventing or treating a disease;

(C) Citation of a publication or reference, if the citation refers to a disease use, and if, in the context of the labeling as a whole, the citation implies treatment or prevention of a disease, e.g., through placement on the immediate product label or packaging, inappropriate prominence, or lack of relationship to the product's express claims;

(D) Use of the term "disease" or "diseased," except in general statements about disease prevention that do not refer explicitly or implicitly to a specific disease or class of diseases or to a specific product or ingredient; or

(E) Use of pictures, vignettes, symbols, or other means;

(v) Belongs to a class of products that is intended to diagnose, mitigate, treat, cure, or prevent a disease;

(vi) Is a substitute for a product that is a therapy for a disease;

(vii) Augments a particular therapy or drug action that is intended to diagnose, mitigate, treat, cure, or prevent a disease or class of diseases;

(viii) Has a role in the body's response to a disease or to a vector of disease;

(ix) Treats, prevents, or mitigates adverse events associated with a therapy for a disease, if the adverse events constitute diseases; or

(x) Otherwise suggests an effect on a disease or diseases.

Dated: October 26, 1999.

Jane E. Henney,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

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Thursday, January 6, 2000

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FEDERAL REGISTER PAGES AND DATE, JANUARY

1-200..... 3
201-344..... 4
345-688..... 5
689-1050..... 6

CFR PARTS AFFECTED DURING JANUARY

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	18 CFR
Executive Orders:	35.....810
12543 (See Notice of December 29, 1999).....199	21 CFR
12544 (See Notice of December 29, 1999).....199	101.....1000
Administrative Orders:	201.....7
Presidential Determinations:	341.....7
No. 2000-9 of December 23, 1999.....689	369.....7
Notices:	Proposed Rules:
December 29, 1999.....199	216.....256
7 CFR	22 CFR
1220.....1	22.....352
Proposed Rules:	514.....352
800.....75	23 CFR
868.....78	655.....9
930.....672	26 CFR
9 CFR	301.....215
93.....345	Proposed Rules:
303.....201	1.....258
381.....201	301.....263
Proposed Rules:	26 CFR
130.....391	1.....701
12 CFR	29 CFR
935.....202	2550.....614
960.....203	30 CFR
Proposed Rules:	250.....217
900.....324	39 CFR
910.....324	Proposed Rules:
917.....81	111.....264
941.....324	206.....403
14 CFR	32 CFR
39...1, 204, 205, 207, 209, 211, 213, 346, 691, 692, 695, 697	Proposed Rules:
71.....348, 349, 699, 700	813.....419
97.....350	33 CFR
382.....352	117.....353, 710
Proposed Rules:	154.....710
39.....250, 251, 254, 395, 397, 399, 401, 0	155.....710
71.....402	38 CFR
108.....560	17.....762
109.....560	51.....762
111.....560	58.....762
129.....560	40 CFR
191.....560	52.....14, 16
15 CFR	82.....716
902.....30	300.....19
Proposed Rules:	721.....354
303.....731	Proposed Rules:
16 CFR	52.....104, 421, 732
1700.....93	180.....425

45 CFR	73.....219, 220	49 CFR	648.....377
Proposed Rules:	76.....375	1.....220	660.....221
160.....427	Proposed Rules:	Proposed Rules:	679.....60, 65, 74, 380
164.....427	73.....270	1244.....732	Proposed Rules:
46 CFR			18.....109
Proposed Rules:	48 CFR	50 CFR	216.....270
356.....646	Proposed Rules:	17.....20	222.....270
47 CFR	1804.....429	216.....30	223.....105
0.....374	1852.....429	300.....59	226.....105
		600.....221	300.....272
			648.....275, 431

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 JANUARY 6, 2000**ENVIRONMENTAL PROTECTION AGENCY**

Air programs:

- Stratospheric ozone protection—
- Essential-use allowances; allocation; published 1-6-00

Air quality implementation plans; approval and promulgation; various States:

- District of Columbia; published 12-7-99

Hazardous waste:

- Mercury-containing lamps (light bulbs); published 7-6-99

INTERIOR DEPARTMENT Fish and Wildlife Service

Endangered and threatened species:

- Critical habitat designation—
- Western snowy plover, Pacific coast population; published 12-7-99

COMMENTS DUE NEXT WEEK**AGRICULTURE DEPARTMENT****Agricultural Marketing Service**

Milk marketing orders:

- Central Arizona and New Mexico-West Texas; comments due by 1-10-00; published 11-10-99

Onions (Vidalia) grown in—

- Georgia; comments due by 1-12-00; published 12-13-99

Spearmint oil produced in Far West; comments due by 1-12-00; published 12-13-99

AGRICULTURE DEPARTMENT**Animal and Plant Health Inspection Service**

Exportation and importation of animals and animal products:

- Scrapie in sheep and goats; movement restrictions and indemnity program;

comments due by 1-14-00; published 1-7-00

AGRICULTURE DEPARTMENT**Farm Service Agency**

Mediation; certified mediation program; comments due by 1-10-00; published 11-9-99

Program regulations:

- Farm loan programs
- account servicing policies; servicing shared
- appreciation agreements; comments due by 1-10-00; published 11-10-99

AGRICULTURE DEPARTMENT**Rural Business-Cooperative Service**

Program regulations:

- Farm loan programs
- account servicing policies; servicing shared
- appreciation agreements; comments due by 1-10-00; published 11-10-99

AGRICULTURE DEPARTMENT**Rural Housing Service**

Program regulations:

- Farm loan programs
- account servicing policies; servicing shared
- appreciation agreements; comments due by 1-10-00; published 11-10-99

AGRICULTURE DEPARTMENT**Rural Utilities Service**

Program regulations:

- Farm loan programs
- account servicing policies; servicing shared
- appreciation agreements; comments due by 1-10-00; published 11-10-99

AGRICULTURE DEPARTMENT

Mediation; certified mediation program; comments due by 1-10-00; published 11-9-99

COMMERCE DEPARTMENT**National Institute of Standards and Technology**

Fastener Quality Act; implementation; comments due by 1-14-00; published 12-15-99

COMMERCE DEPARTMENT National Oceanic and Atmospheric Administration

Endangered and threatened species:

- Sea turtle conservation; Pamlico Sound, NC; closure to mesh gillnet fishing; comments due by 1-10-00; published 12-16-99

- Sea turtle conservation; shrimp trawling requirements

Turtle excluder device; comments due by 1-12-00; published 12-13-99

Fishery conservation and management:

- Alaska; fisheries of Exclusive Economic Zone—
- Bering Sea and Aleutian Islands groundfish; comments due by 1-12-00; published 12-13-99
- Gulf of Alaska groundfish; comments due by 1-12-00; published 12-13-99

DEFENSE DEPARTMENT

Acquisition regulations:

- Voluntary consensus standards (OMB Circular A-119); comments due by 1-10-00; published 11-9-99

Civilian health and medical program of uniformed services (CHAMPUS):

- TRICARE program—
- Family member dental plan; comments due by 1-14-00; published 12-15-99

ENVIRONMENTAL PROTECTION AGENCY

Air pollution control; new motor vehicles and engines: Light-duty vehicles and trucks—

- Pre-production certification procedures; compliance assurance programs; reconsideration petition; comments due by 1-14-00; published 12-17-99

FEDERAL COMMUNICATIONS COMMISSION

Common carrier services:

- Internet telephony and computer based equipment; access by persons with disabilities; comments due by 1-13-00; published 11-19-99

Radio stations; table of assignments:

- California; comments due by 1-10-00; published 12-8-99
- Michigan; comments due by 1-13-00; published 12-8-99
- Texas; comments due by 1-10-00; published 12-8-99

Television broadcasting:

- Satellite Home Viewer Improvement Act; implementation—
- Retransmission consent issues; comments due by 1-12-00; published 12-29-99

FEDERAL LABOR RELATIONS AUTHORITY

Equal Access to Justice Act; implementation:

Attorney fees regulations; comments due by 1-13-00; published 11-29-99

FEDERAL RESERVE SYSTEM

Truth in lending (Regulation Z):

- Short-term cash advances (payday loans); comments due by 1-10-00; published 11-5-99

HEALTH AND HUMAN SERVICES DEPARTMENT**Child Support Enforcement Office**

Child support enforcement program:

- National Medical Support Notice; child support orders; health care coverage provisions; comments due by 1-14-00; published 11-15-99

INTERIOR DEPARTMENT Fish and Wildlife Service

Endangered and threatened species:

- Columbian white-tailed deer; comments due by 1-14-00; published 12-29-99

- Spikedace and loach minnow; comments due by 1-14-00; published 12-10-99

Marine mammals:

- Incidental take during specified activities—
- Beaufort Sea, AK; year-round oil and gas industry operations; polar bears and Pacific walrus; comments due by 1-13-00; published 1-3-00

Incidental taking—

- Beaufort Sea et al., AK; oil and gas industry operations; polar bears and Pacific walruses; comments due by 1-10-00; published 12-9-99

INTERIOR DEPARTMENT National Park Service

Special regulations:

- Denali National Park and Preserve, AK; traditional activities definition; comments due by 1-11-00; published 11-12-99

MINE SAFETY AND HEALTH FEDERAL REVIEW COMMISSION**Federal Mine Safety and Health Review Commission**

Procedural rules; comments due by 1-10-00; published 12-8-99

INTERIOR DEPARTMENT**National Indian Gaming Commission**

Indian Gaming Regulatory Act:

Classification of games;
comments due by 1-10-00; published 11-10-99

NUCLEAR REGULATORY COMMISSION

Rulemaking petitions:

Union of Concerned Scientists; comments due by 1-10-00; published 10-27-99

PERSONNEL MANAGEMENT OFFICE

Pay administration:

Payments during evacuation; comments due by 1-14-00; published 12-15-99

POSTAL SERVICE

Domestic Mail Manual:

SAVE verification procedures and revisions—

Combined postage payment standards; automation letter mail; comments due by 1-10-00; published 12-9-99

SECURITIES AND EXCHANGE COMMISSION

Investment advisers:

Broker-dealers deemed not to be investment advisers; comments due by 1-14-00; published 11-10-99

TRANSPORTATION DEPARTMENT

Coast Guard

Drawbridge operations:

California; comments due by 1-11-00; published 11-12-99

TRANSPORTATION DEPARTMENT

Federal Aviation Administration

Airworthiness directives:

Air Cruisers Co.; comments due by 1-10-00; published 11-9-99

Airbus; comments due by 1-13-00; published 12-14-99

Bell; comments due by 1-14-00; published 11-15-99

Boeing; comments due by 1-10-00; published 11-24-99

British Aerospace; comments due by 1-10-00; published 12-9-99

CFM International; comments due by 1-12-00; published 12-13-99

Dassault; comments due by 1-10-00; published 12-9-99

Fokker; comments due by 1-12-00; published 12-13-99

Israel Aircraft Industries, Ltd.; comments due by 1-10-00; published 12-9-99

McDonnell Douglas; comments due by 1-14-00; published 11-30-99

Transport category airplanes—

Mode ≥C≥ transponders with single Gillham code altitude input; comments due by 1-11-00; published 11-12-99

Airworthiness standards:

Special conditions—

CASA Model C-295 airplane; comments due by 1-12-00; published 12-13-99

Class D airspace; comments due by 1-14-00; published 12-3-99

Environmental impacts; policies and procedures implementation; comment request; comments due by 1-11-00; published 10-13-99

TRANSPORTATION DEPARTMENT

Federal Railroad Administration

Railroad safety enforcement procedures:

Light rail transit operations on general railroad system; safety jurisdiction; joint agency policy statement with Federal Transit Administration; comments due by 1-14-00; published 11-1-99

TREASURY DEPARTMENT

Community Development

Financial Institutions Fund
Community Development
Financial Institutions

Program; implementation; comments due by 1-14-00; published 11-1-99

TREASURY DEPARTMENT

Customs Service

Organization and functions; field organization, ports of entry, etc.:

Puget Sound, WA; port limits; comments due by 1-10-00; published 11-10-99

TREASURY DEPARTMENT

Internal Revenue Service

Income taxes:

Farm income averaging; comments due by 1-14-00; published 10-8-99

LIST OF PUBLIC LAWS

Note: The List of Public Laws for the first session of the 106th Congress has been completed and will resume when bills are enacted into law during the second session of the 106th Congress, which convenes on January 24, 2000.

A Cumulative List of Public Laws for the first session of the 106th Congress will be published in the **Federal Register** on December 30, 1999.

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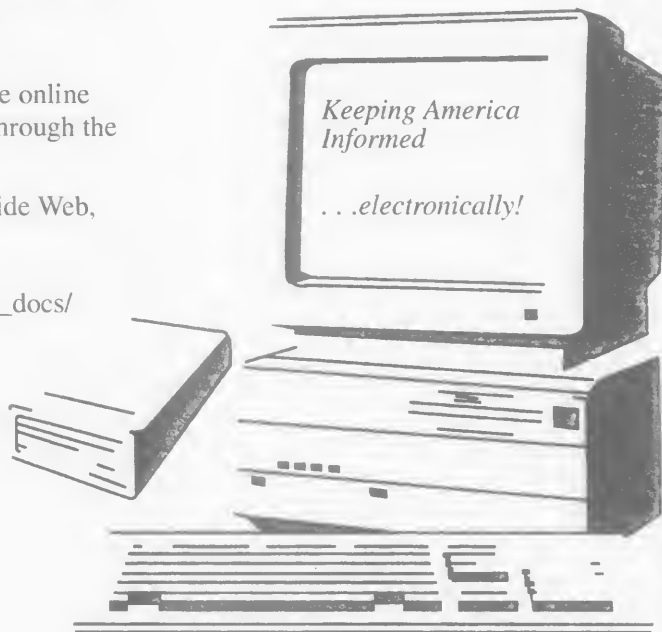
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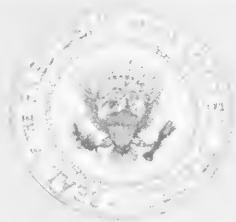


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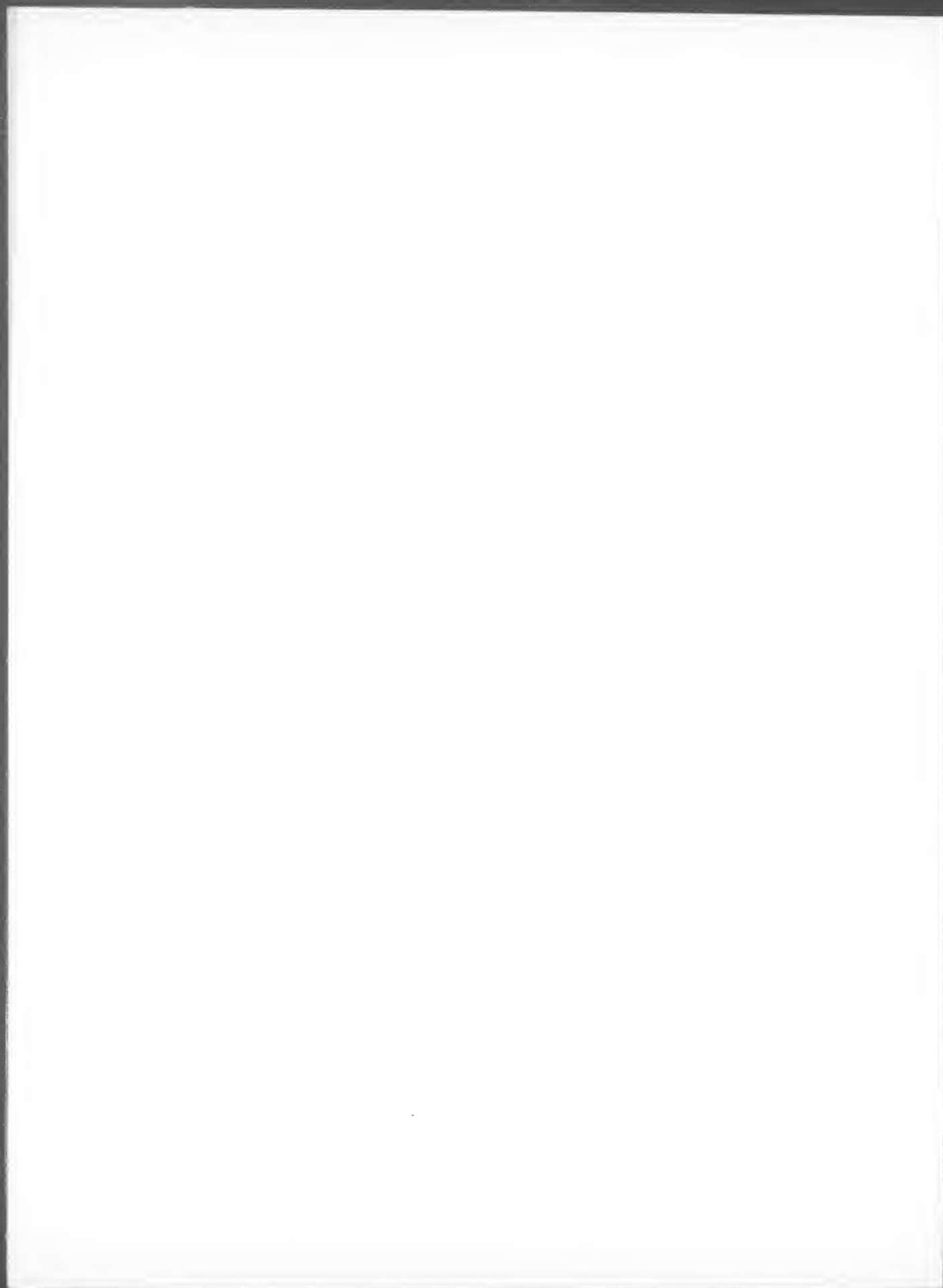
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