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

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NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

5 CFR Part 6901

RINs 2700–AC45, 3209–AA15

Supplemental Standards of Ethical Conduct for Employees of the National Aeronautics and Space Administration

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Final rule; amendment.

SUMMARY: NASA, with the concurrence of the Office of Government Ethics (OGE), is amending its supplemental standards of ethical conduct to remove the designations of officials authorized to perform ethics-related functions. In a separate rulemaking, NASA is adding revised designations to its 14 CFR part 1207 conduct regulations.

EFFECTIVE DATE: November 27, 2001.

ADDRESSES: Code GG, NASA Headquarters, Washington, DC 20546–0001.

FOR FURTHER INFORMATION CONTACT: Laurie P. Rafferty, Senior Ethics Attorney, NASA Headquarters, (202) 358–2028.

SUPPLEMENTARY INFORMATION:

I. Background

Section 2635.105 of 5 CFR authorizes executive branch agencies, with the concurrence of OGE, to publish supplemental regulations necessary to implement their respective ethics programs. In 1994, NASA, with OGE's concurrence, established supplemental standards of ethical conduct for NASA employees. See 59 FR 49335–49338 (Sept. 28, 1994), as codified at 5 CFR part 6901. At the same time, NASA repealed much of its preexisting Standards of Conduct regulation at 14 CFR part 1207, and limited its coverage to conflict of interest waiver procedures under 18 U.S.C. 208 and post-employment procedures under 18 U.S.C. 207(j)(5).

NASA, with OGE's concurrence, now amends its supplemental standards of conduct by removing (and reserving) § 6901.102, which contains the designations of NASA officials authorized to make ethics-related determinations. These internal NASA designations are better covered in NASA's conduct regulations at 14 CFR part 1207. By separate publication in the **Federal Register**, NASA is issuing amended designations at new § 1207.103 of 14 CFR. Moreover, in this rulemaking NASA is correcting a miscitation in the authority citation of the supplemental standards.

II. Matters of Regulatory Procedure

Administrative Procedure Act

Pursuant to 5 U.S.C. 553(a)(2), (b), and (d), NASA has determined that good cause exists for waiving the regular notice of proposed rulemaking, opportunity for public comments, and 30-day delayed effective date for this final rule amendment. This action is being taken because it is in the public interest that this rule, which concerns matters of agency management, personnel, organization, practice and procedure, be effective on the date of publication.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), NASA has considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. Pursuant to 5 U.S.C. 605(b), NASA certifies that this rule will not have a significant economic impact on a substantial number of small entities because the rule only affects the operations of NASA and its employees. Accordingly, no regulatory flexibility analysis is required.

Executive Order 12866 Determination

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, is not subject to review under section 3(d) of that Order because it is limited to NASA's organization, management and/or personnel matters, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

Collection of Information

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

Federalism

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

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. NASA has determined that the rule will not result in expenditures by State, local, or tribal governments or by the private sector of $100 million or more. The rule affects only the internal organization of NASA. Accordingly, NASA has not prepared a budgetary impact statement or specifically addressed regulatory alternatives.

List of Subjects in 5 CFR Part 6901

Conflict of interests, Ethical conduct, Government employees, Organization and functions (Government agencies).

Dated: November 5, 2001.

Daniel S. Goldin,

Administrator, National Aeronautics and Space Administration.

Approved: November 9, 2001.

Amy L. Comstock,

Director, Office of Government Ethics

For the reasons discussed in the preamble, NASA, with the concurrence of OGE, amends 5 CFR part 6901 as follows:

PART 6901—SUPPLEMENTAL STANDARDS OF ETHICAL CONDUCT FOR EMPLOYEES OF THE NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

1. The authority citation for part 6901 is revised to read as follows:

Authority: 5 U.S.C. 7301; 5 U.S.C. App. (Ethics in Government Act of 1978); 42 U.S.C. 2473(c)(1); E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306; 5 CFR 2635.105, 2635.403(a), 2635.802(a), 2635.803.

§ 6901.102 [Removed and Reserved]

2. Section § 6901.102 is removed and reserved.

[FR Doc. 01–29424 Filed 11–26–01; 8:45 am]

BILLING CODE 7510–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 01–ASO–13]

Amendment of Class E Airspace; Dayton, TN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Class E airspace at Dayton, TN. A Global Positioning System (GPS) Standard Instrument Approach Procedure (SIAP), helicopter point in space approach, has been developed for Bradley Memorial Hospital, Cleveland, TN. As a result, additional controlled airspace extending upward from 700 feet Above Ground Level (AGL) is needed to accommodate the SIAP. This action amends the Class E5 airspace for Dayton, TN, to the south in order to include the point in space approach serving Bradley Memorial Hospital.

EFFECTIVE DATE: 0901 UTC, February 21, 2002.

FOR FURTHER INFORMATION CONTACT: Walter R. Cochran, Manager, Airspace Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–5627.

SUPPLEMENTARY INFORMATION:

History

On October 12, 2001, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) by amending Class E airspace at Dayton, TN, (66 FR 52076). This action provides adequate Class E airspace for IFR operations at the Bradley Memorial Hospital. Designations for Class E airspace extending upward from 700 feet or more above the surface are published in FAA Order 7400.9J, dated August 31, 2001, and effective September 16, 2001, which is incorporated by reference in 14 CFR part 71.1. The Class E designation listed in this document will be published subsequently in the Order.

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received.

The Rule

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) amends Class E airspace at Dayton, TN, for the Bradley Memorial Hospital.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (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) does not warrant preparation of a Regulatory Evaluation, as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, 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; EO 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 Federal Aviation Administration Order 7400.9J, Airspace Designations and Reporting Points, dated August 31, 2001, and effective September 16, 2001, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASO TN E5 Dayton, TN [Revised]

Dayton, Mark Anton Airport, TN
(Lat. 35°29′10″N, long. 84°55′52″W)
Hardwick Field Airport(Lat. 35°13′12″N, long. 84°49′57″W)
Bledsoe County Hospital, Pikeville, TN
Point in Space Coordinates
(Lat. 35°37′34″N, long. 85°10′38″W)
Bradley Memorial Hospital, Cleveland, TN
Point in Space Coordinates
(Lat. 35°10′45″N, long. 84°52′56″W)

That airspace extending upward from 700 feet or more above the surface within a 12.5-mile radius of Mark Anton Airport, and that airspace within a 6.5-mile radius of Hardwick Field Airport, and that airspace within a 6-mile radius of the point in space (lat. 35°37′34″N, long. 85°10′38″W)serving Bledsoe County Hospital, Pikeville, TN, and that airspace within a 6-mile radius of the point in space (lat. 35°10′52″N, long. 84°52′56″W) serving Bradley Memorial Hospital Cleveland, TN; excluding that airspace within the Athens, TN, Class E airspace area.

* * * * *

Issued in College Park, Georgia, on November 16, 2001.

Wade T. Carpenter,

Acting Manager, Air Traffic Division, Southern Region.

[FR Doc. 01–29480 Filed 11–26–01; 8:45 am]

BILLING CODE 4910–13–M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

14 CFR Part 1207

RIN 2700–AC37

Standards of Conduct

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Final rule; amendment.

SUMMARY: NASA is amending its standards of conduct regulations. These amendments: change the procedure for NASA employees requesting waivers of the conflict of interests statute at 18 U.S.C. 208 to reflect organizational changes; repeal the general conflict of interests waivers at 14 CFR 1207.102(b); and revise the designations of officials

authorized to perform ethics-related functions and move those designations from 5 CFR part 6901 to 14 CFR part 1207, Subpart A.

EFFECTIVE DATE: November 27, 2001.

ADDRESSES: Code GG, NASA Headquarters, Washington, DC 20546–0001.

FOR FURTHER INFORMATION CONTACT: Laurie P. Rafferty, Senior Ethics Attorney, NASA Headquarters, (202) 358–2028.

SUPPLEMENTARY INFORMATION:

I. Background

Section 2635.105 of 5 CFR authorizes executive agencies, with the concurrence of the Office of Government Ethics (OGE), to publish supplemental regulations necessary to implement their respective ethics programs. On September 28, 1994, NASA, with OGE's concurrence, published in the **Federal Register** a final rule establishing supplemental standards of ethical conduct for NASA employees (59 FR 49335–49338). In addition, on that date, NASA redesignated its preexisting Standards of Conduct regulations at 14 CFR part 1207, and limited the coverage of the latter part to conflict of interests waivers under 18 U.S.C. 208 and post-employment procedures under 18 U.S.C. 207(j)(5).

By separate publication in the **Federal Register**, NASA is deleting the designations of officials authorized to make ethics-related determinations from 5 CFR 6901.102. Designations of NASA officials authorized to make ethics-related determinations are being published in amended form at 14 CFR 1207.103 as part of NASA's conduct regulations. The amendments include the Associate Deputy Administrator and the Chief of Staff among those delegated authority to make ethics-related determinations under 5 CFR part 2635 as to NASA Headquarters employees and for matters affecting employees Agencywide.

The procedures for requesting conflict of interests waivers under 18 U.S.C. 208 are being revised to reflect organizational changes to clarify the officials with approving authority for various classes of NASA employees. Specifically, the amended regulation reserves to the Administrator approval authority for waivers requested by key officials, including members of the Senior Executive Service, other positions classified above the GS–15 level (or otherwise requiring the filing of Public Financial Disclosure Reports), astronauts, and other specified sensitive positions. For other employees, the approval authority is established as the appropriate Center Director or, for Headquarters employees, the Associate Administrator for Headquarters Operations. Moreover, in light of the Governmentwide conflict of interests exemptions at subpart B of 5 CFR part 2640, NASA is deleting its superseded exemptions at 14 CFR 1207.102(b). Finally, in this rulemaking NASA is correcting a miscitation in the authority citation for this part 1207.

II. Matters of Regulatory Procedure

Administrative Procedure Act

Pursuant to 5 U.S.C. 553(a)(2), (b), and (d), NASA has determined that good cause exists for waiving the regular notice of proposed rulemaking, opportunity for public comments, and 30-day delayed effective date for this final rule amendment. This action is being taken because it is in the public interest that this rule, which concerns matters of agency management, personnel, organization, practice, and procedure, and which sets forth the procedure by which certain restrictions on NASA employees may be relieved, be effective on the date of publication.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), NASA has considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. Pursuant to 5 U.S.C. 605(b), NASA certifies that this rule will not have a significant economic impact on a substantial number of small entities because the rule only affects the operations of NASA and its employees. Accordingly, no regulatory flexibility analysis is required.

Executive Order 12866 Determination

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, is not subject to review under section 3(d) of that Order because it is limited to NASA's organization, management and/or personnel matters, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

Collection of Information

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

Federalism

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

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. NASA has determined that the rule will not result in expenditures by State, local, or tribal governments or by the private sector of $100 million or more. The rule affects only the internal organization of NASA. Accordingly, NASA has not prepared a budgetary impact statement or specifically addressed regulatory alternatives.

List of Subjects in 14 CFR Part 1207

Administrative practice and procedure, Authority delegations (Government agencies), Conflict of interests, Ethical conduct, Organization and functions (Government agencies).

Dated: November 5, 2001.

Daniel S. Goldin,

Administrator, National Aeronautics and Space Administration.

For the reasons set out in the preamble, NASA amends 14 CFR part 1207, subpart A, as follows:

PART 1207—STANDARDS OF CONDUCT

Subpart A—General Provisions

1. The authority citation for part 1207 is revised to read as follows:

Authority: 5 U.S.C. 7301; 18 U.S.C. 207–208; 42 U.S.C. 2473(c)(1); 5 CFR 2635.102(b); 5 CFR part 2637; 5 CFR part 2640.

2. Revise § 1207.102 to read as follows:

§ 1207.102 Waiver of prohibition in 18 U.S.C. 208.

(a) *Prohibition.* Employees are prohibited by criminal statute, 18 U.S.C. 208(a), from participating personally and substantially in an official capacity in any particular matter in which, to their knowledge, they, or any person

whose interests are imputed to them under the statute, have a financial interest, if the particular matter will have a direct and predictable effect on that interest.

(b) *Specific waiver available.* A NASA employee may request a waiver of this prohibition. NASA may grant a specific waiver of the prohibition only if the Agency determines that the employee's financial interest is not so substantial as to be deemed likely to affect the integrity of the employee's services. The waiver must be obtained before the employee participates in the matter.

(c) *Officials authorized to make waiver determinations.* (1) For the employees listed below, waivers must be approved by the Administrator or Deputy Administrator. No further delegation is authorized.

(i) Employees who are required by 5 CFR 2634.202 to file Public Financial Disclosure Reports;

(ii) Employees who are appointed under authority of section 203(c)(2) (''NASA Excepted Positions'') or section 203(c)(10) (''Alien Scientists'') of the National Aeronautics and Space Act of 1958, as amended (42 U.S.C. 2473(c)(2) and 2473(c)(10));

(iii) Astronauts and astronaut candidates;

(iv) Chief Counsel; and

(v) Procurement Officers.

(2) For all other Headquarters employees, the Associate Administrator for Headquarters Operations may approve waivers of 18 U.S.C. 208. This authority may not be redelegated.

(3) For all other Center employees, the Center Director or Deputy Center Director may approve waivers of 18 U.S.C. 208. This authority may not be redelegated.

(d) *Procedures for specific waiver.* The employee's request for a waiver must be in writing. The request must describe the particular matter involved, the relevant duties of the employee, and the exact nature and amount of the disqualifying financial interest.

(1) *Headquarters employees.* (i) Those Headquarters employees described in paragraph (c)(1) of this section must submit their requests to the Official-in-Charge of the Headquarters office in which they are employed and to the General Counsel for concurrence. The Official-in-Charge will then submit the request to the Administrator with recommendations on the proposed waiver.

(ii) Other Headquarters employees must submit their requests to the Associate General Counsel (General) for concurrence, and to the Associate Administrator for Headquarters Operations for approval.

(2) *Center employees.* (i) Those Center employees described in paragraph (c)(1) of this section must submit their requests to the Center Chief Counsel for concurrence and then to the Director of the Center where they are employed. The Center Director will provide the request, with recommendations, to the appropriate Enterprise Associate Administrator and to the General Counsel for review and submission to the Administrator.

(ii) Other Center employees must submit their requests to the Center Chief Counsel for concurrence, and then to their Center Director or Deputy Center Director for approval.

(3) Copies of approved waivers must be forwarded to the Associate Administrator for Human Resources and Education, the General Counsel, and the Office of Government Ethics.

(e) *Cross-references.* For regulations concerning general waiver guidance and exemptions under 18 U.S.C. 208, see 5 CFR part 2640.

3. Add § 1207.103 to subpart A to read as follows:

§ 1207.103 Designations of responsible officials.

(a) *Designated Agency Ethics Official.* The General Counsel of NASA is the Designated Agency Ethics Official and is delegated the authority to coordinate and manage NASA's ethics program as set forth in 5 CFR 2638.203.

(b) *Alternate Designated Agency Ethics Official.* The Associate General Counsel (General) is the Alternate Designated Agency Ethics Official.

(c) *Deputy Ethics Officials.* The following officials are designated as Deputy Ethics Officials:

(1) The Deputy General Counsel;

(2) The Associate General Counsel (General);

(3) The Senior Ethics Attorney assigned to the Associate General Counsel (General); and

(4) The Chief Counsel at each NASA Center and Component Facility.

(d) *Agency Designee.* As used in 5 CFR part 2635, the term ''Agency Designee'' refers to the following:

(1) For employees at NASA Headquarters, or for matters affecting employees Agencywide, the Associate Deputy Administrator, the Designated Agency Ethics Official, the Alternate Designated Agency Ethics Official, or the Chief of Staff; and

(2) For Center employees, the Center Director, who may delegate specific responsibilities of the Agency Designee to the Center Chief Counsel or to another official who reports directly to the Center Director.

(e) *Cross-references.* For regulations on the appointment, responsibilities, and authority of the Designated Agency Ethics Official, Alternate Designated Agency Ethics Official, and Deputy Ethics Officials, see 5 CFR part 2638. For the responsibilities of the Agency Designee, see 5 CFR part 2635.

[FR Doc. 01–29425 Filed 11–26–01; 8:45 am]

BILLING CODE 7510–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 207, 607, and 807

[Docket No. 98N–1215]

RIN 0910–AB21

Foreign Establishment Registration and Listing

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to amend its regulations pertaining to the registration of foreign establishments and the listing of human drugs, animal drugs, biological products, and devices. The final rule requires foreign establishments whose products are imported or offered for import into the United States to register with FDA and to identify a United States agent. The final rule implements section 417 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) as it pertains to foreign establishment registration.

DATES: This rule is effective February 11, 2002.

Compliance date: FDA will begin enforcing the requirements in 21 CFR part 207 on May 28, 2002, and in 21 CFR part 807 on April 26, 2002.

ADDRESSES: Submit written or electronic comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy, Planning, and Legislation (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of May 14, 1999 (64 FR 26330), FDA published a proposed rule to implement section 417

of FDAMA (Public Law 105–115). Section 417 of FDAMA amended section 510(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(i)) to require, in part, that:

(1) Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or a device that is imported or offered for import into the United States shall register with the Secretary the name and place of business of the establishment and the name of the United States agent for the establishment.

(2) The establishment shall also provide the information required by subsection (j). (Section 510(j) of the act pertains to product listing.)

Generally speaking, before FDAMA's enactment, foreign establishments could, but were not required to, register with FDA. FDA, through its regulations, did require foreign establishments to list their products regardless of whether the foreign establishment was registered (see, e.g., former section 510(i) of the act, 21 CFR 207.40(a), 38 FR 6257, 6258 through 6259, and 6262 through 6263 (March 7, 1973) (final rule implementing the Drug Listing Act of 1972)). This difference in registration and listing requirements confused some foreign establishments and led some to not comply with the listing requirement. Additionally, the lack of registration information on foreign establishments sometimes made it difficult to determine the source of specific imported products, particularly products that were impure, counterfeit products, or products whose safety or efficacy had not been established.

FDAMA changed this situation by requiring all foreign establishments engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or a device that is imported or offered for import into the United States to register. It also emphasized that foreign establishments must list their products and required, for the first time, foreign establishments to identify a United States agent.

Consequently, the proposed rule sought to amend the establishment registration and listing regulations in part 207 (21 CFR part 207) (human and animal drugs and biologics), part 607 (21 CFR part 607) (human blood and blood products), and part 807 (21 CFR part 807) (human devices). In general, the proposal removed the distinctions between domestic and foreign establishments where appropriate, required foreign establishments to identify a United States agent, and described some of the United States agent's duties.

The proposal also made minor technical amendments, such as updating addresses of FDA offices and the names of marketing applications, to be consistent with current FDA practices.

The comment period for the proposed rule was originally scheduled to end on July 28, 1999. On July 23, 1999, the Government of Canada requested that FDA extend the comment period for 60 days, stating that the proposed requirements could present significant cost and compliance burdens on small and medium-sized Canadian establishments. The Government of Canada requested the extension so that it could: (1) Ensure that affected Canadian establishments were aware of the proposed rule, and (2) prepare informed comments. The request arrived too late for FDA to announce an extension of the comment period, so FDA published a document in the **Federal Register** of August 9, 1999 (64 FR 43114), reopening the comment period from August 9, 1999, to October 8, 1999.

II. Comments on the Proposed Rule

FDA received over 35 comments on the proposed rule. Domestic and foreign establishments, particularly Canadian establishments, submitted most comments, although the Government of Canada, the trade agency for the Government of Ontario, Canada, Canadian and American trade associations, law firms, and FDA employees also submitted comments.

To make it easier to identify comments and FDA's responses to the comments, the word Comment in parenthesis, will appear before the description of the comment, and the word Response in parenthesis, will appear before FDA's response. FDA has also numbered each comment to make it easier to identify a particular comment. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance or the order in which it was submitted.

A. General Comments

Several comments addressed general issues that were not directed to any particular codified provision.

(Comment 1) Two comments expressed general support for the rule. One comment said that the rule brings a'' desired level of consistency in requirements for both domestic and international manufacturing activities'' and will enable FDA to identify and locate firms and products made abroad, thus enhancing public health and safety.

In contrast, one comment, submitted by a law firm in the United States, asserted that FDA should not require foreign establishments to register if their products are not commercially distributed in the United States. As an example, the comment said the rule should not apply if the product is sent to a foreign trade zone. The comment acknowledged that section 510(i) of the act does not expressly say that the product must be imported or offered for import into the United States ''for commercial distribution,'' but claimed that section 510(j) of the act suggests that only those who manufacture, prepare, propagate, compound, or process products for commercial distribution must register. The comment further claimed that excluding some foreign establishments from the registration requirement would also be consistent with FDAMA because FDAMA sought to reduce regulatory burdens.

(Response) FDA agrees, in part, with the comment, but only to the extent that it involves products that are shipped to foreign trade zones and never enter domestic commerce. In brief, a foreign trade zone (also known as a Free Trade Zone) is a federally sanctioned site where foreign and domestic goods are considered to be outside of the U. S. Customs territory. While in a foreign trade zone, the goods can be stored, tested, sampled, displayed, repaired, manipulated, assembled, salvaged, repackaged, cleaned, processed, relabeled, mixed, destroyed, or inspected (and, if approved by the foreign trade zone board, manufactured). If the goods are reexported from the foreign trade zone, no customs duties are paid, but if the goods enter U. S. commerce, duties would apply.

It is important to note that, while the U. S. Customs Service does not assess duties on goods in a foreign trade zone, those goods are subject to FDA's jurisdiction. However, FDA agrees that if a foreign establishment sends human drugs, animal drugs, devices, or biological products to a foreign trade zone and the product is re-exported from the foreign trade zone to another country without ever entering U. S. commerce, the foreign establishment is not required to register or list the products that were sent to the foreign trade zone. (These foreign establishments may voluntarily register and list their products, but the final rule does not require them to do so).

If the goods do enter U. S. commerce from a foreign trade zone, the foreign establishment must register and list its products. In this situation, the foreign establishment is like any other foreign establishment that exports a product to the United States. In other words, if the

goods are sold in the United States, the fact that those goods may have initially entered the United States through a foreign trade zone does not relieve the foreign establishment from registration and listing requirements.

FDA, therefore, has amended the foreign establishment registration and listing provisions at §§ 207.40(a), 607.40(a), and 807.40(a) to exclude drugs and devices that enter a foreign trade zone and are re-exported from the United States without ever entering domestic commerce.

(Comment 2) The same comment, in asking FDA to exempt foreign establishments from registration and listing requirements if their products are imported into the United States but are not marketed in the United States, suggested registering these foreign establishments is ''simply not necessary'' and that FDA defer to foreign authorities in such cases. The comment stated that foreign countries, whether exporting or receiving a product, can impose their own registration requirements on foreign manufacturers. The comment added that FDA is authorized to enter cooperative arrangements with foreign countries to determine whether drugs or devices should enter the United States.

(Response) FDA agrees, in part, and disagrees, in part, with the comment. The agency agrees that it is unnecessary to require a foreign establishment to register and list its products provided that the product enters the United States through a foreign trade zone and is later re-exported without ever entering domestic commerce. However, the fact that a foreign country may have its own registration requirements or that FDA may enter cooperative arrangements with foreign countries does not, by itself, justify an exemption from the act's registration and listing requirements. Foreign registration requirements may differ considerably from FDA's requirements or may not exist at all; likewise, cooperative arrangements may not exist or would have to be negotiated in order to obtain registration information from a foreign government.

(Comment 3) One comment asked FDA to work with the U. S. Customs Service in order to prevent any unnecessary interruption in the flow of goods and to facilitate communications between agencies at ports of entry.

(Response) FDA has worked and will continue to work closely with the Customs Service on various issues affecting the importation and exportation of FDA-regulated products and will notify the Customs Service about this final rule. Additionally, FDA will ''phase-in'' the rule so that foreign establishments will have an opportunity to adjust to these regulatory requirements. (Details concerning registration schedules for parts 207, 607, and 807 appear later in this document in section II.F entitled ''Registration Schedules.'') Consequently, the rule should not create any ''unnecessary interruption'' in imports of human drugs, animal drugs, biologics, blood and blood products, or devices.

B. Comments on the United States Agent Requirement

1. Comments on the Number of United States Agents, Including Requests to Exempt Firms in Certain Countries From Having a United States Agent

As stated earlier, section 510(i) of the act requires foreign establishments to identify a United States agent. The preamble to the proposed rule explained that FDA interpreted this provision as requiring the agent to be an individual, firm, or company physically located in the United States (see 64 FR 26330 at 26331). The preamble to the proposed rule added that the United States agent could not be a mailbox, answering machine or answering service, or any other place where an individual acting as the foreign establishment's agent is not physically present and that FDA interprets section 510(i) of the act as requiring only one agent for each foreign establishment.

(Comment 4) Some comments would amend the rule to allow or to require more than one agent per establishment. Two comments advocated one agent per product, and one of these comments said that foreign establishments should identify the United States agent as part of a drug master file or veterinary master file. One comment supported requiring one United States agent for each product and U. S. customer. Other comments suggested that a foreign establishment should be able to designate more than one agent or as many agents as it wished. In general, these comments explained that a foreign establishment may supply multiple U. S. companies or have multiple U. S. distributors. The comments said that, under these circumstances, a foreign establishment cannot select one company or distributor as its United States agent due to potential conflicts of interest, potential harm to the foreign establishment's proprietary interests, or frequent changes in its distributors. Some comments said that a distributor could not be a United States agent for more than one foreign establishment. One comment also argued that FDA already has names and addresses of agents for each product as part of a drug master file, so FDA should allow foreign establishments to have more than one United States agent.

(Response) Section 510(i) of the act clearly and unequivocally requires foreign establishments to register the name of a United States agent. As stated in the preamble to the proposed rule, FDA interprets section 510(i) of the act as allowing only one United States agent for each foreign establishment because section 510(i) of the act refers to the United States agent in singular, rather than plural, terms (see 64 FR 26330 at 26331). FDA continues to believe that this interpretation is efficient (because FDA would communicate or interact with only one United States agent rather than multiple agents who represent, or purport to represent, the same foreign establishment) and consistent with the statutory language. Thus, FDA declines to amend the rule to increase the number of United States agents per foreign establishment.

FDA also declines to amend the rule to have foreign establishments identify the United States agent as part of their drug master files or veterinary master files. Section 510(i)(1) of the act considers the United States agent to be part of a foreign establishment's registration requirement, so requiring a foreign establishment to name its United States agent as part of the registration process is consistent with the act.

(Comment 5) Many comments, particularly from Canadian sources, objected to having any United States agent. These comments would revise the rule to eliminate or suspend a United States agent requirement, either for Canadian firms or for firms in countries meeting certain criteria. The comments offered numerous reasons why FDA should not require certain foreign firms, particularly Canadian firms, to have a United States agent. The reasons cited most often were (in no particular order): (a) The requirement will be expensive; (b) the requirement results in a competitive disadvantage for Canadian firms doing business in the United States because Canada does not impose similar obligations on U. S. firms; (c) an agent will not be as knowledgeable as company officials concerning the company's products or training an agent to be knowledgeable will be burdensome, expensive, and time-consuming; (d) Canada and the United States share time zones, business ethics, language, and communications capabilities so a United States agent will not significantly enhance communications between FDA and Canadian firms; (e) FDA has not shown any need for a United States agent; (f)

firms with a history of good communications with FDA should be exempt from the United States agent requirement; and (g) the requirement will act as a trade barrier between Canada and the United States. One comment said a United States agent is unnecessary because FDA can work with the U. S. Customs Service to prevent unapproved devices from entering the United States. Some Canadian firms indicated that they would ask the Canadian Government to impose similar requirements against U. S. firms if FDA did not create an exemption.

A few comments suggested that FDA create exemptions for Canadian firms or firms in countries meeting certain criteria. One comment from an United States trade association advocated an exemption from the United States agent requirement for ''establishments in those countries with whom the United States has negotiated free trade agreements,'' arguing that FDA's ''interpretation'' of section 417 of FDAMA may pose an ''unreasonable barrier to trade,'' that registration and listing information should be enough to protect consumers, and that ''we run the risk of our partners in these agreements placing similar burdens on American companies.'' Other comments would exempt firms in countries that have no communications problems with the United States or FDA; countries that do not have a similar agent requirement that applies against U. S. firms; or countries where English is spoken and where firms can communicate directly with FDA.

(Response) FDA appreciates the concerns expressed by the comments. However, section 510(i) of the act does not contain any mechanism or any criteria for exempting certain foreign establishments or foreign establishments located in certain countries, in geographical regions, or in countries with no communications problems with the United States or FDA. Neither does it provide for a deferral of the United States agent requirement. The statutory language is clear—a foreign establishment ''shall register * * * the name of the United States agent for the establishment'' (see section 510(i) of the act). The most logical interpretation of the term, ''United States agent,'' is that the agent must be in the United States. If Congress intended foreign establishments to be able to designate agents outside the United States, the words ''United States'' would be unnecessary in section 510(i) of the act. Indeed, if Congress intended to require foreign establishments to be able to designate agents outside the United States, there would be no need for any agent at all because FDA could simply contact the foreign establishment directly. It is a well settled principle of statutory interpretation that, ''Absent clear congressional intent to the contrary, we will assume the legislature did not intend to pass vain or meaningless legislation'' (*Coyne* & *Delany* v. *Blue Cross* & *Blue Shield of Virginia*, 102 F.3d 712, 715 (4th Cir. 1996); see also *Halverson* v. *Slater*, 129 F.3d 180, 185 (D.C. Cir. 1997) (Congress cannot be presumed to do a futile thing).) Thus, the most straightforward reading of section 510(i) of the act is that foreign establishments must register the name of a United States agent and that the United States agent must be in the United States. So, despite the assertions made by one comment, one cannot fairly criticize FDA's ''interpretation'' of the act as being erroneous or claim that FDA's interpretation of the act is creating an ''unreasonable barrier'' to trade.

FDA sees no need to alter the rule based on those comments claiming that the United States agent requirement will create competitive disadvantages or trade barriers, increase costs to foreign establishments, or lead foreign countries to impose similar requirements against U. S. firms. The United States agent requirement is consistent with U. S. trade obligations under the relevant international agreements.

(Comment 6) One comment explained that small businesses might find the United States agent requirement to be economically feasible if multiple foreign establishments could share the same agent.

(Response) FDA has no objections to having one United States agent represent multiple foreign establishments. However, FDA reminds firms to select their United States agents carefully to guard against any conflict of interest and to account for any confidentiality or other business concerns.

2. Comments on the United States Agent's Duties or Responsibilities

(Comment 7) The preamble to the proposed rule cautioned foreign establishments to select their agents carefully due to potential conflicts of interest and issues involving trade secrets or confidential commercial information (see 64 FR 26330 at 26334). One comment acknowledged FDA's advice, but said that FDA's interest in enhanced communication and rapid acquisition of information would be best served if foreign establishments could determine the number of agents they need according to their business and proprietary needs. Another comment said that the rule would compel foreign establishments to designate persons other than their U. S. distributors as their United States agents because foreign establishments might be unwilling to give a distributor potential access to confidential information. The comment said this would increase costs of retaining a United States agent.

(Response) FDA disagrees with the comments. FDA expects to initiate most, if not all, communications between the agency and a United States agent. Thus, it would obviously be more efficient if FDA only had to contact one United States agent for a particular foreign establishment rather than sort through a list of agents to determine whether a foreign establishment had designated or authorized a particular agent to address a particular issue.

As for advising foreign establishments to select their United States agents carefully, FDA was emphasizing that its interactions with a United States agent could involve proprietary information, particularly in emergency situations (see 64 FR 26330 at 26334). FDA must be able to communicate freely with a United States agent in these situations; otherwise, if the United States agent is unable or unauthorized to speak to FDA, the United States agent has little or no value in serving as a contact between FDA and the foreign establishment. FDA takes no position whether a foreign establishment should select a U. S. distributor to be its United States agent.

(Comment 8) Several comments addressed the United States agent's duties under the rule. Under proposed §§ 207.40(c)(2), 607.40(d)(2), and 807.40(d)(2), the United States agent would be responsible for assisting FDA in communications with the foreign establishment, responding to questions concerning the foreign establishment's products that are imported or offered for import into the United States, and assisting FDA in scheduling inspections of the foreign establishment. The proposal also authorized FDA to provide information or documents to the United States agent if FDA is unable to contact the foreign establishment directly or expeditiously.

One comment said that the agent's duties were very flexible, reasonable, and represented a ''vast improvement'' over an earlier approach taken by FDA for device manufacturers, while another comment said the proposed rule appropriately imposed no duty on the agent to file annual submissions for devices. In contrast, other comments misinterpreted the rule as requiring the United States agent to submit all documents, such as premarket

notifications, annual certifications, and registration and listing information, to FDA, or to be the only contact between a foreign establishment and FDA. The comments argued that the agent would only become an obstacle to communications between FDA and foreign establishments or, in the case of device firms, would be performing the same duties as the firm's official correspondent.

(Response) FDA intentionally imposed very few duties on the United States agent. Thus, contrary to the views expressed in some comments, FDA is not requiring the agent to submit all documents—or any particular document—to FDA on behalf of a foreign establishment or to be a foreign establishment's sole contact with FDA. The final rule, like the proposal, only requires that the agent assist FDA in communications with the foreign establishment, to respond to questions concerning the foreign establishment's products that are imported or offered for import into the United States, and to assist FDA in scheduling inspections of the foreign establishment. The final rule also authorizes FDA to provide information or documents to the United States agent if FDA is unable to contact the foreign establishment directly or expeditiously. Foreign establishments have the discretion to give their United States agents additional tasks and may always contact FDA directly, with or without their United States agents.

FDA does wish to clarify, however, that the United States agent, as established in section 510(i) of the act and this final rule, is different, both in the underlying legal authority for the requirement and its application to FDA-regulated products, from the ''U.S.-designated agent'' in the existing § 807.40(c). The ''U.S.-designated agent'' applied solely to device manufacturers, and FDA stayed the effective date of the ''U.S.-designated agent'' requirement in the **Federal Register** of July 23, 1996 (61 FR 38345). (In fact, because this final rule rewrites § 807.40 entirely, the ''U.S.-designated agent'' language from § 807.40 no longer appears.) In contrast, the United States agent requirement applies to human drug, animal drug, biologics (including blood and blood products), and device establishments, and is required by section 510(i) of the act. Section 510(i) of the act did not create any specific duties for the United States agent, and so FDA, under this rulemaking, prescribed very few duties for the United States agent.

(Comment 9) One comment stated that, at the port of entry, the importer of record has the burden of resolving any import problems. The comment said that because the U. S. Customs Service and FDA regulate imports, it is unclear how regulatory differences between the Customs Service and FDA would be reconciled. The comment said that if a foreign establishment selects company A as its United States agent, company A's role in resolving import problems would be unclear if another company was the importer of record.

(Response) The comment misinterprets the rule. The United States agent, under parts 207, 607, and 807, has no duties or responsibilities to the Customs Service. Furthermore, with regard to imported products, the final rule requires the United States agent to respond to questions regarding the foreign establishment's products that are imported or offered for import into the United States (see, e.g., § 207.40(c)(2)). The preamble to the proposed rule indicated that these questions might concern the product's distribution in the United States (see 64 FR 26330 at 26333). In other words, the rule does not require the United States agent to respond to inquiries from the Customs Service. The final rule does not require the United States agent to resolve any import problems alone or to resolve any import problems immediately at a port of entry. The final rule does not require the United States agent to be responsible for legal issues surrounding the product's admission into the United States. In the comment's hypothetical example, FDA regulations would not require company A to resolve import problems raised by FDA or the Customs Service, although FDA believes that the United States agent could play an important role in resolving such problems by facilitating communication with the foreign establishment, working with the importer of record, or even, when appropriate, helping resolve the problem.

3. Miscellaneous Comments Regarding the United States Agent Requirement

(Comment 10) Several comments asked about the United States agent's liability. One comment asked FDA to clarify that FDA would not hold the agent legally responsible if, after the agent had made reasonable attempts to transmit documents or information to the foreign establishment, the foreign establishment failed to respond adequately to FDA. The comment suggested that FDA revise the rule to limit the agent's liability to ''a fulfillment of the agent's responsibility * * * on behalf of the foreign firm'' and to not hold the agent liable for any violation of the act by the foreign firm. Another comment expressed a similar opinion, stating that FDA had not considered whether a United States agent would be liable for the foreign establishment's actions.

Another comment expressed concern about the United States agent's exposure to litigation from parties in the United States who sue the foreign establishment. Two other comments said that they had surveyed various U. S. firms or contacted U. S. attorneys and found that none were willing to act as a United States agent; one comment indicated that U. S. firms were concerned about their potential legal liability.

(Response) In general, FDA does not intend to hold the United States agent responsible for violations of the act committed by a foreign establishment. FDA wants the United States agent to assist in communications with the foreign establishment, to respond to questions about the foreign establishment's products, and to help schedule inspections of the foreign establishment. If a foreign establishment violates the act, FDA would pursue action against that foreign establishment. Examples of instances where FDA might take action against the United States agent would be where the agent submitted false information to FDA or the agent and the foreign establishment were effectively the same entity. Given the limited nature of the United States agent's potential liability to FDA, the agency declines to amend the rule to address liability issues.

As for the United States agent's liability in third party litigation (i.e., situations where a private party sues the foreign establishment and attempts to attach or enforce a judgment by attaching the United States agent's assets), such issues are beyond the scope of this rule. FDA does not have authority to insulate United States agents from such litigation, and such litigation would be a matter of State, rather than Federal, law.

(Comment 11) One comment asked FDA to provide additional support and details on the United States agent requirement. The comment suggested that FDA should identify persons who can serve as United States agents and make that information publicly available through FDA's website or other publications. The comment also said FDA should consider its enforcement needs regarding office location, personnel qualifications, and necessary communications capabilities.

(Response) Given the final rule's broad, general descriptions of the United States agent's duties, details regarding the United States agent's office location, the agent's personnel qualifications, and communications

capabilities are not necessary at this time. If such details become necessary or desirable in the future, FDA will consider whether additional documents, such as a guidance document or rulemaking, are needed.

As for identifying persons who might serve as United States agents, FDA's Center for Devices and Radiological Health is considering whether to list persons who have expressed an interest in being United States agents. The list would be made available over the Internet, but FDA cautions that the list should not be interpreted as endorsing any person on the list or as suggesting that those persons are particularly trained or qualified to act as United States agents.

(Comment 12) The proposed rule would require a foreign establishment to report changes in the United States agent's name, address, or phone number within 5 days of the change. The preamble to the proposed rule invited comment as to whether a United States agent should be able to report such changes to FDA itself (see 64 FR 26330 at 26333). The preamble to the proposed rule explained that, on rare occasions, FDA has contacted individuals whom their establishments had identified as their agent or representative only to find that the individual had terminated its relationship with the establishment or was unaware that the establishment had designated that individual as its representative (id.).

One comment would permit a United States agent to notify FDA about changes to its name or address or even whether a person no longer serves as a foreign establishment's United States agent.

(Response) FDA agrees and has revised §§ 207.40(c)(3), 607.40(d)(3), and 807.40(b)(3) so that United States agents may report changes themselves.

(Comment 13) Several comments supported discussions between FDA and its Canadian counterparts to reach an agreement that would eliminate the need for a United States agent for Canadian firms or let Canadian authorities act on FDA's behalf on matters involving Canadian firms. Another comment stated that it understood that the U. S. Department of Agriculture and FDA had a ''reciprocal relationship'' with the Canadian Food Inspection Agency (CFIA) that enables U. S. regulatory authorities to inspect Canadian firms where possible and, where geographically impossible, obtain information from Canadian authorities regarding a Canadian firm's products, their origin, inspection status, and other information.

(Response) Although FDA and its Canadian counterparts have a history of cooperation on regulatory matters of mutual interest, section 510(i) of the act and other laws administered by FDA do not contain a mechanism for exempting countries from the United States agent requirement. Consequently, negotiations seeking an administrative exemption from the United States agent requirement would not be productive.

Similarly, an agreement with a foreign country regarding inspection results does not relieve foreign manufacturers from complying with section 510(i) of the act. Neither does it relieve FDA from enforcing section 510(i) of the act.

(Comment 14) Several comments asserted that trade agreements restricted the ability of the United States to require foreign establishments to have a United States agent. Most comments referred to the North American Free Trade Agreement (NAFTA), the United States-Canada Free Trade Agreement, and/or the General Agreement on Tariffs and Trade (GATT) to declare that a United States agent requirement would hinder trade or would be an unreasonable barrier to trade. Other comments simply referred to unnamed trade agreements and did not explain how the United States agent requirement violated those trade agreements. One comment stated that NAFTA provides for recovery of lost profits under certain conditions and that FDA must consider NAFTA matters before issuing regulations that could affect North American trade. Another comment said that NAFTA prevents the United States from requiring foreign establishments to have a United States agent when Canada does not have a similar requirement for U. S. firms.

Other comments raised other trade issues, stating that the United States agent requirement will prompt some foreign establishments to withdraw from the U. S. market, resulting in an adverse effect on U. S. consumers. Some comments suggested that they would ask their governments to enact similar requirements against U. S. companies. A small number of comments feared that other countries, after discovering that the United States requires foreign establishments to have an agent, would enact similar legislation or claimed that their own foreign country did not impose such requirements on U. S. establishments.

(Response) FDA disagrees with the comments that suggested that the rule violates relevant trade agreements. Both GATT and NAFTA permit parties to adopt measures for the protection of human health as well as measures to secure compliance with permissible laws. The rule accurately implements the legitimate public health objectives of facilitating communication and scheduling of inspections with foreign establishments and is not a disguised restriction on trade. Furthermore, it does not violate the national treatment provisions of the trade agreements because the requirement parallels the domestic registration requirements of providing the name of an accessible individual responsible to the establishment.

As for those comments claiming that the rule will prompt some foreign establishments to withdraw from the U. S. market or lead to foreign legislation targeting U. S. companies, such matters are speculative and outside the scope of this regulation.

As for those comments claiming that their own country does not have a similar requirement that would apply against U. S. establishments, FDA is aware of several agent-like requirements imposed by foreign countries. These requirements vary in the obligations imposed and the industries affected, but, regardless of their nature, the existence or non-existence of foreign statutory requirements does not alter the fact that section 510(i) of the act requires foreign establishments to have a United States agent.

(Comment 15) Most comments did not object to requiring foreign establishments to register their establishments. The comments often explained that their own country's laws or regulations required establishments to register or that FDA would be treating domestic and foreign establishments alike. However, one comment objected to having a United States agent because, it argued, FDA does not require establishments in the United States to have an agent. The comment also criticized the ''U.S.-designated agent'' requirement (which never became effective) as treating foreign establishments differently than U. S. establishments.

(Response) Section 510(i) of the act clearly requires foreign establishments engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or a device that is imported or offered for import into the United States to register and to name a United States agent. Although the comment is correct that the act does not impose a United States agent requirement on U. S. establishments, there would be no need to amend the act to impose such a requirement on U. S. establishments because, by virtue of being located in the United States, they already should have employees located

in the United States whom FDA can contact when necessary.

C. Comments on Proposed Changes to Part 207 (Human Drugs, Biologics, and Animal Drugs)

1. General Comments

(Comment 16) One comment said that foreign establishments that make a bulk chemical intermediate do not have to register or list because a bulk chemical intermediate is not a drug. The comment then suggested that, because a new drug application (NDA) holder processes both bulk chemical intermediates and bulk drug substances into a finished drug product, there is no valid basis for requiring a foreign bulk drug substance manufacturer to register if a foreign bulk chemical intermediate manufacturer does not register. The comment suggested that the NDA holder simply list both foreign suppliers in the NDA rather than require a foreign bulk drug substance establishment to register.

(Response) FDA declines to revise the rule as suggested by the comment. The comment's claim regarding different regulatory burdens between bulk chemical intermediate product manufacturers and bulk drug substance manufacturers is misleading because it neglects to consider the role of each substance in a drug. Chemical intermediates, in general, are materials that are produced during a manufacturing process and undergo further molecular change or processing before they become an active pharmaceutical ingredient. Bulk drug substances, under § 207.3(a)(4), are substances that are represented for use in a drug and that, ''when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or finished dosage form of the drug * * *.'' Thus, chemical intermediates and bulk drug substances are not alike.

In other words, a chemical intermediate undergoes one or more molecular changes during manufacturing to become a different chemical, but the chemical intermediate, in its original form, is not intended or suitable for use as an active ingredient. Requiring establishments that manufacture chemical intermediates to register and to list, therefore, would not provide much helpful information to FDA and, for that reason, is not necessary to protect the public health.

In contrast, if a firm makes a bulk drug substance, the bulk drug substance does not require molecular change to become pharmacologically active. Thus, because a bulk drug substance, like a finished drug, may provide pharmacological activity, it makes sense to require establishments that manufacture bulk drug substances to register and list.

(Comment 17) One comment asked FDA to clarify which biological products fall under part 207 and to explain the rationale for including or excluding biological products from part 207. The comment offered no reason why this clarification was necessary.

(Response) Deciding whether a biological product should be registered under parts 207, 607, or 807 depends largely on how the product is defined. In brief, section 201(g)(1)(B) and (g)(1)(C) of the act (21 U.S.C. 321(g)(1)(B) and (g)(1)(C)) defines ''drug'' as ''articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals'' and as ''articles (other than food) intended to affect the structure or any function of the body of man or other animals.'' Section 201(h) of the act, in part, defines ''device'' as ''an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory'' which is ''intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals'' or ''intended to affect the structure or any function of the body of man or other animals'' and ''which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.''

Section 510(i) of the act, in turn, requires foreign establishments engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States to register the name and place of business of the establishment and the name of a United States agent and to provide listing information. Thus, if a biologic meets the definition of drug or device, as defined in the act, a foreign manufacturer for that biologic must register (including the name of its United States agent) and submit listing information. Implementing regulations for the registration and listing requirements in section 510 of the act are divided among parts 207 (drugs (including biologics) and animal drugs), 607 (blood and blood products), and 807 (devices).

It is impractical to explain further which biologics may or may not be regulated under part 207 or to explain the rationale for their inclusion or exclusion. FDA's experience demonstrates that, despite FDA's intentions to provide advice or clarity, whenever the agency attempts to provide complete descriptions of the products that are subject to a particular regulation or part, the descriptions are either misconstrued as being exhaustive or definitive (so that persons whose products are not identified or even slightly different from the products mentioned in the description claim that they are exempt from the rule) or must be constantly revised to add new products and to remove old products. FDA, therefore, finds it more practical, less confusing, and a better use of its resources to refrain from providing the detailed explanations sought by the comment. If an establishment is unsure which registration and listing requirements apply, it should contact the Center for Biologics Evaluation and Research (CBER).

2. Definitions (§ 207.3)

Proposed § 207.3 defined two terms: ''commercial distribution'' and ''United States agent.'' The proposal in § 207.3(a)(5) defined ''commercial distribution'' as:

> any distribution of a human drug except for investigational use under part 312 of this chapter, and any distribution of an animal drug or animal feed bearing or containing an animal drug for noninvestigational uses, but the term does not include internal or interplant transfer of a bulk drug substance between registered establishments within the same parent, subsidiary, and/or affiliate company. For foreign establishments, the term ''commercial distribution'' shall have the same meaning except that the term shall not include distribution of any drug that is neither imported nor offered for import into the United States.

FDA meant to clarify that, for foreign establishments, commercial distribution does not include distribution of a human or animal drug that is neither imported nor offered for import into the United States. This change was intended to reflect the statutory language limiting the registration requirement to those foreign establishments that are ''engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or a device that is imported or offered for import *into the United States*'' (emphasis added), as well as the definition of ''interstate commerce'' in section 201(b) of the act.

(Comment 18) One comment sought further clarification of the term ''commercial distribution'' and how it determined who must register under

§ 207.20. The comment asked whether a foreign establishment that supplies a bulk active drug ingredient to the U. S. holder of an NDA for incorporation into a finished product must register and list its products and whether the act of supplying the bulk active drug ingredient was ''commercial distribution.'' The comment asserted that if FDA required the foreign bulk active ingredient establishment to register and list, it would impose a greater obligation on the foreign establishment than on an affiliated company of the NDA holder. The comment asserted that the transfer or shipment of bulk drug substances between affiliates does not constitute commercial distribution.

(Response) Section 510(i) of the act applies to any foreign establishment engaged in the ''manufacture, preparation, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States * * * .'' Section 201(g)(1) of the act defines ''drug,'' in part, as ''articles intended for use as a component'' of a drug. Thus, a foreign bulk drug manufacturer who ships bulk active ingredients to a U. S. firm is subject to section 510(i) of the act and must register the foreign establishment (including a United States agent) and list its products.

FDA disagrees with the comment's assertion that requiring a foreign bulk drug manufacturer to register and list would impose a greater duty than one that would apply to an NDA holder's affiliate company. Under § 207.3(a)(5), only internal or interplant transfers of bulk drug substances between registered establishments within the same parent, subsidiary, and/or affiliate company fall outside the definition of ''commercial distribution.'' Thus, under § 207.3(a)(5), an affiliate firm would have to be registered just like the foreign establishment.

(Comment 19) One comment sought additional definitions or explanations of terms in part 207. The comment said FDA should amend the definitions to state specifically that establishments, both foreign and domestic, that make biological products must register and list. The comment claimed that biologics manufacturers are sometimes unaware that they must register and list. The comment also asked FDA to clarify whether biologic source suppliers must register.

(Response) FDA declines to amend the rule to include an express reference to biologics establishments. Part 207 already contains sufficient indications to show that the requirements apply to biologics establishments, so further clarification is unnecessary, and the statutory definition of ''drug,'' in section 201 of the act, includes biological products.

Furthermore, revising part 207 to include an express reference to biologics establishments might increase any confusion in the biologics industry or force FDA to make similar changes throughout title 21 of the CFR each time the word ''drug'' appears. Otherwise, a biologics firm might argue that the absence of an express reference to biologics in any given regulation meant that the regulation did not apply to biologics. The result would be confusion as to which rules did or did not apply to biologics. While it might ultimately be beneficial for FDA to examine all of its regulations to clarify their scope or coverage, a large scale reexamination and editorial effort is outside the scope of this rule.

As for the question whether biologics source suppliers must register, registration is required if the product that is imported or offered for import to the United States meets the definition of ''drug'' in section 201(g) or ''device'' in section 201(h) of the act and if the foreign establishment is not otherwise exempt from the registration requirement.

(Comment 20) Proposed § 207.3(a)(11) defined ''United States agent'' as ''a person residing or maintaining a place of business in the United States whom a foreign establishment designates as its agent.'' FDA received no comments on the definition in § 207.3(a)(11), but one comment did address the identical definition at § 807.3. The comment noted that the preamble to the proposed rule stated that the definition of ''United States agent'' excluded mailboxes, answering machines or services, or other places where an individual acting as the foreign establishment's agent is not physically present (see 64 FR 26330 at 26331). The comment suggested that FDA revise the definition of ''United States agent'' to mention these exclusions.

(Response) FDA agrees with the comment and has revised the definition of ''United States agent'' in §§ 207.3(a)(11), 607.3(j), and 807.3(r) accordingly.

3. Establishment Registration and Product Listing for Human Blood and Blood Products and for Medical Devices (§ 207.7)

Proposed § 207.7(a) would revise the address for the office in CBER that receives the registration and listing information.

FDA received no comments on this provision and has finalized it without change.

4. Exemptions for Establishments (§ 207.10)

Proposed § 207.10 would delete the word ''domestic'' from its title, so that the provision pertains to exemptions for both foreign and domestic establishments. The proposal would also revise the description of establishments that are exempt from registration.

FDA received no comments on this provision and has finalized it without change.

5. Who Must Register and Submit a Drug List (§ 207.20)

Proposed § 207.20(a) would clarify that the exemptions are under section 510(g) of the act or subpart B (''Exemptions'') of part 207. This would be an editorial change to place all exemptions that apply to drug manufacturers in subpart B of part 207 and would remove all exemptions from subpart D.

The proposal would also revise paragraph (a) of § 207.20 so that the language requiring owners and operators to register their establishments and to list drugs, whether or not the output of the establishment or any particular drug so listed enters interstate commerce, would apply only to domestic firms. FDA proposed this change because it does not intend to require foreign establishments to list drugs that do not enter interstate commerce by being imported or offered for import into the United States.

The proposal would also make some minor edits to § 207.20(a) by: (a) Deleting the phrase ''at this time'' because the phrase is unnecessary, (b) moving the parenthetical language referring to Type B and Type C medicated feed so that it refers accurately to animal feeds bearing or containing an animal drug rather than to animal feeds generally, and (c) revising the parenthetical language so that it refers to Type B ''or'' Type C medicated feed. The proposed rule would also add ''abbreviated new drug applications'' and ''abbreviated new animal drug applications'' to the list of marketing applications in § 207.20(c). These applications were inadvertently omitted from previous rulemakings amending part 207.

(Comment 21) In the preamble to the proposed rule, FDA noted that § 207.20(a) permits a company to submit listing information on behalf of a parent, subsidiary, and/or affiliate company for all establishments when operations are

conducted at more than one establishment and there exists joint ownership and control among all the establishments. FDA interpreted this provision, and similar provisions at §§ 607.20(a) and 807.20(a), as including foreign establishments to which the same conditions apply (see 64 FR 26330 at 26332).

One comment asked FDA to explain what ‘‘ affiliate companies ’’ and ‘‘ joint ownership and control ’’ are. The comment said that the rule allows reporting by affiliate companies where there is joint ownership and control, but does not explain what those terms mean.

(Response) The act and a commonly used law dictionary can provide some help on interpreting the terms ‘‘ affiliate companies ’’ and ‘‘ joint ownership and control.’’ Section 735(9) of the act (21 U.S.C. 379g(9)) defines ‘‘affiliate,’’ for purposes of fees relating to drugs, as meaning ‘‘a business entity that has a relationship with a second business entity if, directly or indirectly—(A) one business entity controls, or has the power to control, the other business entity; or (B) a third party controls, or has power to control both of the business entities.’’ This definition is similar to one that appears in *Black's Law Dictionary*, which defines ‘‘affiliation,’’ in terms of corporations, as legally enforceable control of stock of corporations by the same interests (see *Black's Law Dictionary* 80 (4th ed. 1968)). Thus, an ‘‘affiliate company’’ is one that is legally controlled, directly or indirectly, by another company or can be controlled by another company; mere business links are not sufficient. *Black's Law Dictionary* defines ‘‘joint owners’’ as ‘‘two or more persons who jointly own and hold title to property’’ and ‘‘control’’ as ‘‘power or authority to manage, direct, superintend, restrict, regulate, direct, govern, administer, or oversee’’ (id. at 1260 and 399). Thus, ‘‘joint ownership and control’’ suggests that two or more persons own the companies at issue and share managerial or supervisory responsibilities.

(Comment 22) One comment suggested that FDA revise § 207.20(a) and similar language in §§ 607.20(a) and 807.20(a) to allow a foreign parent company to register and list on behalf of its foreign subsidiaries. The comment explained that the rule allows parent companies to list on behalf of their subsidiaries, but does not allow them to register their subsidiaries. The comment suggested that section 510(i) and (j) of the act give FDA the flexibility to allow parent companies to register on behalf of their subsidiaries and that this would also enable foreign establishments to name a single official who would be responsible for registration and listing information, thereby facilitating the development of a single, unified registration and listing system.

(Response) FDA agrees with the comment and has amended §§ 207.20(a), 607.20(a), and 807.20(a) to allow parent companies to register and list on behalf of their subsidiaries.

(Comment 23) One comment said that FDA should ‘‘recognize’’ that distributors may list drug products and that the manufacturers of those drug products, whether foreign or domestic, should not have to list the same drugs. The comment asserted that the Drug Listing Act of 1972 was not intended to require ‘‘dual listing’’ by a manufacturer if a distributor supplied the same information. The comment said FDA's current practice (which requires manufacturers to list drugs even if a distributor lists those drugs) is contrary to the Drug Listing Act of 1972, FDA's regulations at § 207.20(b), and the Paperwork Reduction Act. The comment said requiring ‘‘additional’’ listing has no practical utility, is wasteful to the regulated industry, and costly to consumers.

(Response) Although the comment is outside the scope of the rule in the sense that it has no direct bearing on foreign establishment registration, listing, or the United States agent requirement, FDA disagrees with the comment. Section 207.20(b) applies to owners and operators of establishments that are ‘‘*not otherwise required to register under section 510 of the act*’’ and that ‘‘*distribute under their own label or trade name* a drug manufactured or processed by a registered establishment’’ (emphases added). It states that these owners and operators may elect to submit listing information directly to FDA and to obtain a Labeler Code. The regulation, therefore, clearly states that these distributors: (1) Do not have to register (whereas manufacturers must register); (2) are distributing drugs under their own label or trade name (which will be different from the labels and names used by the manufacturer); and (3) have discretion to decide whether they wish to list the drugs (because § 207.20(b) says that these persons ‘‘may elect’’ to submit listing information to FDA).

More importantly, the comment overlooks the value in having these distributors and manufacturers list drugs. Section 207.20(b) applies where the distributor uses its own label or trade name on a drug, but does not manufacture the drug itself. So, if these distributors and drug manufacturers list the drugs that they put into commercial distribution, FDA will be able to link the distributor's drugs back to their manufacturer(s) even though the distributor is using a different label or name for the drug.

To illustrate how this works, assume that a distributor, named Delta, distributes two drugs that it calls Alpha and Beta. Alpha is made by a U. S. manufacturer, named Domestic Co., which sells Alpha under the name X, while Beta is made by a foreign manufacturer, named Foreign Co., and sold under the name Y. If, as the comment apparently requests, Delta—but not Domestic Co., or Foreign Co., had to list the drugs, FDA might find it difficult to link Alpha and Beta to their respective manufacturers. If, on the other hand, the manufacturers, but not Delta, had to list the drugs, FDA might find it difficult to know that drug X and Alpha are the same or that drug Y and Beta are the same. When viewed from this perspective, the drug listing information from both the distributor and manufacturers serves the practical purpose of providing a link between seemingly different drugs, and so, contrary to the comment, the drug listing information is not redundant or unnecessary.

(Comment 24) One comment said that FDA, in the past, has allowed foreign drug establishments to authorize a representative to register and list on its behalf. The comment asked FDA to clarify that foreign drug establishments may continue this practice.

(Response) Foreign drug establishments may continue to have representatives register and submit drug listing information on their behalf. Neither section 510(i) of the act, nor this final rule, requires foreign drug establishments to complete or to submit registration and listing information themselves, but foreign drug establishments are responsible for the accuracy of the information submitted to FDA and for complying with the registration and listing requirements.

(Comment 25) One comment suggested that if a biologic intermediate is licensed, then the license holder for the intermediate and the license holder for the final product must register and list the product.

(Response) In general, if an establishment has a licensed biological product, the establishment, whether foreign or domestic, must register and list its products. FDA would consider the product to fall within the definition of ‘‘drug’’ or ‘‘device’’ in section 201(g) or (h) of the act, so section 510(i) of the act would require registration and product listing.

(Comment 26) One comment asked whether biologics source suppliers must register.

(Response) As stated earlier, registration is required if the product that is imported or offered for import to the United States meets the definition of ''drug'' or ''device'' in section 201(g) or (h) of the act and if the establishment is not otherwise exempt from the registration requirement.

If the establishment is unsure about whether or not they should register, they should contact the appropriate product review division in CBER. If the establishment is unsure about which product review division to contact, they should contact the Office of Compliance and Biologics Quality at 301–827–6190 for assistance.

(Comment 27) One comment claimed that, because the rule excluded establishments whose drugs are not imported or offered for import into the United States, the rule contradicted FDA's ''Policy Statement Concerning Cooperative Manufacturing Arrangements for Licensed Biologics'' (hereinafter referred to as ''the cooperative manufacturing policy''), which appeared in the **Federal Register** on November 25, 1992 (57 FR 55544). The comment focused on foreign manufacturers of bulk substances who sell their products to other foreign manufacturers who use them in making a finished product.

(Response) The cooperative manufacturing policy discussed several types of manufacturing arrangements for establishments who wish to cooperate in the manufacture of a licensed biological product and made no distinctions between foreign and domestic manufacturers. FDA drafted the policy statement to describe the then-current licensing policies in CBER ''for meeting the increased demand for flexible manufacturing arrangements'' (57 FR 55544).

The first manufacturing arrangement discussed in the policy concerned short supply arrangements. In a short supply arrangement, a manufacturer obtains materials from another facility under certain conditions because the manufacturer needs to obtain source materials only due to ''unusual circumstances where the source material is scarce or growth requirements so peculiar that production is uncommon'' (57 FR 55544 at 55545). The policy was silent as to whether firms who provide source material under a short supply arrangement must register or list, so it neither supports nor conflicts with this rule. FDA advises foreign establishments who provide source material under a short supply arrangement to register and to list if they meet the terms in section 510(i) of the act and this final rule. In other words, registration and listing is required if the foreign establishment is engaged in manufacturing, preparing, propagating, compounding, or processing a drug or device that is imported or offered for import into the United States (and the establishment does not otherwise qualify for an exemption from the registration and listing requirements).

The second arrangement discussed in the policy concerned divided manufacturing arrangements where two *registered* manufacturers jointly participate in manufacturing a product (emphasis added). Under this scenario, both manufacturers are manufacturing the product, so, even if the manufacturers were both foreign establishments, they would be subject to the registration requirements in this rule because they are engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States. So, the policy, as it applies to divided manufacturing arrangements, does not conflict with the rule.

The third and fourth arrangements discussed in the policy pertain to shared and contract manufacturing arrangements. In shared manufacturing arrangements, two or more manufacturers may perform different manufacturing tasks, but are not licensed to perform all manufacturing aspects. The policy advised manufacturers in shared manufacturing arrangements to register and to list in accordance with part 207. If the manufacturers are located in a foreign country, FDA considers both to be manufacturing a product to be imported or offered for import into the United States and would expect both manufacturers to register and to list the products that are being imported or offered for import. Consequently, the policy does not conflict with the rule.

As for contract manufacturing arrangements, these arrangements involve a licensed manufacturer who engages another manufacturing facility (referred to as the ''contract manufacturer'') to perform all or some of the steps to manufacture a biological product (see 57 FR 55544 at 55546). Clearly, the licensed manufacturer, as the entity who obtains marketing approval and sells the product, must register and list its product even if the licensed manufacturer is a foreign establishment. Registration and listing would be required because, under section 510(i) of the act, the licensed manufacturer is manufacturing, preparing, propagating, compounding, or processing a drug that is imported or offered for import into the United States. The same would be true for foreign contract manufacturers; if a foreign contract manufacturer's manufacturing steps can be considered to be manufacturing, preparing, propagating, compounding, or processing a drug that is imported or offered for import into the United States, then the foreign contract manufacturer falls within section 510(i) of the act and must register and list.

FDA further notes that the cooperative manufacturing policy statement simply represents FDA's advice whereas this rule implements section 510(i) of the act and creates enforceable obligations. Therefore, even if there were any conflict between the policy statement and this rule, foreign establishments must comply with this rule.

6. Times for Registration and Drug Listing (§ 207.21)

Proposed § 207.21 would correct an administrative oversight by adding ''abbreviated new drug applications'' and ''abbreviated new animal drug applications'' to the list of marketing applications in that section. The effect would be to state, expressly, that an owner or operator of an establishment that has just begun manufacturing or processing drugs should register within 5 days after submitting an NDA, abbreviated new drug application, new animal drug application, abbreviated new animal drug application, medicated feed mill license application, antibiotic application, or a biologics license application to manufacture a biological product.

(Comment 28) One comment said FDA failed to address biological manufacturing sites that are currently licensed, but not registered. The comment asked when these firms should register.

(Response) FDA recently began efforts to create an electronic registration program for all establishments, both foreign and domestic, that are subject to part 207. As a result, FDA is amending § 207.21(a) to delete the registration schedule and its reference to Form FDA–2656 (Registration of Drug Establishment).

Foreign establishments subject to part 207 should register by May 28, 2002.

(Comment 29) One comment said that FDA should create a special schedule for foreign establishment registration, rather than use the existing schedule, because foreign establishments might find it difficult to register quickly or immediately (depending on when the

rule becomes effective). The comment said FDA should also consider the implications of company mergers, name changes, burdens of complying with new registration schedules, and multiple product types.

(Response) As stated above, foreign establishments subject to part 207 should register by May 28, 2002. This should give foreign establishments sufficient time to comply with the registration and listing requirements even if they are aware of impending mergers, name changes, or other future business considerations.

7. Information Required in Registration and Drug Listing (§ 207.25)

Section 207.25(b)(2) requires the numbers for various marketing applications to be included in the drug listing information submitted to the agency. For example, if an NDA were assigned number 20–570, the application number that would be included in the drug listing information would be NDA 20–570.

The proposed rule would add abbreviated new animal drug applications to the list of marketing applications in § 207.25. This action was necessary because abbreviated new animal drug applications were inadvertently omitted.

(Comment 30) One comment asked whether § 207.25(b)(3), which requires an establishment to provide the ''license number of the manufacturer'' as part of the drug product listing form, applies to numbers assigned to biologics license applications.

(Response) When FDA approves a biologics license application, the applicant receives a United States license number. The United States license number is different from the biologics license application number and is the number that should be reported on the drug listing form for biological products in § 207.25(b)(3).

8. Inspection of Registrations and Drug Listings (§ 207.37)

Proposed § 207.37(a) would update the addresses in the Center for Drug Evaluation and Research (CDER) where copies of registration forms filed by establishments are available for inspection and would state that copies of registration forms submitted by foreign establishments are available for inspection at the Office of Compliance in CDER. Copies of forms submitted by domestic establishments would continue to be available for inspection at FDA district offices and at the Office of Compliance in CDER.

The proposal would also update the addresses in § 207.37(b).

(Comment 31) One comment claimed the current procedures for examining drug listing information are ''cumbersome and inconvenient'' and that FDA should makes its processes more transparent and its procedures readily available. The comment said FDA should post the information on the Internet.

(Response) In general, FDA has taken various steps to make information more readily available. The agency will take the comment's suggestion under advisement, but, due to resource limitations and other agency priorities, it cannot, at this time, make drug listing information available electronically or estimate when it will be able to do so.

9. Drug Listing Requirements for Foreign Drug Establishments (§ 207.40)

Proposed § 207.40(a) would require foreign establishments whose drugs are imported or offered for import into the United States to comply with the establishment registration and listing requirements in subpart C of part 207 (''Procedures for domestic drug establishments''), unless exempt under subpart B of part 207 (''Exemptions''). Proposed § 207.40(b) would prohibit the importation of drugs from unregistered foreign establishments, prohibit the importation of unlisted drugs, and require foreign establishments to submit registration and listing information, including labels and labeling, in English. Proposed § 207.40(c) would, among other things, require each foreign establishment to submit the name, address, and phone number of its United States agent as part of the establishment's initial and updated registration information, and to describe the United States agent's responsibilities.

(Comment 32 and Response) FDA, on its own initiative, is revising the reference to drugs imported for investigational use in § 207.40(b). The rule stated that drugs for investigational use must comply with 21 CFR part 312. FDA is revising the provision to add a reference to part 511 (21 CFR part 511) because investigational new animal drugs are subject to part 511. This change should have no effect on foreign establishments because the Center for Veterinary Medicine has not required foreign establishments to list investigational new animal drugs.

FDA is also revising § 207.40(b) and its prohibition on the importation or the offer to import drugs from unregistered foreign establishments. FDA is adding a reference to section 801(d)(3) of the act (21 U.S.C. 381(d)(3)) so that drugs imported under section 801(d)(3) of the act may be admitted into the United States even if the foreign establishment is not registered. The agency is taking this step because section 801(d)(3) of the act imposes very few restrictions on the admission of drug components that are imported into the United States for further processing or incorporation into a product that will be exported from the United States. The agency is making similar changes to §§ 607.40(b) and 807.40(c).

(Comment 33) Proposed § 207.40(c)(2) would require the United States agent to assist FDA in communications with the foreign drug establishment, respond to questions concerning the foreign drug establishment's products that are imported or offered for import into the United States, and assist FDA in scheduling inspections of the foreign drug establishment. One comment would revise the rule to allow multinational companies with many foreign affiliates to designate an employee at the foreign affiliate as the United States agent and to list an employee in the United States as an alternate. The comment said this would make communications between FDA and foreign establishments more efficient because the foreign employee would be able to answer questions more directly and schedule inspections more readily.

(Response) FDA declines to revise the rule as suggested by the comment. FDA reiterates that it interprets the term ''United States agent'' as meaning that the agent is physically located in the United States. If the United States agent could be located in any foreign country, section 510(i) of the act would not have to refer to a ''United States'' agent. Indeed, if the agent could be in any foreign country, the agent requirement might even by invalid or questioned as an intrusion into a foreign country's corporate or employment laws.

So, the rule does not prevent a multinational firm from designating an employee located in the United States as its agent who could, if necessary, consult a foreign employee to respond to any questions FDA might have, schedule an inspection, or work with a foreign employee on other issues relevant to the United States agent's duties.

(Comment 34) Proposed § 207.40(c)(3) would require foreign establishments to report changes in the United States agent's name, address, or phone number within 5 days of the change. One comment stated that there may not be an adequate number of firms or persons who can act as United States agents and that foreign establishments will have to identify and locate such persons. The comment asked FDA to provide 30 days,

rather than 5 days, for foreign establishments to identify its United States agent. Similarly, another comment said a 5-day period is too short and asked FDA to allow 10-business days or 14-calendar days.

(Response) FDA has revised § 207.40(c)(3), and similar requirements at §§ 607.40(d)(3), and 807.40(b)(3), to give foreign establishments and United States agents 10-business days to report changes.

(Comment 35) As stated earlier, one comment asserted that FDA should not require foreign establishments to register if their products are not commercially distributed in the United States. The comment said that foreign establishments which send goods to a foreign trade zone and later re-export those goods from the United States without entering them into U. S. commerce should be exempt from registration requirements.

(Response) FDA agrees with the comment, but only as it pertains to foreign establishments who send products into foreign trade zones and whose products are re-exported from the United States without having entered domestic commerce. FDA, therefore, has amended §§ 207.40(a), 607.40(a), and 807.40(a) accordingly.

D. Proposed Changes to Part 607 (Human Blood and Blood Products)

1. Definitions (§ 607.3)

a. Definition of ''commercial distribution.'' Proposed § 607.3(e) would revise the definition of ''commercial distribution'' to state that, for foreign establishments, commercial distribution does not include distribution of any blood or blood product that is neither imported nor offered for import into the United States. The preamble to the proposed rule explained that this change was intended to make the definition, insofar as foreign establishments are concerned, consistent with the language of section 510(i)(1) of the act.

FDA received no comments on this provision and has finalized it without change.

b. Definition of ''United States agent.'' Proposed § 607.3(j) would define ''United States agent'' as ''any person residing or maintaining a place of business in the United States whom a foreign establishment designates as its agent.'' This definition was identical to that in proposed § 207.3(a)(11).

(Comment 36) FDA received no comments addressing proposed § 607.3(j). However, as stated earlier, the agency did receive a comment which sought to revise the identical definition at § 807.3 to expressly exclude mailboxes, answering machines or services, or other places where an individual acting as the foreign establishment's agent is not physically present.

(Response) FDA agrees with the comment and has revised the definition of ''United States agent'' in § 607.3(j) and the identical definitions in §§ 207.3(a)(11) and 807.3(r), accordingly.

2. Establishment Registration and Product Listing of Blood Banks and Other Firms Manufacturing Human Blood and Blood Products (§ 607.7)

Section 607.7(b) and (c) provides an address for CBER from which registration forms may be obtained and to which they may be sent. The proposed rule would amend § 607.7(b) and (c) to update the address.

FDA received no comments on this provision and has finalized it without change.

3. Who Must Register and Submit a Blood Product List (§ 607.20)

Proposed § 607.20(a) would revise the description of owners and operators who must register their establishments and list their products. The proposal would clarify that only domestic firms must register and submit a list of every blood product in commercial distribution, ''whether or not the output of such blood product establishment or any particular blood product so listed enters interstate commerce.'' This would mean that foreign establishments do not have to list blood products that are not sold or offered for sale in the United States.

(Comment 37) As stated earlier, one comment suggested that FDA revise § 207.20(a) and similar language in §§ 607.20(a) and 807.20(a) to allow a foreign parent company to register and list on behalf of its foreign subsidiaries. The comment explained that the rule allows parent companies to list on behalf of their subsidiaries, but does not allow them to register their subsidiaries.

(Response) FDA agrees with the comment and has amended §§ 207.20(a), 607.20(a), and 807.20(a) to allow parent companies to register and list on behalf of their subsidiaries.

4. How and Where to Register Establishments and List Blood Products (§ 607.22)

Proposed § 607.22 would update the addresses from which registration and listing forms may be obtained. The proposal would also delete the language in § 607.22(b) concerning tapes for computer input and the submission of proposed formats for FDA review and approval because the option for using computer tapes was never used.

FDA received no comments on this provision and has finalized it without change.

5. Information Required for Establishment Registration and Blood Product Listing (§ 607.25)

Proposed § 607.25(a) would delete the word ''ZIP'' from the phrase ''post office ZIP code.'' FDA proposed this change because many foreign countries do not use the term ''ZIP'' code.

FDA received no comments on this provision and has finalized it without change. However, the agency, on its own initiative, is also amending § 607.25(b)(3) regarding the registration number of a parent establishment. Section 607.25(b)(3), as revised, now clarifies that for each blood product listed, the registration number of the parent establishment is required and that ''an establishment not owned, operated, or controlled by another firm or establishment is its own parent establishment.'' FDA is making this change to be consistent with changes to the Form FDA 2830 (Blood Establishment Registration and Product Listing).

6. Amendments to Establishment Registration (§ 607.26)

Currently, § 607.26 requires changes in individual ownership, ''corporate or partnership structure location or blood-product handling activity'' to be reported. The proposal would revise this language to read as ''Changes in individual ownership, corporate or partnership structure, location, or blood-product handling activity'' to clarify that changes in corporate or partnership structure or location or blood-product handling activity are to be reported.

FDA received no comments on this provision and has finalized it without change.

7. Additional Blood Product Listing Information (§ 607.31)

Proposed § 607.31(a) would authorize the Director of CBER, rather than the Commissioner of Food and Drugs (the Commissioner), to perform various actions, such as making a request or a finding, before requiring additional blood product listing information. The proposal reflected the fact that the center director, rather than the Commissioner, performs those functions.

The proposal would also delete § 607.31(b) that pertains to the voluntary reporting of information on the quantity

of blood product distributed. FDA proposed to delete the text in paragraph (b) of § 607.31 because the form specified in the rule, Form FD–2831 (Blood Establishment Resource Summary), is obsolete, and the provision has not been used.

FDA received no comments on this provision and has finalized it without change.

8. Notification of Registrant; Blood Product Establishment Registration Number and NDC Labeler Code (§ 607.35)

Section 607.35(a) currently states that the Commissioner will provide a validated copy of Form FD–2830 to the location shown for the registering establishment. The proposal would amend § 607.35(a) to state that a copy will also be sent to the reporting official if that official is at another address. The proposal would also substitute the ''Director of the Center for Biologics Evaluation and Research'' for the ''Commissioner'' because the center director, rather than the Commissioner, is the official who provides the validated copy.

FDA received no comments on this provision and has finalized it without change.

9. Inspection of Establishment Registrations and Blood Product Listings (§ 607.37)

Proposed § 607.37 would update the addresses where filed forms are available for inspection or where requests for information regarding blood establishment registration and listing should be sent.

FDA received no comments on this provision and has finalized it without change.

10. Establishment Registration and Blood Product Listing Requirements for Foreign Blood Product Establishments (§ 607.40)

Proposed § 607.40(a) would require foreign establishments to comply with establishment registration requirements in addition to blood product listing requirements. To complement this change, the proposal would revise the title to § 607.40 to read as ''Establishment registration and blood product listing requirements for foreign blood product establishments.''

Proposed § 607.40(b) would enable FDA to prohibit the importation of blood products from unregistered foreign establishments, in addition to prohibiting the importation of unlisted blood products. This prohibition would be similar to § 207.40(b) and would be consistent with sections 301(p) and 501(a) (21 U.S.C. 331(p) and 351(a)), and 801(a) of the act. Proposed § 607.40(b) would also add establishment registration information to types of information that must be submitted in the English language.

Proposed § 607.40(c) would require foreign blood product establishments to submit the name and address of the establishment and the name of the individual responsible for submitting the establishment registration and product listing information as part of the establishment registration and blood product listing. Proposed § 607.40(c) would also require foreign establishments to report any changes in their registration or listing information.

Proposed § 607.40(d) would require each foreign blood product establishment to submit the name, address, and phone number of one United States agent as part of its initial and updated registration information and describe the United States agent's responsibilities. Changes to the United States agent's name, address, or phone number would, under proposed § 607.40(d), be reported to FDA within 5 days of the change.

(Comment 38) FDA received no comments on this provision, but, as stated earlier, one comment asserted that FDA should not require foreign establishments to register if their products are not commercially distributed in the United States. The comment said that foreign establishments which send goods to a foreign trade zone and later re-export those goods from the United States without entering them into United States commerce should be exempt from registration requirements.

(Response) FDA agrees with the comment, but only as it pertains to foreign establishments who send products into foreign trade zones and whose products are re-exported from the United States without having entered domestic commerce. FDA, therefore, has amended §§ 207.40(a), 607.40(a), and 807.40(a) accordingly.

(Comment 39) FDA received no comments on § 607.40, but, as stated earlier, received comments on similar language in § 207.40 regarding the time period for reporting changes to the United States agent's name, address, or phone number. The comments would increase the time period to 10-business days or 14-calendar days.

(Response) FDA agrees with the comment and has revised §§ 207.40(c)(3), 607.40(d)(3), and 807.40(b)(3) to give foreign establishments and United States agents 10 business days to report changes.

11. Exemptions for Blood Product Establishments (§ 607.65)

Proposed § 607.65 would revise paragraphs (c), (d), and (e) so that the exemptions described in those paragraphs would apply to both foreign and domestic persons or establishments. For example, proposed § 607.65(c) would exempt domestic and foreign persons who manufacture blood products solely for use in research, teaching, or analysis, while proposed § 607.65(d) would exempt carriers, both foreign and domestic, who receive, carry, hold, or deliver blood products in their usual course of business. Proposed § 607.65(e) would exempt domestic and foreign persons who engage solely in the manufacture of in vitro diagnostic blood products and reagents that are not subject to licensing under section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262).

FDA received no comments on this provision and has finalized it without change.

12. Miscellaneous Biologics Comments

(Comment 40) One comment said that the document entitled ''Policy Statement Concerning Cooperative Manufacturing Arrangements for Licensed Biologics,'' which appeared in the **Federal Register** on November 25, 1992 (57 FR 55544), discusses registration requirements for firms in cooperative manufacturing arrangements, but does not specifically address ''who was responsible for the registration process (i.e., the license holder of the final product versus the establishment owner of the bulk drug substance').''

(Response) FDA issued the cooperative manufacturing policy in 1992, 6 years before FDAMA amended section 510(i) of the act to require foreign establishments to register. While FDA is currently updating the policy, comments concerning the policy are outside the scope of this rule.

Yet with regard to the comment's cooperative manufacturing scenario, section 510(i) of the act requires any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States to register the name and place of business of the establishment and the name of a United States agent for the establishment. Thus, in a cooperative manufacturing arrangement, if a foreign bulk drug substance establishment imports or offers to import the bulk drug into the United States, the foreign establishment must

register. Likewise, the license holder of the final product, whether foreign or domestic, must register because, by obtaining the license (and presumably intending to sell the drug), the license holder is engaged in the manufacture, preparation, propagation, compounding, or processing of a drug (see section 510(a)(1), (b), and (i) of the act).

E. Proposed Changes to Part 807 (Devices)

1. Definitions (§ 807.3)

a. Definition of ''commercial distribution.'' Section 807.3(b) currently defines ''commercial distribution,'' in part, as ''any distribution of a device intended for human use which is held or offered for sale * * * .''

Similar to the proposed changes to §§ 207.3 and 607.3, the proposed rule would create a new § 807.3(b)(4) to state that, for foreign establishments, commercial distribution does not include distribution of a device that is neither imported nor offered for import into the United States.

FDA received no comments on this provision and has finalized it without change.

b. Definition of ''United States agent.'' Proposed § 807.3(r) would define a ''United States agent'' as ''any person residing or maintaining a place of business in the United States whom a foreign establishment designates as its agent.''

(Comment 41) As stated earlier, FDA received one comment on the definition of United States agent. The comment noted that the preamble to the proposed rule stated that the definition of ''United States agent'' excluded mailboxes, answering machines or services, or other places where an individual acting as the foreign establishment's agent is not physically present (see 64 FR 26330 at 26331). The comment suggested that FDA revise the definition of ''United States agent'' to mention these exclusions.

(Response) FDA agrees with the comment and has revised the definition of ''United States agent'' in §§ 207.3(a)(11), 607.3(j), and 807.3(r) accordingly.

2. Who Must Register and Submit a Device List (§ 807.20)

Section 807.20(a) currently requires an ''owner or operator of an establishment not exempt under section 510(g) of the act'' or subpart D of part 807 who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use to register and to submit listing information. It also states that an owner or operator shall register and list devices ''whether or not the output of the establishments or any particular device so listed enters interstate commerce.''

Proposed § 807.20(a) would clarify that an owner or operator ''shall'' register and list (unless it is otherwise exempt from such requirements). The proposal would also clarify that the language requiring owners and operators to register their establishments and to list devices, even if the devices do not enter interstate commerce, applies only to domestic firms.

The proposal would also amend the title of subpart B of part 807, ''Procedures for Domestic Device Establishments,'' to remove the word ''domestic.'' This would reflect the fact that the act's registration and listing requirements now apply both to domestic establishments and to foreign establishments whose devices are imported or offered for import into the United States.

The proposal would also delete § 807.20(a)(6) pertaining to persons acting as the U.S.-designated agent.

(Comment 42) One comment asked if a foreign establishment that supplies components to U. S. manufacturers must register and list if the U. S. manufacturer incorporates those components into a device.

(Response) Section 807.65(a) states that a ''manufacturer of raw materials or components to be used in the manufacturer or assembly of a device who would not otherwise be required to register under the provisions of this part'' is exempt from the registration requirements.

(Comment 43) One comment asked if devices that are licensed under section 351 of the PHS Act must be listed and whether their manufacturers must be registered.

(Response) Section 510(i) of the act makes no distinction between establishments whose products are subject to the act or whose products are subject to the PHS Act. It requires all foreign establishments that are engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States to register (including the name of a United States agent) and to list their products.

Consequently, if a foreign establishment has devices that are licensed under section 351 of the PHS Act, then that foreign establishment must register and list its products. Most devices that are licensed under section 351 of the PHS Act will contain or use blood or blood components, so establishments that manufacture such licensed products would be subject to the registration and listing requirements for blood and blood products (part 607) rather than the registration and listing requirements for devices. FDA has revised § 607.3(b) to state expressly that, for purposes of the blood and blood product registration and listing requirements, blood and blood products include products which meet the definition of a device under the act and are licensed under section 351 of the PHS Act.

(Comment 44) One comment asked FDA to clarify whether foreign establishments may continue to authorize an initial importer in the United States to list devices on the foreign establishment's behalf. The comment explained that, in the past, FDA has allowed initial importers to list devices if the foreign establishment certifies that it does not ship its devices to anyone else in the United States. The comment added that, under § 807.25(d), the official correspondent for the foreign establishment would remain as the contact point for registration and listing matters.

(Response) The final rule requires foreign manufacturers to register and to list. In other words, FDA is discontinuing its policy that allowed ''sole'' initial importers to list devices. FDA is discontinuing the policy because, even though importers believed they were the ''sole'' importer, FDA sometimes found there were multiple ''sole'' importers. Each importer listed devices, and the lists would differ. The submission of multiple, and sometimes different, device lists from persons who claimed to be the ''sole'' initial importer for a particular foreign establishment created confusion and uncertainty about the device lists. Therefore, FDA is requiring foreign establishments to register and to list their devices and will not accept lists from ''sole'' initial importers.

(Comment 45) One comment asked FDA to clarify whether contract manufacturers must register or list devices. The comment explained that proposed § 807.20(a)(2) suggests that contract manufacturers do not have to list devices, but does not expressly exempt contract manufacturers from the registration requirements. The comment added that § 807.20(c) appears to exempt contract manufacturers from registration requirements and suggested that both foreign and domestic contract manufacturers be exempt from registration requirements.

(Response) The comment is correct that § 807.20(a)(2) exempts contract manufacturers from the listing

requirements, while the language in § 807.20(c)(1) was intended to exempt contract manufacturers from registration and listing requirements. However, the agency is considering more substantial revisions to part 807, and these revisions will include changes to the requirements for contract manufacturers. As a result, FDA declines to amend § 807.20(a)(2) and (c)(1) as suggested by the comment, and the agency encourages foreign contract manufacturers to register.

(Comment 46) One comment noted that, under § 807.20(a)(2), contract manufacturers do not have to list devices, and that § 807.22(c)(1) does not require initial importers to submit a list of devices. The comment suggested that FDA move the language regarding initial importers from § 807.22(c)(1) to § 807.20(a)(2) to enhance clarity and consistency.

(Response) The comment goes beyond the scope of the rule. While FDA agrees that §§ 807.20(a)(2) and 807.22(c)(1) could be written more clearly and consistently, the agency is considering more substantial revisions to part 807. Therefore, FDA declines to amend this rule to make the changes suggested by the comment.

(Comment 47) As stated earlier, one comment suggested that FDA revise § 207.20(a) and similar language in §§ 607.20(a) and 807.20(a) to allow a foreign parent company to register and list on behalf of its foreign subsidiaries. The comment explained that the rule allows parent companies to list on behalf of their subsidiaries, but does not allow them to register their subsidiaries.

(Response) FDA agrees with the comment and has amended §§ 207.20(a), 607.20(a), and 807.20(a) to allow parent companies to register and list on behalf of their subsidiaries.

3. Information Required or Requested for Establishment Registration and Device Listing (§ 807.25)

Proposed § 807.25 would delete the word ''ZIP'' from the term, ''post office ZIP Code,'' because the term ''ZIP Code'' is not used in many foreign countries.

FDA received no comments on this provision and has finalized it without change.

4. Establishment Registration and Device Listing for United States Agents of Foreign Establishments (§ 807.40)

Proposed § 807.40 would delete the existing language in § 807.40 entirely and replace it with general descriptions of the foreign establishment's obligations and the United States agent's role. The proposal would also use the term ''foreign establishment,'' rather than ''foreign manufacturer,'' and revise the title to § 807.40 to be more consistent with section 510 of the act.

Proposed § 807.40(a) would require any foreign establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into the United States to register and list its devices in conformance with subpart B of part 807 (''Procedures for Device Establishments''). This would have foreign establishments comply with the same procedures as domestic establishments.

The proposal would also require the official correspondent for the foreign establishment to facilitate communication between the establishment's management and FDA. This change complements the requirement for an official correspondent in § 807.25(d).

Proposed § 807.40(b) would require each registered foreign establishment to submit the name, address, and phone number of its United States agent as part of its registration information. The proposal would also require the agent to reside or maintain a place of business in the United States, but would allow (rather than require) a foreign establishment to designate its United States agent as its official correspondent. The preamble to the proposed rule explained that designating the United States agent as the official correspondent may be more efficient than having a separate United States agent and an official correspondent, but the proposed rule would give foreign establishments flexibility in deciding how to allocate their resources in this area and what the United States agent's responsibilities would be (see 64 FR 26330 at 26337). The preamble to the proposed rule also noted that electronic product manufacturers, under § 1005.25 (21 CFR 1005.25), must designate a permanent resident of the United States as the manufacturer's agent upon whom service of process may be made for and on behalf of the manufacturer as provided in section 360(d) of the Radiation Control for Health and Safety Act of 1968. The preamble to the proposed rule suggested that manufacturers of products that are both medical devices and electronic products might wish to consider whether their agents, under § 1005.25, can also serve as their United States agent under proposed § 807.40 and perform the duties expected of a United States agent (id.).

Like proposed §§ 207.40 and 607.40, proposed § 807.40(b) would require the United States agent, upon request from FDA, to assist the agency in communications with the foreign establishment, to respond to questions regarding devices imported or offered for import, and to assist FDA in scheduling inspections of the foreign establishment. Proposed § 807.40(b) would also enable FDA, when it is unable to contact the foreign manufacturer directly or expeditiously, to provide information or documents to the United States agent and for that act to be considered equivalent to providing the same information or documents to the foreign establishment, and would further require a foreign establishment to report to FDA changes in the United States agent's name, address, or phone number within 10 days of the change.

Proposed § 807.40(c), like proposed §§ 207.40(b) and 607.40(b), would prohibit the importation of devices that have not been listed or manufactured, prepared, propagated, compounded, or processed at a registered foreign establishment.

(Comment 48) One comment noted that § 807.40(a) requires the official correspondent to facilitate communications between a firm and FDA while proposed § 807.40(b)(2) would require the United States agent to facilitate communications between a foreign establishment and FDA. The comment suggested revising § 807.40(a) to require the official correspondent to facilitate communications pertaining to registration and listing. The comment said this would help distinguish between the official correspondent and the United States agent.

(Response) FDA agrees with the comment and has revised § 807.40(a) accordingly. This change would make the official correspondent's role, for foreign establishments, more consistent with that for domestic establishments, as seen in § 807.25(d) (official correspondent for a domestic establishment is the point of contact for matters relating to registration and listing).

(Comment 49) As stated earlier, one comment asserted that FDA should not require foreign establishments to register if their products are not commercially distributed in the United States. The comment said that foreign establishments which send goods to a foreign trade zone and later re-export those goods from the United States without entering them into U. S. commerce should be exempt from registration requirements.

(Response) FDA agrees with the comment, but only as it pertains to foreign establishments who send products into foreign trade zones and

whose products are re-exported from the United States without having entered domestic commerce. FDA, therefore, has amended §§ 207.40(a), 607.40(a), and 807.40(a) accordingly.

(Comment 50) Two comments sought to exempt foreign establishments from the United States agent requirement if the foreign establishment makes class I devices. The comments asserted that these devices present little or no risk to consumers so requiring these establishments to have a United States agent would increase costs to those establishments and provide little or no benefit.

(Response) FDA declines to amend the rule as suggested by the comments. Section 510(i) of the act does not base the United States agent requirement on a product's level of risk, and FDA's interpretation of section 510(i) of the act would be more consistent and fair if it applied the United States agent requirement to all foreign establishments regardless of their device classifications.

Additionally, § 807.40 only requires the United States agent to assist in communications with the foreign establishment, to respond to questions regarding devices imported or offered for import, and to assist in scheduling inspections of the foreign establishment. These duties are not dependent on a device's classification. For example, FDA might ask the United States agent to help schedule an inspection of the foreign establishment. Such assistance could facilitate the inspection, regardless of the device classification for the foreign establishment's products.

5. Miscellaneous Device Comments

(Comment 51) One comment would revise the title for part 807 to delete the word ''distributors.'' The comment said that FDA does not require distributors to register or list devices.

(Response) The proposed rule used an incorrect title for part 807; the current title for part 807 refers to manufacturers and initial importers of devices and does not refer to distributors. Therefore, no changes are necessary.

(Comment 52) One comment offered several suggestions on how to revise the registration and listing forms for device establishments. The comment would also redesignate the forms and make corresponding changes in part 807 whenever a provision referred to a form by its designation.

(Response) FDA has or will address issues regarding its registration and listing forms as part of the process of seeking approval, under the Paperwork Reduction Act of 1995, for the revised information collection requirements in those forms.

(Comment 53) One comment said that FDA must amend § 807.65, ''Exemptions for device establishments,'' so that certain exemptions would not apply for foreign establishments. The comment said that the following exemptions should not apply to foreign establishments:

1. Section 807.65(d) for licensed practitioners;

2. Section 807.65(e) for pharmacies, surgical supply outlets, or other similar retail establishments making final deliveries or sales to the ultimate user;

3. Section 807.65(f) for persons who manufacture, prepare, propagate, compound, or process devices solely for use in research, teaching, or analysis and do not introduce such devices into commercial distribution; and

4. Section 807.65(i) for persons who dispense devices to the ultimate consumer or whose major responsibility is to render a service necessary to provide the consumer with a device or the benefits to be derived from the use of a device.

The comment explained that amending § 807.65 in this manner would be similar to the limitations on exemptions in proposed §§ 207.10 and 607.65.

(Response) FDA agrees with the comment and has amended § 807.65 accordingly. Section 510(g)(5) of the act gives FDA discretion to decide whether to exempt a class of persons from the registration requirements. Here, in the case of § 807.65(d) and (e), the exemptions are expressly or implicitly dependent on a person's compliance with Federal, State, or local laws, and so FDA has insufficient information to make a finding, under section 510(g)(5) of the act, to justify an exemption for foreign practitioners, pharmacies, surgical supply outlets, and other similar establishments.

For § 807.65(f) and (i), FDA, again, has insufficient information to make a finding, under section 510(g)(5) of the act, to justify an exemption for foreign establishments engaged in those practices. Consequently, the exemptions in § 807.65(d), (e), (f), and (i) will apply only to domestic persons or establishments.

F. Registration Schedules

The preamble to the proposed rule indicated that FDA would develop a staggered schedule for foreign establishment registration for foreign establishments subject to part 207. FDA explained that a staggered schedule might be needed because part 207 applies to human drugs, animal drugs, and biologics. The preamble to the proposed rule also stated that FDA did not intend to develop any special registration schedules for parts 607 and 807 because, compared to part 207, fewer foreign manufacturers are subject to the registration requirements in parts 607 and 807.

After the proposed rule had appeared in the **Federal Register**, FDA began efforts to create an electronic registration program for all establishments subject to part 207. Thus, for foreign human drug, animal drug, and biologics establishments subject to part 207, a staggered registration schedule is no longer necessary. Foreign establishments subject to part 207 should register by May 28, 2002.

For foreign blood and blood product establishments subject to part 607, no special registration schedules are necessary. FDA has determined that the foreign establishments subject to part 607 have previously submitted information that fulfills the registration requirement (with the exception of the United States agent requirement), and CBER will contact those manufacturers to obtain information regarding the United States agent for each establishment.

For foreign device establishments, FDA will begin enforcing the requirements in part 807 beginning on April 26, 2002.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), 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). Under the Regulatory Flexibility Act, if a rule has a significant impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities. Title II of the Unfunded Mandates Reform Act requires that agencies prepare a written assessment and economic analysis before proposing 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).

The final rule is consistent with the principles set out in the Executive order and in these two statutes. As explained below, FDA finds that the final rule does not require a Regulatory Flexibility Analysis. Also, because the rule does not impose any mandates on State, local, or tribal governments, or the private sector, that will result in an expenditure in any 1 year of $100 million or more, FDA is not required to perform a cost-benefit analysis according to the Unfunded Mandates Reform Act.

The new economic burdens imposed by the rule will involve broader requirements for foreign firms with respect to the registration of establishments and to the designation of United States agents. First, some foreign manufacturers will have to register their establishment before importing drugs, biological products, or devices into the United States. As stated earlier, before FDAMA amended section 510 of the act to require foreign establishment registration, many foreign establishments voluntarily registered their establishments, but all foreign establishments that imported or offered for import drugs, blood and blood products, and devices into the United States were required to list their products. The registration and listing activities used forms prepared by FDA.

FDA is able to estimate the rule's economic impact by using time and hourly wage estimates for registration. FDA estimates the labor costs associated with establishment registration are small, ranging from $25 per hour for device establishments, $20 per hour for blood and blood product establishments, and $100 per hour for drug establishments. These costs are based on information obtained primarily from domestic establishments, and FDA assumes that the average costs for foreign establishments will be similar. FDA also estimates that completing an establishment registration form will range from 15 minutes to 1 hour (depending on the form used). These estimates are derived from the estimated registration costs for domestic establishments and foreign establishments that voluntarily registered before FDAMA's enactment.

For devices subject to part 807, the agency's device establishment data base presently includes about 8,200 foreign establishments, of which almost 3,000 are unregistered establishments with listed products. FDA's paperwork officials estimate that registration activities would take about 15 minutes at a cost of about $6.25 per facility. Thus, the one-time cost to register these foreign device establishments would be about $18,750 (3,000 x 15 minutes x $25 per hour). For the remaining device firms, the paperwork costs would be minimal, consisting of the time required to name a United States agent.

For blood and blood products subject to part 607, FDA records suggests there are 98 foreign establishments and that all have voluntarily registered with FDA. Therefore, the cost to register these foreign establishments should be minimal and consist of the time required to name a United States agent.

For drugs and biological products subject to part 207, FDA records suggest there are 5,630 foreign establishments, but the number of foreign establishments that have already registered cannot easily be determined. Thus, even if all of these foreign establishments must register, the one-time cost to register would be about $281,500 (5,630 x 30 minutes x $100 per hour).

(Comment 54) Several comments, almost all from medical device companies, criticized the proposed rule as not estimating the economic impact of the United States agent requirement. One comment declared that the United States agent requirement would ''easily'' exceed $100 million, but did not explain how it arrived at that conclusion. Another comment stated that the Regulatory Flexibility Act requires U. S. agencies to analyze regulatory options that would minimize any significant impact on small entities and claimed that FDA failed to conduct that analysis. Other comments said FDA must consider the insurance costs for a United States agent, retainer fees, office costs, hourly rates, and/or daily rates. One comment implied that the rule was intended to lower FDA's operating costs while transferring more responsibilities and costs to foreign establishments. Another comment sought more time to determine the rule's economic impact.

(Response) FDA disagrees with the comments. The comments did not provide any evidence to support their claims that the United States agent requirement would result in costs exceeding $100 million. In response to the comments, FDA examined the costs of retaining a United States agent. Several persons have contacted FDA to express an interest in becoming a United States agent, and their fees have ranged between $750 and $2,000 annually.

FDA does not have a precise estimate of the number of foreign device firms that would need to develop an arrangement with a United States agent, but the agency's establishment data base identifies about 6,400 foreign device establishments that show only a foreign address for their ''official correspondent.'' If each of these 6,400 device establishments incurred costs of $1,000 to obtain a United States agent, the total industry annual cost would be about $6,400,000.

Similarly, FDA does not know the precise number of drug establishments that would incur costs to retain a United States agent. The agency believes, however, that the added costs for most pharmaceutical firms would be minimal, because under current rules (21 CFR 314.50(a)), all applications and supplements to approved applications must already ''contain the name and address of, and be countersigned by, an attorney, agent, or other authorized official who resides or maintains a place of business within the United States.'' Bulk drug establishments not holding an approved application could generally rely on the primary purchaser of their product to serve as their United States agent. Thus, while many foreign drug establishments would incur some additional paperwork costs, the additional costs would be minimal.

(Comment 55) One comment said FDA failed to offer exemptions from the United States agent requirement to small- and medium-sized Canadian firms as required under the Regulatory Flexibility Act.

(Response) The agency examined, but rejected, alternatives to the proposed rule. The registration information required by FDA is minimal, consisting largely of the establishment's address, names of owners or responsible officials, and additional identifying information on the establishment (such as type of establishment, types of products at the establishment, type of ownership). Similarly, identification of the United States agent requires minimal information (name, address, phone number). An alternative that required less information from foreign establishments would not provide sufficient information to identify the foreign establishment's location, a responsible person at the foreign establishment, or the type of establishment, thereby complicating any effort to locate or contact the foreign establishment or to determine whether the foreign establishment complied with the appropriate statutory and regulatory requirements. FDA also rejected an alternative that would eliminate the United States agent requirement for small- and medium-sized firms; section 510(i) of the act expressly requires foreign establishment to have a United States agent and does not provide for

exemptions from the United States agent requirement.

Moreover, as stated earlier, FDA does not object to having multiple firms use the same United States agent. Neither the act nor these regulations require a foreign establishment to enter an exclusive arrangement with its United States agent. In other words, several foreign establishments could use the same agent or ''share'' an agent, so long as the foreign establishments and the United States agent meet their regulatory obligations. This may reduce the United States agent's cost for small- and medium-sized firms.

Finally, the agency is not required to prepare a Regulatory Impact Analysis under the Regulatory Flexibility Act, because the rule will not have a significant economic effect on a substantial number of small entities. The term ''small entity'' is defined (5 U.S.C. 601(6)) to include the term ''small business,'' which, in turn, is defined (5 U.S.C. 601(3)) to have the ''same meaning as the term small business concern.'' The term ''business concern'' is defined by the Small Business Administration (SBA), at 13 CFR 121.105(a), in relevant part, as a business entity ''with a place of business located in the United States or which makes a significant contribution to the U.S. economy through payment of taxes or use of American products, materials or labor.'' Although some foreign firms would meet the SBA definition of a ''business concern'' because of their significant contribution to the United States economy (even though they do not operate primarily in the United States), it is unlikely that a substantial number that do not already have a U. S. presence that could act as a United States agent would be significantly impacted by this rule.

The Unfunded Mandates Reform Act (Public Law 104–114) requires that agencies prepare an assessment of anticipated costs and benefits before proposing 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 or more (adjusted annually for inflation). Because the total expenditures under the final rule will not result in a 1-year expenditure of $100 million or more, FDA is not required to perform a cost-benefit analysis under the Unfunded Mandates Reform Act.

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description for the information collection requirements are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Foreign Establishment Registration and Listing

Description: The final rule requires foreign establishments that import or offer to import human drugs, animal drugs, biologics, blood products, and devices into the United States to register and to name a United States agent. This information is required by section 510(i)(1) of the act, as amended by section 417 of FDAMA.

Although section 510(i)(2) of the act also requires foreign establishments to list their products at FDA, the final rule does not include such a requirement because FDA's existing regulations already require foreign manufacturers to submit such lists, and the agency has already obtained OMB approval for the information collection burden associated with product listing for parts 207 and 607 (for part 207, the OMB approval number is 0910–0045 and expires on April 30, 2001; for part 607, the OMB approval number is 0910–0052 and expires on February 28, 2003). Through this notice, FDA is also seeking approval for the device listing requirements insofar as they will be applied to foreign establishments.

Description of Respondents: Persons and businesses, including small businesses.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	No. of Responses perRespondent	Total Annual Responses	Hours per Response	Total Hours
207.21(a)	2,463	1	2,463	0.5	1,231.5
207.22(a) and 207.40	5,630	1	5,630	0.5	2,815
207.25(b)	53	4.3	228	0.5	114
607.22(a) and 607.40	98	1	98	1	98
607.26	1	1	1	0.5	0.5
607.31	1	1	1	10	10
807.22(a) and 807.40	7,200	1	7,200	0.25	1,800
807.22(b)	27,720	1	27,720	0.5	13,860
807.31(c)	7	1	7	0.5	3.5
Total					19,932.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Respondents	No. of Responses perRespondent	Total Annual Responses	Hours per Response	Total Hours
807.31	6,480	10	64,800	0.5	32,400

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]—Continued

21 CFR Section	No. of Respondents	No. of Responses perRespondent	Total Annual Responses	Hours per Response	Total Hours
Total					32,400

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The above estimates were based on the number of foreign establishments that currently list drugs or devices (as required by existing FDA regulations), the annual average number of new foreign establishments that voluntarily registered or began importing devices, and comparable burden hour estimates for registration by domestic establishments.

For device listing by foreign establishments, the above estimates are based on the number of foreign establishments that currently list devices and comparable burden hour estimates and annual frequency per response estimates for domestic firms. FDA has also made a correction to the total hour figure for § 807.31(e) to change 4 hours to 3.5 hours; the correction represents the accurate figure resulting from the mathematical calculation of 7 annual responses multiplied by 0.5 hours per response.

The estimated recordkeeping burden for § 807.31 is based on FDA's experience with foreign device establishments. FDA's experience suggests that, for foreign device establishments, there are approximately 9 owners or operators for every 10 foreign device establishments. Therefore, because FDA records indicate that there are 7,200 foreign device establishments, the estimated number of recordkeepers required to maintain the initial historical files is 6,480 (7,200 x 0.90 = 6,480).

The information collection provisions of this final rule have been submitted to OMB for review.

Prior to the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies 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. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

List of Subjects

21 CFR Part 207

Drugs, Reporting and recordkeeping requirements.

21 CFR Part 607

Blood.

21 CFR Part 807

Confidential business information, Imports, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, Title 21 of the Code of Federal Regulations is amended as follows:

PART 207—REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL DISTRIBUTION

1. The authority citation for part 207 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360b, 371, 374, 381, 393; 42 U.S.C. 262, 264, 271.

2. Section 207.3 is amended by revising paragraph (a)(5) and by adding paragraph (a)(11) to read as follows:

§ 207.3 Definitions.

(a) * * *

(5) *Commercial distribution* means any distribution of a human drug except for investigational use under part 312 of this chapter, and any distribution of an animal drug or animal feed bearing or containing an animal drug for noninvestigational uses, but the term does not include internal or interplant transfer of a bulk drug substance between registered establishments within the same parent, subsidiary, and/or affiliate company. For foreign establishments, the term ''commercial distribution'' shall have the same meaning except that the term shall not include distribution of any drug that is neither imported nor offered for import into the United States.

* * * * *

(11) *United States agent* means a person residing or maintaining a place of business in the United States whom a foreign establishment designates as its agent. This definition excludes mailboxes, answering machines or services, or other places where an individual acting as the foreign establishment's agent is not physically present.

* * * * *

3. Section 207.7 is amended by revising paragraph (a) to read as follows:

§ 207.7 Establishment registration and product listing for human blood and blood products and for medical devices.

(a) Owners and operators of human blood and blood product establishments shall register and list their products with the Center for Biologics Evaluation and Research (HFM–375), 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, on Form FDA–2830 (Blood Establishment Registration and Product Listing), in accordance with part 607 of this chapter. Such owners and operators who also manufacture or process other drug products at the same establishment shall, in addition, register and list all such other drug products with the Drug Listing Branch in accordance with this part.

* * * * *

4. Section 207.10 is amended by revising the section heading and the introductory text to read as follows:

§ 207.10 Exemptions for establishments.

The following classes of persons are exempt from registration and drug listing in accordance with this part under section 510(g)(1), (g)(2), and (g)(3) of the act, or because FDA has found, under section 510(g)(5) of the act, that their registration is not necessary for the protection of the public health. The exemptions in paragraphs (a) and (b) of this section are limited to pharmacies, hospitals, clinics, and public health agencies located in any State as defined in section 201(a)(1) of the act.

* * * * *

5. Section 207.20 is amended by revising paragraphs (a) and (c) to read as follows:

§ 207.20 Who must register and submit a drug list.

(a) Owners or operators of all drug establishments, not exempt under section 510(g) of the act or subpart B of this part 207, that engage in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs shall register and submit a list of every drug in commercial distribution (except that registration and listing information may be submitted by the parent, subsidiary, and/or affiliate company for all establishments when operations are conducted at more than one establishment and there exists joint ownership and control among all the establishments). Drug listing is not required for the manufacturing, preparation, propagation, compounding, or processing of an animal feed bearing or containing an animal drug (i.e., a Type B or Type C medicated feed), nor is drug listing required for establishments engaged in drug product salvaging. Drug products manufactured, prepared, propagated, compounded, or processed in any State as defined in section 201(a)(1) of the act must be listed whether or not the output of such establishments or any particular drug so listed enters interstate commerce. No owner or operator may register an establishment if any part of the establishment is registered by any other owner or operator.

* * * * *

(c) Before beginning manufacture or processing of a drug subject to one of the following applications, an owner or operator of an establishment is required to register before the agency approves it: A new drug application, an abbreviated new drug application, a new animal drug application, an abbreviated new animal drug application, a medicated feed mill license application, or a biologics license application.

* * * * *

6. Section 207.21 is amended by revising paragraph (a) to read as follows:

§ 207.21 Times for registration and drug listing.

(a) The owner or operator of an establishment entering into the manufacture or processing of a drug or drugs shall register the establishment within 5 days after the beginning of the operation and shall submit a list of every drug in commercial distribution at that time. If the owner or operator of the establishment has not previously entered into such an operation, the owner or operator shall register within 5 days after submitting a new drug application, abbreviated new drug application, new animal drug application, abbreviated new animal drug application, medicated feed mill license application, or a biologics license application. Owners or operators shall renew their registration information annually.

* * * * *

§ 207.25 [Amended]

7. Section 207.25 *Information required in registration and drug listing* is amended in paragraph (b)(2) by removing ''or new animal drug application number'' and by adding in its place the phrase ''new animal drug application number, or abbreviated new animal drug application number''.

8. Section 207.37 is amended by revising the introductory text of paragraph (a) and by revising paragraph (b) to read as follows:

§ 207.37 Inspection of registrations and drug listings.

(a) A copy of the Form FDA–2656 (Registration of Drug Establishment) filed by the registrant will be available for inspection in accordance with section 510(f) of the act, at the Division of Labeling and Non-Prescription Drug Compliance (HFD–310), Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855. In addition, copies of these forms for establishments located within a particular geographic area are available for inspection at FDA district offices responsible for that geographical area. Copies of forms submitted by foreign drug establishments are available for inspection at the Foreign Inspection Team (HFD–322), Office of Compliance, Center for Drug Evaluation and Research, 7520 Standish Pl., Rockville, MD 20855. Upon request and receipt of a stamped, self-addressed envelope, the Division of Labeling and Non-Prescription Drug Compliance, the Foreign Inspection Team, or the appropriate FDA district office will verify registration numbers or provide the location of a registered establishment.

* * * * *

(b) Requests for information about registrations and drug listings of an establishment should be directed to the Information Management Team (HFD–095), Office of Information Technology, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 or, with respect to the information described in paragraph (a) of this section, to the FDA district office responsible for the geographic area in which the establishment is located.

9. Section 207.40 is revised to read as follows:

§ 207.40 Establishment registration and drug listing requirements for foreign establishments.

(a) Foreign drug establishments whose drugs are imported or offered for import into the United States shall comply with the establishment registration and drug listing requirements in subpart C of this part, unless exempt under subpart B of this part or unless the drugs enter a foreign trade zone and are re-exported from that foreign trade zone without having entered U. S. commerce.

(b) No drug may be imported or offered for import into the United States unless it is listed as required in subpart C of this part and manufactured, prepared, propagated, compounded, or processed at a registered foreign drug establishment; however, this restriction does not apply to a drug imported or offered for import under the investigational use provisions in part 312 of this chapter, or the investigational new animal drug use provisions in part 511 of this chapter, or to a component of a drug imported under section 801(d)(3) of the act. Foreign drug establishments shall submit all listing information, including labels and labeling, and registration information in the English language.

(c) Each foreign drug establishment required to register under paragraph (a) of this section shall submit the name, address, and phone number of its United States agent as part of its initial and updated registration information in accordance with subpart C of this part. Each foreign drug establishment shall designate only one United States agent.

(1) The United States agent shall reside or maintain a place of business in the United States.

(2) Upon request from FDA, the United States agent shall assist FDA in communications with the foreign drug establishment, respond to questions concerning the foreign drug establishment's products that are imported or offered for import into the United States, and assist FDA in scheduling inspections of the foreign drug establishment. If the agency is unable to contact the foreign drug establishment directly or expeditiously, FDA may provide information or documents to the United States agent, and such an action shall be considered to be equivalent to providing the same information or documents to the foreign drug establishment.

(3) The foreign drug establishment or the United States agent shall report changes in the United States agent's name, address, or phone number to FDA within 10-business days of the change.

PART 607—ESTABLISHMENT REGISTRATION AND PRODUCT LISTING FOR MANUFACTURERS OF HUMAN BLOOD AND BLOOD PRODUCTS

10. The authority citation for part 607 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 371, 374, 381, 393; 42 U.S.C. 262, 264, 271.

11. Section 607.3 is amended by revising paragraphs (b) and (e) and by adding paragraph (j) to read as follows:

§ 607.3 Definitions.

* * * * *

(b) *Blood and blood product* means a drug which consists of human whole blood, plasma, or serum or any product derived from human whole blood, plasma, or serum, hereinafter referred to as ''blood product.'' For the purposes of this part only, blood and blood product also means those products that meet the definition of a device under the Federal Food, Drug, and Cosmetic Act and that are licensed under section 351 of the Public Health Service Act.

* * * * *

(e) *Commercial distribution* means any distribution of a blood product except under the investigational use provisions of part 312 of this chapter, but does not include internal or interplant transfer of a bulk product substance between registered establishments within the same parent, subsidiary, and/or affiliate company. For foreign establishments, the term ''commercial distribution'' shall have the same meaning except that the term shall not include distribution of any blood or blood product that is neither imported nor offered for import into the United States.

* * * * *

(j) *United States* agent means a person residing or maintaining a place of business in the United States whom a foreign establishment designates as its agent. This definition excludes mailboxes, answering machines or services, or other places where an individual acting as the foreign establishment's agent is not physically present.

12. Section 607.7 is amended by revising paragraphs (b) and (c) to read as follows:

§ 607.7 Establishment registration and product listing of blood banks and other firms manufacturing human blood and blood products.

* * * * *

(b) Forms for registration of an establishment are obtainable on request from the Center for Biologics Evaluation and Research (HFM–375), 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, or at any of the Food and Drug Administration district offices.

(c) The completed form should be mailed to the Center for Biologics Evaluation and Research (HFM–375), 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448.

13. Section 607.20 is amended by revising paragraph (a) to read as follows:

§ 607.20 Who must register and submit a blood product list.

(a) Owners or operators of all establishments, not exempt under section 510(g) of the act or subpart D of this part, that engage in the manufacture of blood products shall register and submit a list of every blood product in commercial distribution (except that registration and listing information may be submitted by the parent, subsidiary, and/or affiliate company for all establishments when operations are conducted at more than one establishment and there exists joint ownership and control among all the establishments). Blood products manufactured, prepared, propagated, compounded, or processed in any State as defined in section 201(a)(1) of the act must be listed whether or not the output of such blood product establishment or any particular blood product so listed enters interstate commerce.

* * * * *

14. Section 607.22 is revised to read as follows:

§ 607.22 How and where to register establishments and list blood products.

(a) The first registration of an establishment shall be on Form FD–2830 (Blood Establishment Registration and Product Listing) obtainable on request from the Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research (HFM–375), 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, or from Food and Drug Administration district offices. Subsequent annual registration shall also be accomplished on Form FD–2830, which will be furnished by the Food and Drug Administration before November 15 of each year to establishments whose product registration for that year was validated under § 607.35. The completed form shall be mailed to the preceding address before December 31 of that year.

(b) The first list of blood products and subsequent June and December updatings shall be on Form FD–2830, obtainable upon request as described in paragraph (a) of this section.

15. Section 607.25 is amended in the second sentence in paragraph (a) by removing the word ''ZIP'', and by revising paragraph (b)(3) to read as follows:

§ 607.25 Information required for establishment registration and blood product listing.

* * * * *

(b) * * *

(3) For each blood product listed, the registration number of the parent establishment. An establishment not owned, operated, or controlled by another firm or establishment is its own parent establishment.

16. Section 607.26 is amended by revising the first sentence to read as follows:

§ 607.26 Amendments to establishment registration.

Changes in individual ownership, corporate or partnership structure, location, or blood-product handling activity shall be submitted on Form FDA–2830 (Blood Establishment Registration and Product Listing) as an amendment to registration within 5 days of such changes. * * *

17. Section 607.31 is revised to read as follows:

§ 607.31 Additional blood product listing information.

(a) In addition to the information routinely required by §§ 607.25 and 607.30, the Director of the Center for Biologics Evaluation and Research may require submission of the following information by letter or by **Federal Register** notice:

(1) For a particular blood product so listed, upon request made by the Director of the Center for Biologics Evaluation and Research for good cause, a copy of all advertisements.

(2) For a particular blood product so listed, upon a finding by the Director of the Center for Biologics Evaluation and Research that it is necessary to carry out the purposes of the act, a quantitative listing of all ingredients.

(3) For each registrant, upon a finding by the Director of the Center for Biologics Evaluation and Research that it is necessary to carry out the purposes of the act, a list of each listed blood product containing a particular ingredient.

(b) [Reserved]

18. Section 607.35 is amended by revising paragraph (a) to read as follows:

§ 607.35 Notification of registrant; blood product establishment registration number and NDC Labeler Code.

(a) The Director of the Center for Biologics Evaluation and Research will provide to the registrant a validated copy of Form FD–2830 (Blood Establishment Registration and Product Listing) as evidence of registration. This validated copy will be sent to the location shown for the registering establishment, and a copy will be sent to the reporting official if at another address. A permanent registration number will be assigned to each blood product establishment registered in accordance with these regulations.

* * * * *

19. Section 607.37 is amended by revising the introductory text of paragraph (a) and by revising paragraph (b) to read as follows:

§ 607.37 Inspection of establishment registrations and blood product listings.

(a) A copy of the Form FD–2830 (Blood Establishment Registration and Product Listing) filed by the registrant will be available for inspection under section 510(f) of the act, at the Department of Health and Human Services, Food and Drug Administration, Office of Communication, Training and Manufacturers' Assistance (HFM–40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. In addition, for domestic firms, the same information will be available for inspection at each of the Food and Drug Administration district offices for firms within the geographical area of such district office. Upon request and receipt of a self-addressed stamped envelope, verification of registration number, or location of registered establishment will be provided. The following information submitted under the blood product listing requirements is illustrative of the type of information that will be available for public disclosure when it is compiled:

* * * * *

(b) Requests for information regarding blood establishment registrations and blood product listings should be directed to the Department of Health and Human Services, Food and Drug Administration, Office of Communication, Training and Manufacturers' Assistance (HFM–40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448.

20. Section 607.40 is revised to read as follows:

§ 607.40 Establishment registration and blood product listing requirements for foreign blood product establishments.

(a) Every foreign establishment shall comply with the establishment registration and blood product listing requirements contained in subpart B of this part, unless exempt under subpart D of this part or unless the blood product enters a foreign trade zone and is re-exported from that foreign trade zone without having entered U. S. commerce.

(b) No blood product may be imported or offered for import into the United States unless it is the subject of a blood product listing as required under subpart B of this part and is manufactured, prepared, propagated, compounded, or processed at a registered foreign establishment; however, this restriction does not apply to a blood product imported or offered for import under the investigational use provisions of part 312 of this chapter or to a blood product imported under section 801(d)(4) of the act. The establishment registration and blood product listing information shall be in the English language.

(c) Each foreign establishment required to register under paragraph (a) of this section shall, as part of the establishment registration and blood product listing, submit the name and address of the establishment and the name of the individual responsible for submitting establishment registration and blood product listing information. Any changes in this information shall be reported to the Food and Drug Administration at the intervals specified for updating establishment registration information in § 607.26 and blood product listing information in § 607.30(a).

(d) Each foreign establishment required to register under paragraph (a) of this section shall submit the name, address, and phone number of its United States agent as part of its initial and updated registration information in accordance with subpart B of this part. Each foreign establishment shall designate only one United States agent.

(1) The United States agent shall reside or maintain a place of business in the United States.

(2) Upon request from FDA, the United States agent shall assist FDA in communications with the foreign establishment, respond to questions concerning the foreign establishment's products that are imported or offered for import into the United States, and assist FDA in scheduling inspections of the foreign establishment. If the agency is unable to contact the foreign establishment directly or expeditiously, FDA may provide information or documents to the United States agent, and such an action shall be considered to be equivalent to providing the same information or documents to the foreign establishment.

(3) The foreign establishment or the United States agent shall report changes in the United States agent's name, address, or phone number to FDA within 10-business days of the change.

21. Section 607.65 is amended by revising the introductory text to read as follows:

§ 607.65 Exemptions for blood product establishments.

The following classes of persons are exempt from registration and blood product listing in accordance with this part 607 under the provisions of section 510(g)(1), (g)(2), and (g)(3) of the act, or because the Commissioner of Food and Drugs has found, under section 510(g)(5), that such registration is not necessary for the protection of the public health. The exemptions in paragraphs (a), (b), (f), and (g) of this section are limited to those classes of persons located in any State as defined in section 201(a)(1) of the act.

* * * * *

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES

22. The authority citation for part 807 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374, 381, 393; 42 U.S.C. 264, 271.

23. Section 807.3 is amended by revising paragraphs (b) and (r) to read as follows:

§ 807.3 Definitions.

* * * * *

(b) *Commercial distribution* means any distribution of a device intended for human use which is held or offered for sale but does not include the following:

(1) Internal or interplant transfer of a device between establishments within the same parent, subsidiary, and/or affiliate company;

(2) Any distribution of a device intended for human use which has in effect an approved exemption for investigational use under section 520(g) of the act and part 812 of this chapter;

(3) Any distribution of a device, before the effective date of part 812 of this chapter, that was not introduced or delivered for introduction into interstate

commerce for commercial distribution before May 28, 1976, and that is classified into class III under section 513(f) of the act: *Provided*, That the device is intended solely for investigational use, and under section 501(f)(2)(A) of the act the device is not required to have an approved premarket approval application as provided in section 515 of the act; or

(4) For foreign establishments, the distribution of any device that is neither imported nor offered for import into the United States.

* * * * *

(r) *United States* agent means a person residing or maintaining a place of business in the United States whom a foreign establishment designates as its agent. This definition excludes mailboxes, answering machines or services, or other places where an individual acting as the foreign establishment's agent is not physically present.

* * * * *

Subpart B [Amended]

24. The heading for subpart B of this part is revised to read as follows:

Subpart B—Procedures for Device Establishments

25. Section 807.20 is amended by revising paragraph (a) to read as follows:

§ 807.20 Who must register and submit a device list.

(a) An owner or operator of an establishment not exempt under section 510(g) of the act or subpart D of this part who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use shall register and submit listing information for those devices in commercial distribution, except that registration and listing information may be submitted by the parent, subsidiary, or affiliate company for all the domestic or foreign establishments under the control of one of these organizations when operations are conducted at more than one establishment and there exists joint ownership and control among all the establishments. The term ''device'' includes all in vitro diagnostic products and in vitro diagnostic biological products not subject to licensing under section 351 of the Public Health Service Act. An owner or operator of an establishment located in any State as defined in section 201(a)(1) of the act shall register its name, places of business, and all establishments and list the devices whether or not the output of the establishments or any particular device so listed enters interstate commerce. The registration and listing requirements shall pertain to any person who:

(1) Initiates or develops specifications for a device that is to be manufactured by a second party for commercial distribution by the person initiating specifications;

(2) Manufactures for commercial distribution a device either for itself or for another person. However, a person who only manufactures devices according to another person's specifications, for commercial distribution by the person initiating specifications, is not required to list those devices.

(3) Repackages or relabels a device;

(4) Acts as an initial importer; or

(5) Manufactures components or accessories which are ready to be used for any intended health-related purpose and are packaged or labeled for commercial distribution for such health-related purpose, e.g., blood filters, hemodialysis tubing, or devices which of necessity must be further processed by a licensed practitioner or other qualified person to meet the needs of a particular patient, e.g., a manufacturer of ophthalmic lens blanks.

* * * * *

§ 807.25 [Amended]

26. Section 807.25 *Information required or requested for establishment registration and device listing* is amended in the last sentence of paragraph (a) by removing the word ''ZIP''.

27. Section 807.40 is revised to read as follows:

§ 807.40 Establishment registration and device listing for foreign establishments importing or offering for import devices into the United States.

(a) Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into the United States shall register and list such devices in conformance with the requirements in subpart B of this part unless the device enters a foreign trade zone and is re-exported from that foreign trade zone without having entered U. S. commerce. The official correspondent for the foreign establishment shall facilitate communication between the foreign establishment's management and representatives of the Food and Drug Administration for matters relating to the registration of device establishments and the listing of device products.

(b) Each foreign establishment required to register under paragraph (a) of this section shall submit the name, address, and phone number of its United States agent as part of its initial and updated registration information in accordance with subpart B of this part. Each foreign establishment shall designate only one United States agent and may designate the United States agent to act as its official correspondent.

(1) The United States agent shall reside or maintain a place of business in the United States.

(2) Upon request from FDA, the United States agent shall assist FDA in communications with the foreign establishment, respond to questions concerning the foreign establishment's products that are imported or offered for import into the United States, and assist FDA in scheduling inspections of the foreign establishment. If the agency is unable to contact the foreign establishment directly or expeditiously, FDA may provide information or documents to the United States agent, and such an action shall be considered to be equivalent to providing the same information or documents to the foreign establishment.

(3) The foreign establishment or the United States agent shall report changes in the United States agent's name, address, or phone number to FDA within 10-business days of the change.

(c) No device may be imported or offered for import into the United States unless it is the subject of a device listing as required under subpart B of this part and is manufactured, prepared, propagated, compounded, or processed at a registered foreign establishment; however, this restriction does not apply to devices imported or offered for import under the investigational use provisions of part 812 of this chapter or to a component, part, or accessory of a device or other article of a device imported under section 801(d)(3) of the act. The establishment registration and device listing information shall be in the English language.

28. Section 807.65 is amended by revising the introductory text to read as follows:

§ 807.65 Exemptions for device establishments.

The following classes of persons are exempt from registration in accordance with § 807.20 under the provisions of section 510(g)(1), (g)(2), and (g)(3) of the act, or because the Commissioner of Food and Drugs has found, under section 510(g)(5) of the act, that such registration is not necessary for the protection of the public health. The exemptions in paragraphs (d), (e), (f), and (i) of this section are limited to those classes of persons located in any

State as defined in section 201(a)(1) of the act.

* * * * *

Dated: November 15, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–29393 Filed 11–26–01; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 70

[FRL–7107–4]

RIN 2060–AJ60

Change to Definition of Major Source

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action promulgates a proposed change to the definition of ''major source''. The change would no longer require States to provide that sources in categories subject to standards under section 111 or 112 promulgated after August 7, 1980 must include fugitive emissions in determining major source status under section 302 or part D of title I of the Act. The EPA is making this change to address a petition by the American Mining Congress (now known as the National Mining Association) challenging the requirement in the current regulation that sources in all section 111 or 112 categories must count fugitive emissions, regardless of when the section 111 or 112 standards were promulgated, in determining major source status under section 302 or part D of title I. By making this change, we will also allow full approval in several State programs that contain the August 7, 1980 date.

EFFECTIVE DATE: November 27, 2001.

ADDRESSES: Docket No. A–93–50 contains information considered by EPA in developing the promulgated rule and is available for public inspection between 8:00 a.m. and 5:30 p.m., Monday through Friday, excluding Federal holidays, at the following address: U.S. EPA, Air and Radiation Docket and Information Center (6102), 401 M Street SW, Washington, DC 20460, telephone (202) 260–7548. The docket is located at the above address in room M–1500, Waterside Mall (ground floor). A reasonable fee may be charged for copying docket materials.

FOR FURTHER INFORMATION CONTACT: For further information, contact Mr. Raymond H. Vogel, Jr., Operating Permits Group, Information Transfer and Program Implementation Division (MD–12), Office of Air Quality Planning and Standards, U.S. EPA, Research Triangle Park, North Carolina 27711, telephone number (919) 541–3153, facsimile number (919) 541–5509, electronic mail address: *vogel.ray@epa.gov.*

SUPPLEMENTARY INFORMATION:

Regulated Entities

Categories and entities potentially affected by this action include facilities currently required to obtain title V permits by State programs because of having been required to count fugitive emissions for sources in categories subject to section 111 or 112 standards promulgated *after* August 7, 1980.

World Wide Web (WWW)

After signature, the final rule will be posted on the policy and guidance page for newly proposed or final rules of EPA's Technology Transfer Network at *http://www.epa.gov/ttn/oarpg/t5.html.* For more information, call the TTN HELP line at (919) 541–5384.

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I. Background and Public Participation

Title V of the Clean Air Act (the Act) requires EPA to promulgate regulations governing the establishment of operating permits programs. The current regulations were promulgated on July 21, 1992 and codified at 40 CFR part 70. All major sources are required to obtain Title V operating permits. Major sources include those sources subject to prevention of significant deterioration (PSD) and nonattainment new source review (NSR), and any other sources with the potential to emit 100 tons per year of an air pollutant. To determine major source status under section 302 or part D of title I, the current rules require you to count fugitive emissions if you are subject to a standard under section 111 or 112, regardless of when the standard was promulgated. The EPA proposed to revise the definition of ''major source'' for section 302 and part D of title I in August, 1994 to limit the requirement to count fugitive emissions to source categories regulated by section 111 or 112 standards promulgated as of August 7, 1980. (See 59 FR 44460, August 29, 1994.) We proposed this revision in response to a petitioner who asserted that EPA could not require that fugitive emissions be counted for determining major source status until EPA conducted rulemaking as required under section 302(j) of the Act. The EPA has not performed such rulemaking; therefore, we are today revising the rule to add the August 7, 1980 date. In the future, EPA will consider doing rulemaking under section 302(j) for individual source categories.

Subsequently, in August 1995, EPA proposed to revise the same part of the ''major source'' definition that it had proposed to change in 1994, this time to limit the requirement to count fugitive emissions for section 111 or 112 standards to those standards for which EPA had performed the rulemaking required under section 302(j). (See 60 FR 45530, August 31, 1995.) This change was proposed simply for administrative reasons, to allow EPA to avoid revising part 70 each time it performed a section 302(j) rulemaking. Today's rule does not adopt this language because some commenters expressed concern about knowing whether EPA had performed the latest section 302(j) rulemaking and which source categories they must as a result consider in determining major source status. Nevertheless, EPA will approve a State program that adopts the language we proposed in August, 1995 in lieu of the language promulgated in today's rule because the 1995 language effectively covers the same source categories.

The EPA also proposed in the same 1995 notice to delete the phrase ''but only with respect to those air pollutants that have been regulated for that category.'' The EPA proposed to delete this phrase to make the regulatory definitions of part 70 consistent with the corresponding provisions of the PSD and NSR nonattainment programs (hereafter, the term ''NSR'' is used to refer collectively to both programs). As

mentioned later in this preamble, today's rule takes final action by deleting this phrase.

Under today's final rule, for purposes of determining whether a source is a major source under section 302 or part D of title I, a source belonging to a source category subject to a section 111 or 112 standard is required to include fugitive emissions of all regulated pollutants under section 302 or part D of title I in its calculation of major source status only if the standard was promulgated as of August 7, 1980. Under today's final rule, for purposes of determining whether a source is a major source under section 302 or part D of title I, State title V permitting programs are not required to provide that sources belonging to categories subject to section 111 or 112 standards promulgated *after* August 7, 1980 must include fugitive emissions of all regulated pollutants under section 302 or part D of title I in calculating major source status. Sources must, however, continue to include fugitive emissions of all hazardous air pollutants in determining major source status under section 112 of the Act.

The final rule takes effect today, November 27, 2001. State permitting authorities with programs that currently provide the August 7, 1980 limitation on including fugitive emissions need take no action, since their rules would be consistent with this final rule with respect to the August 7, 1980 date. Other permitting authorities may, but are not required to, revise their programs to include the August 7, 1980 limitation. That is, States may include requirements that are more stringent than the Federal requirements, by requiring sources subject to section 111 or 112 standards promulgated after August 7, 1980 to count fugitive emissions in major source determinations under section 302 or part D of title I. (See section 116 of the Act which allows States, within certain exceptions, to adopt requirements that are not less stringent than the requirements of the Act.)

Except where legislative action is needed as described in the following paragraph, States must revise their programs by November 27, 2002 to delete the phrase ''but only with respect to those air pollutants that have been regulated for that category.'' The Administrator specifies a deadline of 12 months for submittal of program revisions to delete the ''but only with respect to'' phrase in light of the narrow scope of the revision required of State programs. Authority for this deadline is provided in 40 CFR 70.4(i)(1), which specifies that the deadline for submittal of revisions to State part 70 programs following revision of relevant Federal regulations is 180 days or ''such other period as the Administrator may specify, following notification * * *'' Today's notice is the notification that triggers the 12-month deadline.

If a State can demonstrate that additional legal authority is needed, the deadline for submittal of a revised program to delete the phrase ''but only with respect to those air pollutants that have been regulated for that category'' is November 27, 2003. Authority for this deadline is the same provision in 40 CFR 70.4(i)(1) described in the preceding paragraph for the 12-month deadline.

Any sources that become subject to part 70 because of revisions to State programs deleting the ''but only with respect to'' phrase must apply for title V permits either within 12 months of EPA's approval of the revised State program or by an earlier deadline that the permitting authority establishes. As provided in section 503(c) of the Act and 40 CFR 70.5(a)(1)(i), a timely application for a source applying for a permit for the first time is one that is submitted within 12 months after the source becomes subject to the operating permits program or on or before such earlier date as the permitting authority may establish.

II. Response to Comments on Proposed Rule

A. Proposal To Insert August 7, 1980 Date Into Paragraph (2)(xxvii) of the ''Major Source'' Definition

The preamble for the proposed rule in August 1994 described the rationale for the proposed revision. Public comments were solicited at the time of proposal and a public hearing was held. Industry representatives, regulatory agencies, environmental groups, and the general public were given the opportunity to comment on the proposed rule and to provide additional information during and after the public comment period, and at the public hearing.

We received comments on this proposed rule revision, including a number of comments from industry in support of inserting the August 7, 1980 date in paragraph (2)(xxvii) of the major source definition. However, several regulatory agencies opposed this change. One of these agencies commented that source categories regulated by new source performance standards (NSPS) are the significant source categories and for this reason should be required to include fugitive emissions for purposes of applicability determinations. Another agency commented that State fee levels for title V were based on an evaluation of sources that would be subject to the program under the original major source definition, and to change that definition could result in fewer emission fees which could adversely affect State permitting programs.

The EPA responds that we do agree that sources in categories subject to section 111 standards are significant sources of emissions. We also understand that States may have forecasted emission fees based on the original major source definition, and that overall fees could potentially drop as a result of this change. However, as EPA noted in the preamble to the proposed rule, we did not follow the procedural steps necessary under section 302(j) to expand the scope of sources for which fugitive emissions must be counted in making major source determinations. (See 59 FR 44460, 44514.) Because the Agency is required to undertake rulemaking under section 302(j) before it can require the inclusion of fugitive emissions of regulated pollutants under section 302 or part D of title I in major source determinations and because this rulemaking has not occurred for sources subject to section 111 or 112 standards promulgated after August 7, 1980, we have to revise the rule as described.

Finally, today's final rule inserts the August 7, 1980 date using the exact language from the corresponding provisions in the nonattainment NSR and PSD regulations in 40 CFR parts 51 and 52. This ensures that the title V and NSR programs are entirely consistent.

B. Proposal To Delete the Phrase ''but Only With Respect to Those Air Pollutants That Have Been Regulated for That Category''

Today's action also deletes the phrase ''but only with respect to those air pollutants that have been regulated for that category'' from paragraph (2)(xxvii) of the major source definition. The EPA proposed to delete this phrase in its 1995 supplemental proposal to revise part 70. (See 60 FR 45530, August 31, 1995.)

Five industry commenters opposed the deletion of the phrase. Two of these commenters recommended that EPA keep the phrase until it undertakes new rulemaking under section 302(j), at which time the Agency could expand the types of fugitive emissions that must be considered when determining major source status. Two other commenters also noted that the rules implementing title V are intended to ensure that larger sources of potentially harmful emissions are drawn into the program more

quickly than smaller, nonmajor sources. They also noted that the purpose of the title V program is to compile in one permit all the requirements for regulated pollutants emitted from a major source. These commenters believe that neither of these purposes are served by counting the fugitive emissions of unregulated pollutants in the major source determination. Commenters also suggested that there is no need to rush sources subject to section 111 or 112 standards into the permit program on the basis of unregulated emissions, as these sources will be required to have permits independently of the major source program if and when EPA decides to require them to obtain permits. Commenters note that Congress, under section 502(a) of the Act, gives EPA authority to exempt nonmajor sources from the permit program by rule, and that this is evidence of Congressional intent to exclude sources from the program if the emissions of regulated pollutants do not reach major source levels.

Commenters also asserted that it is not necessary to count unregulated fugitive emissions to harmonize the title V program with the NSR program, as EPA has suggested. Any potential problems caused by the inconsistency can be easily cured, they assert, by changing the part 70 rule implementing title V to require that a source required to have a permit under part C or D of the Act is also required to have a title V permit.

The EPA disagrees with the approach advocated by the commenters. The Agency believes it is necessary to have consistent applicability approaches for the title V and NSR programs because title V incorporates major source definitions from section 302 and part D of title I which are used in the NSR program. Inconsistencies between title V and NSR could lead to a source being considered major under nonattainment NSR or PSD, but nonmajor under title V.[1] Being considered nonmajor has certain ramifications in the part 70 program. Title V operating permits for nonmajor sources are required under 40 CFR 70.3(c)(2) to include all the applicable requirements for the emissions units that caused the source to be subject to part 70. If an emission unit at the nonmajor source did not trigger the requirement to apply for a title V permit, then none of that unit's applicable requirements are required to be included in the source's permit.[2] In addition, a part 70 source is required under 40 CFR 70.5(c)(3)(i) to report in its permit application emissions for which it is major as defined by part 70. If EPA adopted inconsistent applicability approaches between title V and NSR, a source could exclude reporting information about emissions for which it is major under title V from its part 70 permit application, even if it had the potential to emit those emissions in major amounts under PSD or nonattainment NSR. Also, deleting the ''but only with respect to those air pollutants that have been regulated for that category'' phrase will not bring fugitive emissions of ''unregulated'' pollutants into major source determinations as commenters assert. Technically, a pollutant is considered regulated once it is subject to regulation under the Act. A pollutant need not be specifically regulated by a section 111 or 112 standard to be considered regulated. (See 61 FR 38250, 38309, July 23, 1996.)

The EPA agrees with commenters who pointed out that any source required to have a permit under part C or D is also required to have a title V permit. (See section 502(a) of the Act.) However, this does not make the source a major source for part 70 and the inconsistencies noted above would still remain. A source required to have a part C or D permit but considered nonmajor for part 70 would be subject to part 70, but would not be required to include all applicable requirements for all emissions units in its title V permit. Additionally, the requirement in part 70 for a source to report emissions of all pollutants for which it is major would not be in effect because the source would be considered nonmajor under part 70. These arguments point to the need for sources which emit or have the potential to emit air pollutants in major amounts under NSR to be treated as major sources under title V. A further argument for consistency is that the PSD program does not include sources with the potential to emit between 100 and 250 tons/year, whereas the title V program does.

The EPA also disagrees with commenters who contend that Congress intended for EPA to exempt or defer all nonmajor sources by including the provision in section 502(a) which allows EPA to exclude nonmajor sources from the title V program by rule. While Congress gave EPA discretion to exempt some categories of nonmajor sources if the Administrator determined that compliance with title V permitting requirements would be impracticable, infeasible or unnecessarily burdensome on such categories, it did not require that EPA exclude all nonmajor sources. In fact, the presumption in section 502(a) is that nonmajor sources subject to a section 111 or 112 standard will be permitted. Congress simply provided that EPA could, in its discretion and after making the necessary finding, exempt some nonmajor sources from the requirement to obtain a title V permit. Requiring consistent applicability approaches is wholly within this Congressional intent, even if it could result in more sources being major under the title V program compared to approaches suggested by commenters.

Finally, EPA disagrees with commenters who contend that sources in a category subject to a section 111 or 112 standard should be deferred from title V if they do not emit major amounts of fugitive pollutants regulated by that specific standard. Under the approach advocated by commenters, a source subject to a section 111 or 112 standard emitting major amounts of fugitive emissions of a pollutant could be considered nonmajor for part 70 if the pollutant was not regulated by the section 111 or 112 standard that applied to the source. In the view of the Agency, if a source emits or has the potential to emit major amounts of fugitive emissions of a regulated pollutant under section 302 or part D of title I, and there has been the requisite rulemaking performed under section 302(j), then the source must be considered major and subject to title V, even if the pollutant is not regulated by a section 111 or 112 standard. Inclusion of fugitive emissions of all regulated pollutants under section 302 and part D of title I, not just those regulated by section 111 or 112 standards, is the approach used in the NSR program. As mentioned previously, EPA believes it is important to maintain consistency between NSR and title V.

In addition, following the commenters' approach would require EPA to exempt sources from title V that emit or have the potential to emit major amounts of fugitive emissions, even if the Agency has undertaken the rulemaking required by section 302(j). Congress clearly expressed its intent in section 502(a) to subject major sources to title V by precluding EPA from exempting major sources from title V requirements. In addition, Congress

[1] Consider, for example, a source that has the potential to emit nonmajor levels of fugitive emissions of particulate matter (PM) regulated by an NSPS and major levels (over 250 tons) of fugitive emissions of volatile organic compounds (VOC's) which are not regulated by this NSPS. If part 70 continued to include the phrase ''but only with respect to those air pollutants that have been regulated for that category,'' the source would be nonmajor for title V because only its PM emissions would be counted. Yet, the source would be major for NSR because of the VOC emissions.

[2] All applicable requirements are required to be included, however, for units that caused the source to be subject to part 70. (See 40 CFR 70.3(c)(2).)

provided a mechanism in section 302(j) for determining whether fugitive emissions must be considered in applicability determinations under section 302 or part D of title I. Where EPA has performed the rulemaking required by section 302(j), as it has for section 111 and 112 standards promulgated as of August 7, 1980, EPA must follow an approach that gives due weight to the Congressional intent expressed in section 502(a) of subjecting major sources to title V. Accordingly, EPA rejects commenters' views and instead adopts an approach that requires sources to have title V permits if they are subject to a section 111 or 112 standard promulgated as of August 7, 1980 and emit or have the potential to emit major amounts of fugitive emissions of any regulated pollutant under section 302 or part D of title I, even if the pollutant is not regulated by the section 111 or 112 standard.

III. Administrative Requirements

A. Executive Order 12866: ''Significant Regulatory Action Determination''

Under Executive Order 12866 (58 FR 51735, October 4, 1993) we must determine whether the regulatory action is ''significant'' and therefore subject to Office of Management and Budget (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, adversely affecting in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety in 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 of 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.

Because this action involves a narrow change to a single regulatory requirement, it has been determined not to meet any of the criteria listed above. Thus, it has been determined that this action is not a ''significant regulatory action'' under the terms of Executive Order 12866, and is not subject to OMB review.

Executive Order 12866 also encourages agencies to provide a meaningful public comment period, and suggests that in most cases the comment period should be 60 days. The EPA provided a 60-day comment period and a public hearing on the entire proposed rule, including the change that is the subject of today's action, in 1994.

B. Regulatory Flexibility Act Compliance as Amended by the Small Business Regulatory Enforcement Fairness Act of 1966 (SBREFA), 5 U.S.C. 601 et seq.

The Regulatory Flexibility Act generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions.

We analyzed the potential impact of the proposed regulatory revisions on small entities and determined that any cost increases would be substantially less than one percent of revenues. Since today's action involves a single regulatory provision of the many that were proposed, we certify that this action will not have a significant economic impact on a substantial number of small entities.

C. Paperwork Reduction Act

The OMB has approved the information collection requirements contained in this rule under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and has assigned OMB control no. 2060–0243.

The Administrator has determined that the net effect of this rule could result in fewer sources submitting applications for title V permits, and accordingly, in less paperwork. Some State and local permitting agencies will be required to revise their title V programs, and to submit them for EPA and public review, and to respond to comments.

Because the amount of paperwork could be reduced for some sources, this action should reduce the overall burden on sources. There could be minimal increase in burden on some permitting authorities that will be required to revise their program; however, that increase in burden should be inconsequential in light of the very limited scope of this rule. Up to 112 permitting authorities are potential one-time respondents, although fewer than 112 should need actual rule changes. Burden means the total time, effort or financial resources expended to generate, and maintain, retain, or provide information to the permitting authority as required by this rule. This includes the time needed to review instructions; develop, acquire, install and use technology and systems for collecting, validating and verifying information or processing and maintaining information; adjust the existing ways to comply with previous instructions and requirements; train personnel to respond to the collection of information; search data sources; complete and review the information; and transmit the information.

D. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The 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 rule is not a major rule as defined by 5 U.S.C. 804(2).

E. 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 to State, local, and tribal governments, in the aggregate, or to 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 of why that alternative was not adopted. 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.

Because of the very limited scope of this action, the EPA has determined that this action contains no regulatory requirements that might significantly or uniquely affect small governments. The EPA has also determined that this action does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. Thus, this proposal is not subject to the requirements of the UMRA.

F. 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. The 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 action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. This action would not alter the overall relationship or distribution of powers between governments for the part 70 program. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

G. Executive Order 13175: Consultation With Tribes

It does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because it does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. Accordingly, this rule is not subject to Executive Order 13175.

H. 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 the EPA determines (1) economically significant as defined under Executive Order 12866, and (2) the environmental health or safety risk addressed by the rule has 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.

This action is not subject to Executive Order 13045, because it is not an economically significant regulatory action as defined by Executive Order 12866, and it does not address an environmental health or safety risk that would have a disproportionate effect on children.

I. Executive Order 13211 (Energy Effects)

This rule is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA), Public Law 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, business practices, etc.) that are developed or adopted by voluntary consensus standard 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 action does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

List of Subjects in 40 CFR Part 70

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: November 19, 2001.

Christine Todd Whitman,

Administrator.

For the reasons set out in the preamble, title 40, chapter I, part 70 of the Code of Federal Regulations is amended as follows:

PART 70—[AMENDED]

1. The authority citation for part 70 continues to read as follows:

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

2. Section 70.2 is amended by revising paragraph (2)(xxvii) of the definition of ''major source'' to read as follows:

§ 70.2 Definitions

* * * * *

Major source * * *

(2) * * *

(xxvii) Any other stationary source category, which as of August 7, 1980 is being regulated under section 111 or 112 of the Act.

* * * * *

[FR Doc. 01–29383 Filed 11–26–01; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Parts 59 and 64

RIN 3067–AD18

Changes to General Provisions and Communities Eligible for the Sale of Insurance Required To Include Future-Conditions Flood Hazard Information on Flood Maps

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Final rule.

SUMMARY: This Final Rule revises the National Flood Insurance Program (NFIP) regulations to include definitions for future-conditions hydrology and for the floodplains that may be shown on Flood Insurance Rate Maps (FIRMs), for informational purposes at the request of the community, to reflect future-conditions hydrology; and establish the zone symbol to be used to identify future-conditions flood hazard areas on FIRMs.

DATES: This Final Rule is effective December 27, 2001.

FOR FURTHER INFORMATION CONTACT: Matthew B. Miller, P.E., Chief, Hazards Study Branch, Hazard Mapping Division, Federal Insurance and Mitigation Administration, FEMA, Washington, DC 20472, (202) 646–3461.

SUPPLEMENTARY INFORMATION:

Background

It was the expressed intent of the U.S. Congress, in enacting the Housing and Urban Development Act of 1968 (commonly referred to as the National Flood Insurance Act of 1968), to ''encourage State and local governments to make appropriate land use adjustments to constrict the development of land which is exposed to flood damage and minimize damage caused by flood losses, and guide the development of proposed future construction, where practicable, away from locations which are threatened by flood hazards * * *'' 42 U.S.C. 4001(e). The revisions to the NFIP regulations documented in this Final Rule are a result of the continuing reappraisal of the NFIP for the purpose of encouraging sound floodplain management to reflect that intent.

Historically, flood hazard information presented on NFIP flood maps has been based on the existing conditions of the floodplain and watershed. When the mapping of flood hazards was initiated under the NFIP, the intent was to reassess each community's flood hazards periodically and, if needed, revise the flood map for that community. Flood hazards may change significantly in areas experiencing urban growth. The FEMA document entitled *Flood Insurance Study Guidelines and Specifications for Study Contractors* (FEMA 37, January 1995) specifies that flood hazard determinations should be based on conditions that are planned to exist in the community within 12 months following completion of the draft Flood Insurance Study (FIS). Examples of future conditions to be considered in the context of FEMA 37 are public works projects in progress, including channel modifications, hydraulic control structures, storm-drainage systems, and various other flood protection projects. These are projects that will be completed in the near future for which completion can be predicted with a reasonable degree of certainty and their completion can be confirmed prior to the new or revised flood map becoming effective. By contrast, future land-use development, such as urban growth, is uncertain and difficult to predict, and has not been considered in the context of the FEMA guidelines.

Communities experiencing urban growth and other changes have expressed a desire to use future-conditions hydrology in regulating watershed development. While some communities do regulate based on future development, others are hesitant to enforce more restrictive standards without Federal support.

From a floodplain management standpoint, future-conditions floodplains can be used, and are being used, by communities to enforce more stringent floodplain management policies than those required by FEMA. By displaying future-conditions floodplains on the FIRM, the community and FEMA are alerting the public that flood hazards may increase in the future due to urban development. Many progressive communities throughout the United States develop future-conditions hydrology and create their own maps to regulate floodplain development. This has resulted in two sets of maps being produced for a community: future-conditions maps for local floodplain management and existing-conditions FIRMs for flood insurance determinations. As a result, these progressive communities have not had a sense of ownership for the FIRMs, and their resources have been directed toward maintaining their own future-conditions maps.

Recent Evaluation and Conclusions

To assist officials in such progressive communities, FEMA undertook an evaluation to determine whether future-conditions flood hazard information could and should be placed on FIRMs and in the accompanying FIS reports. The results of that extensive evaluation are documented in a FEMA report entitled ''Modernizing FEMA's Flood Hazard Mapping Program: Recommendations for Using Future Conditions Hydrology for the National Flood Insurance Program'' (see *www.fema.gov/mit/tsd/FT_hydro.htm*). The specific conclusions reached in the report are as follows:

- The local community should determine the future-conditions land-use and hydrology.
- If the community chooses to adopt a regulatory floodway based on future-conditions hydrology, the use of this floodway should be supported by local ordinances.
- If the community requests that FEMA do so, the future-conditions 1-percent-annual-chance (100-year) floodplain should be shown on the printed FIRM and be designated as Zone X with no base (1-percent-annual-chance) flood elevations (BFEs) shown.
- When possible, three floodplains should be shown on the FIRM: existing-conditions 1-percent-annual-chance (100-year) floodplain, existing-conditions 0.2-percent-annual-chance (500-year) floodplain, and future-conditions 1-percent-annual-chance (100-year) floodplain. However, when the future-conditions 1-percent-annual-chance (100-year) floodplain and the existing-conditions
- 0.2-percent-annual-chance (500-year) floodplain are so close together as to be confusing if both are shown on the printed FIRM, the future-conditions 1-percent-annual-chance (100-year) floodplain should be shown in lieu of the existing-conditions 0.2-percent-annual-chance (500-year) floodplain. When this occurs, appropriate reference should be made to the existing-conditions 0.2-percent-annual-chance

(500-year) floodplain information being shown in the FIS report. For a Digital Flood Insurance Rate Map (DFIRM), appropriate reference also should be made to the existing-conditions 0.2-percent-annual-chance (500-year) floodplain information being included in an associated database.

• BFEs should be shown on the FIRM only for the existing-conditions 1-percent-annual-chance (100-year) floodplain. The future-conditions BFEs should be included in the FIS report (on the Flood Profiles and in the Floodway Data Table), thus providing necessary information to the community to meet their local floodplain management needs. The existing-conditions 0.2-percent-annual-chance (500-year) flood elevations also should be shown on the Flood Profiles in the FIS report to meet the requirements of Executive Order No. 11988 and to provide Federal agencies with information to evaluate the potential effects of any actions they may take in a floodplain.

• The community may choose to show the existing-conditions 0.2-percent-annual-chance (500-year) floodplain on the FIRM and to include the future-conditions.

• 1-percent-annual-chance (100-year) flood elevations only on the Flood Profiles in the FIS report. Various other combinations to display the flood hazard data also are possible. FEMA and the community should work together to produce the most useful FIRM and FIS report for the community.

• From a floodplain management standpoint, FEMA should continue to require regulation of floodplain development based on the existing-conditions data, while local floodplain managers can regulate development based on the future-conditions data.

• From a flood insurance standpoint, FEMA must continue to require flood insurance for structures shown in the existing-conditions 1-percent-annual-chance (100-year) floodplain, or Special Flood Hazard Area (SFHA). Showing the future-conditions floodplain as Zone X should avoid any confusion regarding the mandatory flood insurance requirement. It also will allow insurance policies to be purchased at a reduced rate, as insurance is currently available for structures in the existing-conditions 0.2-percent-annual-chance (500-year) floodplain.

As recommended in the previously referenced FEMA report, FEMA intends to show future-conditions flood hazard information on FIRMs and in collateral FIS reports. This information will be for informational purposes only. No change will be made in the use of existing-conditions data for establishing risk premium rates. Through community participation in the Community Rating System, however, reduced risk premium rates will be available as they are for those communities that enforce more stringent regulatory standards than required by the NFIP.

Synergy With Other FEMA Programs

The inclusion of future-conditions data on FIRMs and related products for communities that request that such data be included is part of a larger FEMA plan to modernize the Flood Hazard Mapping Program and thereby reduce the burden on taxpayers for disaster relief and improve flood hazard mitigation. FEMA plans to facilitate ownership of the flood maps by State and local entities through greatly increased involvement in the flood mapping process through cooperative agreements. FEMA will provide flood mapping funds, technical assistance, and mentoring to partners—termed ''Cooperating Technical Partners''—and those partners will then develop and maintain the flood maps or components thereof. The proposed cooperative agreements recognize that hazard identification and mapping must go hand-in-hand with the responsibility of managing floodplains locally. By creating a strong local program that maintains the connection between mapping and managing flood hazard areas, the NFIP also is strengthened in its ability to reduce the loss of property and life.

FEMA recognition of future-conditions data will be a key factor in the State and local communities assuming increased ownership in the process. By mapping locally pertinent information, local ownership of the flood maps will increase. Because flood conditions and hazards vary locally and regionally, inclusion of those unique local conditions on the flood maps may be warranted. For example, a community may find it useful to identify areas on the FIRM with floodplains based on developed/future hydrologic conditions in addition to the standard features already depicted. In effect, FEMA will maintain national standards while at the same time providing a useful tool to the community. Because the public and the development community will be more aware of future flood hazard conditions, communities will now be more able to implement proactive mitigation measures to address these potential hazards.

In sum, the use of future-conditions hydrology is consistent with modernizing the FEMA Flood Hazard Mapping Program; with promoting better proactive mitigation measures; and with FEMA's desire to be flexible with, and supportive of, those progressive communities that would like to implement stricter land-use regulations.

Planned Implementation

The FEMA plans for implementing the presentation of future-conditions flood hazard information on NFIP flood maps are summarized below.

Map Specifications. The new DFIRM product specifications that are being developed by FEMA will include options that can be invoked depending on the available flood hazard data. This new DFIRM product will include certain basic features and meet certain minimum mapping requirements. Additional options will be included to meet community needs, provided that sufficient funding is available. A review of needs and available data will lead to an estimate of the time and costs and a recommendation on which options to exercise for the final DFIRM product. Procedures for displaying future-conditions floodplains on the new DFIRM will be included in the new FEMA mapping specifications.

Cooperating Technical Partners Activities. As a part of the mapping activities undertaken by communities participating in the Cooperating Technical Partners initiative, an option could be for communities to show the future-conditions 1-percent-annual-chance (100-year) floodplain on the FIRM in addition to the existing-conditions 1-percent-annual-chance (100-year) floodplain. The communities would develop and map existing and future conditions and provide the new floodplain mapping and supporting data to FEMA; in turn, the communities would receive a FIRM that shows both floodplain and is thus a more useful tool for risk assessment and flood hazard mitigation.

Revisions. Because mapping of the future-conditions 1-percent-annual-chance (100-year) floodplains would be implemented on a community level, the flood maps will maintain consistency within community boundaries, regardless of how many map panels the community encompasses. When FEMA receives future-conditions data from communities, FEMA could incorporate the data easily at the time of the conversion to the DFIRM product. Alternatively, communities that require flood hazard updates can submit future-conditions data to be incorporated with the existing-conditions data updates for the DFIRM conversion. Displaying future-conditions data will increase community involvement in the NFIP

and help FEMA build stronger partnerships with communities. If these communities are involved at the beginning of the digital conversion process, they will have a stronger sense of ownership of the DFIRMs, because they will have input on the kind of flood hazard information shown on the maps.

Once FEMA has included future-conditions 1-percent-annual-chance (100-year) floodplains on a flood map, all FEMA- or community-initiated studies, restudies, and revisions will incorporate the future-conditions hydrology that the community has determined. FEMA will perform a technical review of the locally developed data and will include the data in all map updates. Additionally, FEMA will continue to make determinations on whether structures and parcels of land are in or out of the existing-conditions 1-percent-annual-chance (100-year) floodplains shown on the FIRM or DFIRM, and will issue Letters of Map Amendment and Letters of Map Revisions Based on Fill based on these determinations.

Scope of Public Participation

On June 14, 2001, FEMA published a Proposed Rule in the **Federal Register**, at 66 FR 32293. On that date, FEMA invited interested parties to submit written comments to the Rules Docket Clerk, Office of General Counsel, on or before August 13, 2001.

During the comment period provided for in the Proposed Rule, FEMA received letters or e-mail messages from 20 respondents. All of the respondents supported the FEMA decision to include the future-conditions 1-percent-annual-chance (100-year) floodplains on the FIRM. In fact, 30 percent of the respondents recommended that FEMA proceed with finalizing the Proposed Rule without any changes. Other respondents provided multiple recommendations for how FEMA could change and improve the Proposed Rule before finalizing it. Those submitting formal comments on the Proposed Rule included one U.S. Senator; one member of the U.S. House of Representatives; community officials and representatives of local and regional government agencies; representatives of the business community; and representatives of professional environmental and floodplain management associations.

Summary of Comments and FEMA Responses

The comments and recommendations submitted by the respondents to the Proposed Rule may be separated into eight categories. Summaries of each category of comments and FEMA's responses to those comments are summarized below.

Insurance Applications. Several respondents recommended that FEMA establish risk premium rates and mandatory flood insurance purchase requirements for buildings located in the future-conditions floodplains that will be shown on a FIRM or DFIRM when requested by a community.

Risk premium rates are based on accepted actuarial principles. Several factors are considered in establishing risk premium rates, including amount of coverage purchased; location, age, occupancy, and design of the building to be insured; and, for buildings in the SFHA, elevation of the building in relation to the existing-conditions 1-percent-annual-chance (100-year) flood elevation. The current procedure for risk premium rating is consistent with the statutes governing the NFIP. Under the current procedure, structures shown within the SFHA, the area that would be inundated by the 1-percent-annual-chance (100-year) flood based on existing conditions hydrology, are subject to a mandatory flood insurance purchase requirement. FEMA decided to show future-conditions 1-percent-annual-chance (100-year) floodplains on Flood Insurance Rate Maps to support the floodplain management practices of those progressive communities that choose, voluntarily, to implement more restrictive requirements than those required for participation in the NFIP. Because of the uncertain nature of the future-conditions data and the relatively limited number of participating communities that have opted to implement these more restrictive development requirements, it is not practicable to establish risk premium rates and mandatory flood insurance purchase requirements for buildings located in the future-conditions floodplains. Further, we do not plan to require that all communities use future-conditions data to regulate development as a condition of participating in the NFIP.While the Federal mandatory flood insurance purchase requirement will continue to apply only to buildings in SFHAs based on existing-conditions hydrology in participating communities, flood insurance is available in all areas of a participating community, including the area that will be shown as within the future-conditions 1-percent-annual-chance (100-year) floodplain. This is important because approximately 25 percent of the flood insurance claims paid by the NFIP have been for buildings outside the existing-conditions 1-percent-annual-chance (100-year) floodplain, or SFHA. It also is important to note that a lender may determine, on its own as a business decision, that it wishes to require flood insurance for buildings located outside the SFHA to protect its financial risk on the loan.

Expanded Floodplain Management Requirements. Several respondents recommended that FEMA require regulation of development within the future-conditions 1-percent-annual-chance (100-year) floodplain, primarily to support local floodplain administrators in their efforts to discourage unwise floodplain development.

The FEMA decision to show the future-conditions 1-percent-annual-chance (100-year) floodplain was made precisely to support the floodplain management practices of those progressive communities that choose, voluntarily, to implement more restrictive requirements than those required for participation in the NFIP. Through this change and other recent initiatives, FEMA is emphasizing the need for decision-making authority to be at the local level. However, because of the uncertain nature of the future-conditions data and the relatively limited number of participating communities that have opted to implement these more restrictive development requirements, FEMA does not plan to require that communities use future-conditions data to regulate development.

Expanded Definition of ''Future-Conditions Hydrology.'' Some respondents recommended that FEMA expand and clarify the definition of future-conditions hydrology. Specifically, these respondents recommended the following: (1) add clarification that planned structural modifications that would reduce peak flood discharges are not to be included in the community's determination of future conditions; (2) include ''approved development'' as an example of future conditions; (3) include number of units, unit density, and square footage of impervious surface in the definition; and (4) include expected changes in frequency and severity of precipitation events in the definition.

FEMA is implementing the presentation of future-conditions 1-percent-annual-chance (100-year) floodplains on FIRMs to support floodplain management decisions made locally to address land-use changes that will affect hydrology. To ensure maximum flexibility for local community officials, FEMA does not want to be too restrictive in defining future-conditions hydrology. However, as indicated in the previously

referenced FEMA report entitled ''Modernizing FEMA's Flood Hazard Mapping Program: Recommendations for Using Future Conditions Hydrology for the National Flood Insurance Program,'' the future hydrology conditions defined in this Final Rule do not include future construction of flood detention structures or hydraulic structures for the reasons cited below.

The construction of flood detention structures can significantly affect the flood frequency characteristics of a watershed, and the hydrologic effects of flood detention structures are very site specific and difficult to evaluate. Likewise, the effects of projected future hydraulic modifications—changes within a stream or other waterway, such as bridge and culvert construction, fill, and excavation—on flood frequency are site specific and difficult to predict and are considered beyond the scope of this discussion.

Therefore, FEMA revised the definition of future-conditions hydrology presented in Section 59.1 of the NFIP regulations to clarify that the effects of future construction of flood detention structures or hydraulic structures are not to be considered by a community in establishing future-conditions hydrology.

Expanded Depiction of Future-Conditions Floodplains. One respondent recommended that FEMA include the area that would be affected by projected sea level rise in the depiction of the future-conditions 1-percent-annual-chance (100-year) floodplain on the FIRM. As justification, this respondent cited the requirement in the Coastal Zone Management Act of 1972, as amended (16 U.S.C. 1451 et. seq.), that ''* * * coastal states must anticipate and plan for such an occurrence.''

As cited above, FEMA is implementing the presentation of future-conditions 1-percent-annual-chance (100-year) floodplains on FIRMs to support local floodplain management decisions to address land-use changes that will affect hydrology. As FEMA and its community and State partners together move forward with the digital conversion of flood hazard data and production of DFIRMs, greater consideration will be given to including advisory information, such as the project sea level rise. However, inclusion of project sea level rise is outside the scope and intent of this rule change.

Use of Distinctive Screen and Zone Designation for Portraying Future-conditions Floodplain on Maps. Several respondents suggested that FEMA establish a new premium rate zone designation for the future-conditions 1-percent-annual-chance (100-year) floodplain, with a distinctive screen, to differentiate this hazard area from the existing-conditions 0.2-percent-annual-chance (500-year) floodplain. The zone designations that were recommended were Zone F–X, Zone F, Zone AF, Zone U, and Zone D.

FEMA opted to use the Zone X (shaded) screen to depict the future-conditions 1-percent-annual-chance (100-year) floodplain to minimize confusion by users in the lending and insurance industries that use the map to make determinations regarding whether the Federal mandatory flood insurance purchase requirements apply to a particular building. Those users now recognize that areas designated as Zone X (shaded) are subject to some flood hazard, but that the mandatory flood insurance purchase requirement does not apply. Because the risk premium rates for buildings located in the future-conditions 1-percent-annual-chance (100-year) floodplain will be the rate comparable to other areas outside the SFHA, FEMA believes designating these areas as ''Zone X (Future Base Flood)'' will be sufficient distinction.

This presentation decision notwithstanding, two of the recommended zone designations—Zone AF and Zone D—could not be used on the map anyway. The former is likely to be confused with the zone designation used for SFHAs, in which the mandatory flood insurance purchase requirement does apply, and the latter is already used to designate areas of possible, but undetermined flood hazards.

Presentation of Existing- and Future-Conditions Floodplains on Maps. Some respondents suggested that FEMA show the future-conditions 1-percent-annual-chance (100-year) floodplain on the FIRM at all times, even when the boundaries of the future-conditions 1-percent-annual-chance (100-year) floodplain and the existing-conditions 0.2-percent-annual-chance (500-year) floodplain are too close together to be distinguished.

FEMA plans to take a much more flexible approach to the presentation of the existing- and future-conditions floodplains on the FIRM. Because inclusion of this information on the FIRM is voluntary, the community will have the decision-making authority for determining whether to show the future-conditions 1-percent-annual-chance (100-year) floodplain, the existing-conditions 0.2-percent-annual-chance (500-year) floodplain, or both on the FIRM.

Inclusion of Future-Conditions Flood Elevations on Maps. One respondent recommended that FEMA include future-conditions 1-percent-annual-chance (100-year) flood elevations, rounded to the nearest tenth of a foot, adjacent to the BFEs shown in the existing-conditions future-conditions 1-percent-annual-chance (100-year) floodplain on the FIRM.

To minimize confusion and enhance the usability of the FIRM, FEMA plans to include the future-conditions 1-percent-annual-chance (100-year) flood elevations only in the FIS report that will accompany the FIRM. As with the existing-conditions 1-percent-annual-chance (100-year) flood elevations (i.e., BFEs), local floodplain management officials should consult the Flood Profiles included in the FIS report and other available technical support data for more complete elevation data.

Presentation of Future-Conditions Floodplains for Flooding Sources Studied by Approximate Methods. One respondent recommended that FEMA clarify whether the future-conditions 1-percent-annual-chance (100-year) floodplain could be shown on the FIRM for flooding sources that FEMA analyzed using approximate-study methods. The existing-conditions 1-percent-annual-chance (100-year) floodplains for flooding sources studied by approximate methods are designated as Zone A on the FIRM.

The community may establish a future-conditions 1-percent-annual-chance (100-year) floodplain for any flooding source in the community, regardless of the type of study performed by FEMA. If the community performed a detailed study to establish the future-conditions 1-percent-annual-chance (100-year) floodplain, FEMA may request the supporting data for the detailed study and revise and, based on available funding, redesignate the existing-conditions 1-percent-annual-chance (100-year) floodplain as Zone AE. If the community performed an approximate study, FEMA would show the future-conditions 1-percent-annual-chance (100-year) floodplain, designated as Zone X (Future), adjacent to the existing-conditions 1-percent-annual-chance (100-year) floodplain. The designation for the existing-conditions 1-percent-annual-chance (100-year) floodplain would continue to be Zone A.

Timing of Revisions to Mapping and Implementation of Local Regulations. One respondent requested that FEMA clarify when and if local floodplain management regulations must be implemented when FIRM is revised to show the future-conditions 1-percent-annual-chance (100-year) floodplain.

FEMA will revise the FIRM to add the future-conditions 1-percent-annual-chance (100-year) floodplain when requested to do so by the community. FEMA is showing this information on the FIRM for informational purposes only. FEMA will require written assurance from the Chief Executive Officer or other community official that the community has or will proceed with adoption of the future-conditions information. Such assurance is generally in the form of an adopted local ordinance or resolution. The community will have the authority to decide when to implement changes to local floodplain management regulations, which is true with any change that will result in making the local regulations more stringent than the minimum required under the NFIP.

National Environmental Policy Act

This Final Rule is categorically excluded from the requirements of 44 CFR Part 10.8 (d)(2)(ii), Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act

The Acting Administrator of the Federal Insurance and Mitigation Administration certifies that this Final Rule does not have a significant economic impact on a substantial number of small entities in accordance with the Regulatory Flexibility Act, 5 U.S.C. et seq., because it is not expected (1) to have significant secondary or incidental effects on a substantial number of small entities, nor (2) to create any additional burden on small entities. A regulatory flexibility analysis has not been prepared.

Executive Order 12612, Federalism

This Final Rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform

This Final Rule meets the applicable standards of Section 2(b)(2) of Executive Order 12778, Civil Justice Reform.

Executive Order 12866, Regulatory Planning and Review

Promulgation of this Final Rule is required by statute, 42 U.S.C. 4014(f), which also specifies the regulatory approach taken in this Final Rule. To the extent possible under the statutory requirements of 42 U.S.C. 4014(f), this Final Rule adheres to the principles of regulation as set forth in Executive Order 12866, Regulatory Planning and Review.

List of Subjects in 44 CFR Parts 59 and 64

Administrative practice and procedure, Flood insurance, Floodplains, and Reporting and record-keeping requirements.

Accordingly, amend 44 CFR Parts 59 and 64 as follows:

PART 59—GENERAL PROVISIONS

1. The authority citation for Part 59 continues to read as follow:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 43 FR 41943, 3 CFR 1978 Comp., p. 329; E.O. 12127 of Mar. 31, 1979, 44 FR 19367; 3 CFR 1979 Comp., p. 376.

2. Section 59.1 is amended by adding three definitions to read as follows:

§ 59.1 Definitions.

* * * * *

Area of future-conditions flood hazard means the land area that would be inundated by the 1-percent-annual-chance (100-year) flood based on future-conditions hydrology.

* * * * *

Future-conditions flood hazard area, or *future-conditions floodplain*—see *Area of future-conditions flood hazard.*

Future-conditions hydrology means the flood discharges associated with projected land-use conditions based on a community's zoning maps and/or comprehensive land-use plans and without consideration of projected future construction of flood detention structures or projected future hydraulic modifications within a stream or other waterway, such as bridge and culvert construction, fill, and excavation.

* * * * *

PART 64—COMMUNITIES ELIGIBLE FOR THE SALE OF INSURANCE

3. The authority citation for Part 64 continues to read as follow:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 43 FR 41943, 3 CFR 1978 Comp., p. 329; E.O. 12127 of Mar. 31, 1979, 44 FR 19367; 3 CFR 1979 Comp., p. 376.

4. Amend § 64.3 as follows:

a. Revise the introductory text of paragraph (a)(1).

b. In the table in paragraph (a)(1), revise the entry for the zone symbol for Zones B,X.

c. Revise the closing text to paragraph (a)(1).

The revisions read as follows:

§ 64.3 Flood Insurance Maps.

(a) * * *

(1) Flood Insurance Rate Map: This map is prepared after the flood hazard study for the community has been completed and the risk premium rates have been established. The FIRM indicates the risk premium rate zones applicable in the community and when those rates are effective. The FIRM also may indicate, at the request of the community, zones to identify areas of future-conditions flood hazards. The symbols used to designate the risk premium rate zones and future-conditions zones are as follows:

Zone symbol	
* * * * * * *	
B, X	Areas of moderate flood hazards or areas of future-conditions flood hazard.
* * * * * * *	

Areas identified as subject to more than one hazard (flood, mudslide (i.e., mudflow), flood-related erosion) or potential hazard (i.e., future-conditions flooding) will be designated on the FIRM by use of the proper zone symbols in combination.

* * * * *

Dated: November 20, 2001.

Robert F. Shea,

Acting Administrator, Federal Insurance and Mitigation Administration.

[FR Doc. 01–29474 Filed 11–26–01; 8:45 am]

BILLING CODE 6718–04–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 300

[I.D. 110801F]

Fraser River Sockeye and Pink Salmon Fisheries; 2001 Inseason Orders

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

ACTION: Inseason orders.

SUMMARY: NMFS publishes the Fraser River salmon inseason orders regulating salmon fisheries in U.S. waters. The orders were issued by the Fraser River Panel (Panel) of the Pacific Salmon Commission (Commission) and subsequently approved and issued by NMFS during the 2001 sockeye and pink salmon fisheries within the U.S. Fraser River Panel Area. These orders established fishing times, areas, and types of gear for U.S. treaty Indian and all-citizen fisheries during the period the Commission exercised jurisdiction over these fisheries. Due to the frequency with which inseason orders are issued, publication of individual orders is impracticable. The 2001 orders are, therefore, being published in this document to avoid fragmentation.

DATES: Each of the following inseason actions was effective upon announcement on telephone hotline numbers as specified at 50 CFR 300.97(b)(1); those dates and times are listed herein. Comments will be accepted through December 12, 2001.

ADDRESSES: Mail comments to D. Robert Lohn, Regional Administrator, Northwest Region, NMFS, 7600 Sand Point Way N.E., BIN C15700-Bldg. 1, Seattle, WA 98115-0070. Information relevant to this document is available for public review during business hours at the office of the Regional Administrator, Northwest Region, NMFS.

FOR FURTHER INFORMATION CONTACT: David Cantillon, 206–526–4140.

SUPPLEMENTARY INFORMATION: The treaty between the Government of the United States of America and the Government of Canada Concerning Pacific Salmon was signed at Ottawa on January 28, 1985, and subsequently was given effect in the United States by the Pacific Salmon Treaty Act (Act) at 16 U.S.C. 3631 *et seq.*

Under authority of the Act, Federal regulations at 50 CFR part 300 subpart F provide a framework for implementation of certain regulations of the Commission and inseason orders of the Commission's Panel for U.S. sockeye and pink salmon fisheries in the Fraser River Panel Area.

The regulations close the Fraser River Panel Area (U.S.) to U.S. sockeye and pink salmon fishing unless opened by Panel regulation or by inseason regulations published by NMFS that give effect to Panel orders. During the fishing season, NMFS may issue regulations that establish fishing times and areas consistent with the Commission agreements and inseason orders of the Panel. Such orders must be consistent with domestic legal obligations. The Regional Administrator, Northwest Region, NMFS, issues the inseason orders. Official notification of these inseason actions of NMFS is provided by two telephone hotline numbers described at 50 CFR 300.97(b)(1). Inseason orders must be published in the **Federal Register** as soon as practicable after they are issued. Due to the frequency with which inseason orders are issued, publication of individual orders is impractical. Therefore, the 2001 orders are being published in this document to avoid fragmentation.

The following inseason orders were adopted by the Panel and issued for U.S. fisheries by NMFS during the 2001 fishing season. The times listed are local times, and the areas designated are Puget Sound Management and Catch Reporting Areas as defined in the Washington State Administrative Code at Chapter 220-22.

Order No. 01-01: Issued 3 p.m., July 24, 2001.

Treaty Indian Fisheries

Areas 4B, 5 and 6C: Open for drift gillnets from 12 p.m. (noon) Wednesday, July 25 until 12 p.m. (noon) Saturday, July 28, 2001.

Order No. 01-02: Issued 3 p.m., July 27, 2001.

Treaty Indian Fisheries

Areas 4B, 5 and 6C: Extended for drift gillnets from 12 p.m. (noon) Saturday, July 28 until 12 p.m. (noon) Tuesday, July 31, 2001.

Order No. 01-03: Issued 3 p.m., July 30, 2001.

Treaty Indian Fisheries

Areas 4B, 5 and 6C: Extended for drift gillnets from 12 p.m. (noon) Tuesday, July 31, 2001, until 6 a.m Wednesday, August 1, 2001.

Areas 6, 7 and 7A: Open to net fishing from 4 a.m. Tuesday, July 31, 2001, until 6 a.m. Wednesday August 1, 2001.

All-Citizen Fisheries

Areas 7, and 7A Purse Seine: Open from 6 a.m. until 9 p.m. Wednesday, August 1, 2001.

Areas 7 and 7A Gillnet: Open from 8 a.m. until 11:59 p.m. Wednesday, August 1, 2001.

Areas 7 and 7A Reef Net: Open from 5 a.m. until 9 p.m. Thursday, August 2, 2001.

Order No. 01-04: Issued 3 p.m., August 3, 2001.

Treaty Indian Fisheries

Areas 4B, 5 and 6C: Opened for drift gillnets from 6 p.m. Friday, August 3, 2001, until 6 p.m Saturday, August 4, 2001.

Areas 6, 7 and 7A: Remain closed to fishing.

All-Citizen Fisheries

Areas 7, and 7A Purse Seine: Remain closed to fishing.

Areas 7 and 7A Gillnet: Remain closed to fishing.

Areas 7 and 7A Reef Net: Open from 5 a.m. until 9 p.m. Sunday, August 5, 2001.

Order No. 01-05: Issued 5 p.m., August 17, 2001.

Treaty Indian Fisheries

Areas 4B, 5, 6C, 6, 7 and 7A: Remain closed to fishing.

All-Citizen Fisheries

Areas 7, and 7A Purse Seine: Remain closed to fishing.

Areas 7 and 7A Gillnet: Remain closed to fishing.

Areas 7 and 7A Reef Net: Open from 5 a.m. until 9 p.m. Saturday, August 18, 2001, and from 5 a.m. until 9 p.m. Monday, August 20, 2001.

Order No. 01-06: Issued 1 p.m., August 19, 2001.

Treaty Indian Fisheries

Areas 4B, 5, 6C, 6, 7 and 7A: Remain closed to fishing.

All-Citizen Fisheries

Areas 7, and 7A Purse Seine: Remain closed to fishing.

Areas 7 and 7A Gillnet: Remain closed to fishing.

Areas 7 and 7A Reef Net: Remain closed to fishing.

Inseason Order No. 01-06 supersedes all previous inseason orders implementing 2001 orders of the Fraser River Panel.

Order No. 01-07: Issued 4:30 p.m., August 31, 2001.

Treaty Indian Fisheries

Areas 4B, 5, and 6C: Remain closed to fishing.

Areas 7 and 7A Purse Seine: South and east of a line from Iwersen's Dock on Point Roberts to Georgina Point Light at the entrance to Active Pass in British Columbia, open for the taking of pink salmon from 5 a.m. until 9 p.m. Tuesday, September 4, 2001. The retention of sockeye salmon is prohibited.

Areas 6, 7 and 7A Gillnets: Remain closed to fishing.

All-Citizen Fisheries

Areas 7, and 7A Purse Seine: South and east of a line from Iwersen's Dock on Point Roberts to Georgina Point Light at the entrance to Active Pass in British Columbia, open for the taking of pink salmon from 5 a.m. until 9 p.m. Wednesday, September 5, 2001. The retention of sockeye salmon is prohibited.

Areas 7 and 7A Gillnet: Remain closed to fishing.

Areas 7 and 7A Reef Net: South and east of a line from Iwersen's Dock on Point Roberts to Georgina Point Light at the entrance to Active Pass in British Columbia, open for the taking of pink salmon from 5 a.m. until 9 p.m. Saturday, September 1, 2001; from 5 a.m. until 9 p.m. Sunday, September 2, 2001; from 5 a.m. until 9 p.m. Monday, September 3, 2001; from 5 a.m. until 9 p.m. Tuesday, September 4, 2001; and from 5 a.m. until 9 p.m. Wednesday, September 5, 2001. The retention of sockeye salmon is prohibited.

Order No. 01-08: Issued 4:30 p.m., September 5, 2001.

Treaty Indian Fisheries

Areas 4B, 5, and 6C: Remain closed to fishing.

Areas 7 and 7A Purse Seine: Remain closed to fishing.

Areas 6, 7 and 7A Gillnets: Remain closed to fishing.

All-Citizen Fisheries

Areas 7, and 7A Purse Seine: South and east of a line from Iwersen's Dock on Point Roberts to Georgina Point Light at the entrance to Active Pass in British Columbia, open for the taking of pink salmon from 5 a.m. until 9 p.m. Wednesday, September 5, 2001. The retention of sockeye salmon is prohibited.

Areas 7 and 7A Gillnet: Remain closed to fishing.

Areas 7 and 7A Reef Net: South and east of a line from Iwersen's Dock on Point Roberts to Georgina Point Light at the entrance to Active Pass in British Columbia, open for the taking of pink salmon from 5 a.m. until 9 p.m. Wednesday, September 5, 2001; from 5 a.m. until 9 p.m. Thursday, September 6, 2001; from 5 a.m. until 9 p.m. Friday, September 7, 2001; and from 5 a.m. until 9 p.m. Saturday, September 8, 2001. The retention of sockeye salmon is prohibited.

Inseason Order No. 01-08 supersedes all previous inseason orders implementing 2001 orders of the Fraser River Panel.

Order No. 01-09: Issued 3:30 p.m., September 7, 2001.

Treaty Indian Fisheries

Areas 4B, 5, and 6C: Remain closed to fishing.

Areas 7 and 7A Purse Seine: South and east of a line from Iwersen's Dock on Point Roberts to Georgina Point Light at the entrance to Active Pass in British Columbia, open for the taking of pink salmon from 5 a.m. until 9 p.m. Sunday, September 9, 2001. The retention of sockeye salmon is prohibited.

Areas 6, 7 and 7A Gillnets: Remain closed to fishing.

All-Citizen Fisheries

Areas 7, and 7A Purse Seine: South and east of a line from Iwersen's Dock on Point Roberts to Georgina Point Light at the entrance to Active Pass in British Columbia, open for the taking of pink salmon from 5 a.m. until 9 p.m. Monday, September 10, 2001. The retention of sockeye salmon is prohibited.

Areas 7 and 7A Gillnet: Remain closed to fishing.

Areas 7 and 7A Reef Net: South and east of a line from Iwersen's Dock on Point Roberts to Georgina Point Light at the entrance to Active Pass in British Columbia, open for the taking of pink salmon from 5 a.m. until 9 p.m. Friday, September 7, 2001; from 5 a.m. until 9 p.m. Saturday, September 8, 2001; from 5 a.m. until 9 p.m. Sunday, September 9, 2001; from 5 a.m. until 9 p.m. Monday, September 10, 2001; and from 5 a.m. until 9 p.m. Tuesday, September 11, 2001. The retention of sockeye salmon is prohibited.

Inseason Order No. 01-09 supersedes all previous inseason orders implementing 2001 orders of the Fraser River Panel.

Order No. 01-10: Issued 3:30 p.m., September 11, 2001.

Treaty Indian Fisheries

Areas 4B, 5, and 6C: Remain closed to fishing.

Areas 7 and 7A Purse Seine: South and east of a line from Iwersen's Dock on Point Roberts to Georgina Point Light at the entrance to Active Pass in British Columbia, open for the taking of pink salmon from 5 a.m. until 9 p.m. Thursday, September 13, 2001. The retention of sockeye salmon is prohibited.

Areas 6, 7 and 7A Gillnets: Remain closed to fishing.

All-Citizen Fisheries

Areas 7, and 7A Purse Seine: South and east of a line from Iwersen's Dock on Point Roberts to Georgina Point Light at the entrance to Active Pass in British Columbia, open for the taking of pink salmon from 5 a.m. until 9 p.m. Thursday, September 13, 2001. The retention of sockeye salmon is prohibited.

Areas 7 and 7A Gillnet: Remain closed to fishing.

Areas 7 and 7A Reef Net: South and east of a line from Iwersen's Dock on Point Roberts to Georgina Point Light at the entrance to Active Pass in British Columbia, open for the taking of pink salmon from 5 a.m. until 9 p.m. Tuesday, September 11, 2001; from 5 a.m. until 9 p.m. Wednesday, September 12, 2001; from 5 a.m. until 9 p.m. Thursday, September 13, 2001; from 5 a.m. until 9 p.m. Friday, September 14, 2001; from 5 a.m. until 9 p.m. Saturday, September 15, 2001; from 5 a.m. until 9 p.m. Sunday, September 16, 2001; and from 5 a.m. until 9 p.m. Monday, September 17, 2001. The retention of sockeye salmon is prohibited.

Inseason Order No. 01-10 supersedes all previous inseason orders implementing 2001 orders of the Fraser River Panel.

Order No. 01-11: Issued 4:30 p.m., September 13, 2001.

Treaty Indian Fisheries

Areas 4B, 5, and 6C: Remain closed to fishing.

Areas 7 and 7A Purse Seine: South and east of a line from Iwersen's Dock on Point Roberts to Georgina Point Light at the entrance to Active Pass in British Columbia, open for the taking of pink salmon from 5 a.m. until 9 p.m. Thursday, September 13, 2001, and from 5 a.m. until 9 p.m. Friday,

September 14, 2001. The retention of sockeye salmon is prohibited.

Areas 6, 7 and 7A Gillnets: Remain closed to fishing.

All-Citizen Fisheries

Areas 7 and 7A Purse Seine: South and east of a line from Iwersen's Dock on Point Roberts to Georgina Point Light at the entrance to Active Pass in British Columbia, open for the taking of pink salmon from 5 a.m. until 9 p.m. Thursday, September 13, 2001, and from 5 a.m. until 9 p.m. Friday, September 14, 2001. The retention of sockeye salmon is prohibited.

Areas 7 and 7A Gillnet: Remain closed to fishing

Areas 7 and 7A Reef Net: South and east of a line from Iwersen's Dock on Point Roberts to Georgina Point Light at the entrance to Active Pass in British Columbia, open for the taking of pink salmon from 5 a.m. until 9 p.m. Thursday, September 13, 2001; from 5 a.m. until 9 p.m. Friday, September 14, 2001; from 5 a.m. until 9 p.m. Saturday, September 15, 2001; from 5 a.m. until 9 p.m. Sunday, September 16, 2001; and from 5 a.m. until 9 p.m. Monday, September 17, 2001. The retention of sockeye salmon is prohibited.

Inseason Order No. 01-11 supersedes all previous inseason orders implementing 2001 orders of the Fraser River Panel.

Order No. 01-12: Issued 4:30 p.m., September 17, 2001.

Treaty Indian Fisheries

Areas 4B, 5, and 6C: Remain closed to fishing.

Areas 7 and 7A Purse Seine: South and east of a line from Iwersen's Dock on Point Roberts to Georgina Point Light at the entrance to Active Pass in British Columbia, open for the taking of pink salmon from 5 a.m. until 9 p.m. Wednesday, September 19, 2001. The retention of sockeye salmon is prohibited.

Areas 6, 7 and 7A Gillnets: Remain closed to fishing.

All-Citizen Fisheries

Areas 7 and 7A Purse Seine: Remain closed to fishing.

Areas 7 and 7A Gillnet: Remain closed to fishing.

Areas 7 and 7A Reef Net: South and east of a line from Iwersen's Dock on Point Roberts to Georgina Point Light at the entrance to Active Pass in British Columbia, open for the taking of pink salmon from 5 a.m. until 9 p.m. Monday, September 17, 2001; from 5 a.m. until 9 p.m. Tuesday, September 18, 2001; from 5 a.m. until 9 p.m. Wednesday, September 19, 2001; from 5 a.m. until 9 p.m. Thursday, September 20, 2001; from 5 a.m. until 9 p.m. Friday, September 21, 2001; and from 5 a.m. until 9 p.m. Saturday, September 22, 2001. The retention of sockeye salmon is prohibited.

Inseason Order No. 01-12 supersedes all previous inseason orders implementing 2001 orders of the Fraser River Panel.

Order No. 01-13: Issued 1 p.m., September 18, 2001.

Treaty Indian Fisheries

Areas 4B, 5, and 6C: Remain closed to fishing.

Areas 7 and 7A Purse Seine: South and east of a line from Iwersen's Dock on Point Roberts to Georgina Point Light at the entrance to Active Pass in British Columbia, open for the taking of pink salmon from 5 a.m. until 9 p.m. Wednesday, September 19, 2001. The retention of sockeye salmon is prohibited.

Areas 6, 7 and 7A Gillnets: Remain closed to fishing.

All-Citizen Fisheries

Areas 7 and 7A Purse Seine: South and east of a line from Iwersen's Dock on Point Roberts to Georgina Point Light at the entrance to Active Pass in British Columbia, open for the taking of pink salmon from 5 a.m. until 9 p.m. Wednesday, September 19, 2001. The retention of sockeye salmon is prohibited.

Areas 7 and 7A Gillnet: Remain closed to fishing.

Areas 7 and 7A Reef Net: South and east of a line from Iwersen's Dock on Point Roberts to Georgina Point Light at the entrance to Active Pass in British Columbia, open for the taking of pink salmon from 5 a.m. until 9 p.m. Tuesday, September 18, 2001; from 5 a.m. until 9 p.m. Wednesday, September 19, 2001; from 5 a.m. until 9 p.m. Thursday, September 20, 2001; from 5 a.m. until 9 p.m. Friday, September 21, 2001; and from 5 a.m. until 9 p.m. Saturday, September 22, 2001. The retention of sockeye salmon is prohibited.

Inseason Order No. 01-13 supersedes all previous inseason orders implementing 2001 orders of the Fraser River Panel.

Classification

Because these fisheries have been closed, NMFS has determined that good cause exists for this notification to be issued without affording a prior opportunity for public comment because such notification would be unnecessary, impracticable, and contrary to the public interest.

This action is authorized by 50 CFR 300.97, and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 3636(b).

Dated: November 20, 2001.

Jon Kurland,

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

[FR Doc. 01–29495 Filed 11–26–01; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 000831250–0250–01; 111601D]

Fisheries off West Coast States and in the Western Pacific; Coastal Pelagic Species Fisheries; Closure of Directed Fishery for Pacific Mackerel

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

ACTION: Closure of directed fishery for Pacific mackerel.

SUMMARY: NMFS announces the closure of the directed fishery for Pacific mackerel in the exclusive economic zone off the Pacific coast at 12 noon local time (l.t.) on November 21, 2001. For the fishing season beginning July 1, 2001, 6,000 mt of the 13,837-mt harvest guideline was established for a directed fishery. Based on recent landings, more than 6,000 mt of Pacific mackerel has been landed; therefore, the directed fishery is being closed and the trip limit imposed. The intended effect of this action is to ensure that the harvest guideline will be achieved, but not exceeded, and to minimize bycatch of Pacific mackerel while other coastal pelagic species are being harvested.

DATES: Effective 12 noon local time on November 21, 2001, until the effective date of the 2002 fishing season for Pacific mackerel, which will publish in the **Federal Register.**

ADDRESSES: The data that was used as the basis for this action is available for public inspection at the Office of the Acting Regional Administrator, Rodney R. McInnis, Southwest Region (Regional Administrator), NMFS, 501 W. Ocean Boulevard, Suite 4200, Long Beach, CA 90802–4213.

FOR FURTHER INFORMATION CONTACT: James J. Morgan, Southwest Region, NMFS, 562–980–4036.

SUPPLEMENTARY INFORMATION: On July 25, 2001, NMFS announced in the

Federal Register (66 FR 38571) a harvest guideline of 13,837 mt for Pacific mackerel for the fishing season July 1, 2001, through June 30, 2002. A directed fishery of 6,000 mt was established, which, when attained, would be followed by an incidental allowance of 45 percent by weight of Pacific mackerel in a landing of any coastal pelagic species. If a significant amount of the harvest guideline remained unused before the end of the fishing season on June 30, 2002, the directed fishery would be reopened. This approach was taken because of concern about the low harvest guideline's potential negative effect on the harvest of Pacific sardine if the fishery for Pacific mackerel had to be closed.

As of November 8, 2001, 6,079 mt of Pacific mackerel has been landed. The recent harvest rate will lead to reaching the harvest guideline before the end of the season and at a time when sardine harvests are likely to be high; therefore, the incidental allowance of 45 percent by weight will be implemented. This will minimize bycatch of Pacific mackerel while allowing the sardine fishery to be conducted without further restrictions. If a significant portion of the 13,837-mt harvest guideline remains before the end of the fishing season on June 30, 2002, the directed fishery will be reopened.

For the reasons stated here and in accordance with the FMP and its implementing regulations at 50 CFR 660.509, the directed fishery for Pacific mackerel will be closed at 12:00 l.t. on November 21, 2001, after which time no more than 45 percent by weight of a landing of Pacific sardine, northern anchovy, jack mackerel, or market squid may consist of Pacific mackerel.

Classification

This action is required by 50 CFR 660.509 and is exempt from review under Executive Order 12866.

The Assistant Administrator for Fisheries, NOAA finds good cause to waive the requirement to provide opportunity for prior notice and comment on this action pursuant to 5 U.S.C. 553(b)(B), as providing prior notice and opportunity for comment would be impracticable and unnecessary. It is impracticable because the fishery must be closed to prevent overharvest and to allow the sardine fishery to continue. It is unnecessary since this is a minor inseason action and the public had an opportunity to comment on the process that established the season openings and closings.

For these reasons, good cause also exists to waive the 30-day delay in effectiveness requirement of 5 U.S.C. 553 (d)(3).

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

Dated: November 21, 2001.

Bruce C. Morehead,

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

[FR Doc. 01–29484 Filed 11–21–01; 2:51 pm]

BILLING CODE 3510–22–S

Proposed Rules

Federal Register
Vol. 66, No. 228
Tuesday, November 27, 2001

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 AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket No. 01–079–1]

Citrus Canker; Quarantined Areas

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the citrus canker regulations by removing a portion of the quarantined area in Manatee County, FL, from the list of quarantined areas. The regulations require that an area be free from citrus canker for a period of at least 2 years before it may be removed from the list of quarantined areas. Surveys have shown that a portion of the quarantined area in Manatee County, FL, has been free of citrus canker since February 1999. This proposed action would remove restrictions on the interstate movement of regulated articles from that portion of Manatee County, FL.

DATES: We invite you to comment on this docket. We will consider all comments that we receive by December 27, 2001.

ADDRESSES: Please send four copies of your comment (an original and three copies) to: Docket No. 01–079–1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 01–079–1.

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

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

FOR FURTHER INFORMATION CONTACT: Mr. Stephen Poe, Operations Officer, PPQ, APHIS, 4700 River Road Unit 134, Riverdale, MD 20737; (301) 734–8899.

SUPPLEMENTARY INFORMATION:

Background

Citrus canker is a plant disease that affects plants and plant parts, including fresh fruit, of citrus and citrus relatives (Family *Rutaceae*). Citrus canker can cause defoliation and other serious damage to the leaves and twigs of susceptible plants. It can also cause lesions on the fruit of infected plants, which render the fruit unmarketable, and cause infected fruit to drop from the trees before reaching maturity. The aggressive A (Asiatic) strain of citrus canker can infect susceptible plants rapidly and lead to extensive economic losses in commercial citrus-producing areas.

The regulations to prevent the interstate spread of citrus canker are contained in 7 CFR 301.75–1 through 301.75–16 (referred to below as the regulations). The regulations restrict the interstate movement of regulated articles from and through areas quarantined because of citrus canker and provide for the designation of survey areas around quarantined areas. Survey areas undergo close monitoring by Animal and Plant Health Inspection Service (APHIS) and State inspectors for citrus canker and serve as buffer zones against the disease.

Under § 301.75–4(c) of the regulations, any State or portion of a State where an infestation is detected will be designated as a quarantined area and will retain that designation until the area has been free from citrus canker for 2 years.

A 15-square-mile area in the northern part of the quarantined area in Manatee County, FL, has been free of citrus canker since February 1999, and has thus met the requirement for declaration of eradication—that an area be free from citrus canker for a period of at least 2 years. In this case, regular and complete surveys have been conducted on an approximately monthly basis since the infestation was first detected, including surveys of all citrus trees located in both commercial groves and at residential properties. In addition, any wild citrus present in the area has also been surveyed.

Although not required as a condition of declaring eradication in an area, in this case all abandoned citrus orchards in the area, estimated at over 1,000 acres, have also been removed. Abandoned citrus groves present a challenge in conducting surveys, and thus the removal of these groves increases our confidence that citrus canker is no longer present in this area. APHIS and the State of Florida will continue to survey all commercial and private citrus groves on a regular basis at least until citrus canker is fully eradicated statewide.

Therefore, we are proposing to amend the citrus canker regulations by removing a portion of the quarantined area in Manatee County, FL, from the list of quarantined areas. The portion of Manatee County we are proposing to remove from the list of quarantined areas covers approximately 15 square miles in the northern portion of the current quarantined area in Manatee County. The portion of the current quarantined area that would remain on the list of quarantined areas is described in the rule portion of this document. This proposed action would remove restrictions on the interstate movement of regulated articles from the portion of Manatee County, FL, that would be removed from the list of quarantined areas.

Executive Order 12866 and Regulatory Flexibility Act

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

We are proposing to amend the citrus canker regulations by removing a portion of the quarantined area in Manatee County, FL, from the list of quarantined areas. The regulations require that an area be free from citrus canker for a period of at least 2 years before it is removed from the list of quarantined areas. Surveys have shown that a portion of the quarantined area in Manatee County, FL, has been free of citrus canker since February 1999. This proposed action would remove

restrictions on the interstate movement of regulated articles from that portion of Manatee County, FL.

The area we are proposing to remove from quarantine represents only a small portion of the total production in Manatee County. The table below shows statistics for Manatee County after trees were removed to limit the spread of citrus canker.

	Boxes of citrus produced in 1999–2000 season	Total acres January 2000	Total number of trees January 2000
All Round Oranges	8,365,000	21,236	2,631,200
All Grapefruit	422,000	1,197	111,900
Speciality Fruit	279,000	821	98,300
All Citrus	9,066,000	23,254	2,841,400

While producers in the area that would be removed from the list of quarantined areas would benefit from removal of movement restrictions, it is unlikely that the benefit would be big enough to measure statistically. This proposed action would not impose any costs on producers or on government entities.

Most of the citrus producers in and around the quarantined area in Manatee County, FL, would qualify as small entities under Small Business Administration (SBA) guidelines. The Regulatory Flexibility Act requires that the Agency specifically consider the economic impact associated with rule changes on small entities. The SBA defines a firm engaged in agriculture as ''small'' if it has less than $750,000 in annual receipts.

Citrus producers in the area that would be removed from the list of quarantined areas would have greater choice of where to market their fruit. This would benefit producers by providing them with more alternatives. It is unlikely, however, that producer income or expenses would be affected in a measurable way.

It is difficult to quantify the benefits of removing an area from quarantine. While producers would have greater choice of where to market their citrus crops, most of the trees in the quarantined area have been destroyed. It is unlikely that a reduction in the quarantined area would have any measurable effect on producers or consumers.

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

Executive Order 12372

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

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) State and local laws and regulations will not be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

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

List of Subjects in 7 CFR Part 301

Agricultural commodities, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

Accordingly, we are proposing to amend 7 CFR part 301 as follows:

PART 301—DOMESTIC QUARANTINE NOTICES

1. The authority citation for part 301 would continue to read as follows:

Authority: 7 U.S.C. 166, 7711, 7712, 7714, 7731, 7735, 7751, 7752, 7753, and 7754; 7 CFR 2.22, 2.80, and 371.3.

Section 301.75–15 also issued under Sec. 204, Title II, Pub. L. 106–113, 113 Stat. 1501A–293; sections 301.75–15 and 301.75–16 also issued under Sec. 203, Title II, Pub. L. 106–224, 114 Stat. 400 (7 U.S.C. 1421 note).

2. In § 301.75–4, paragraph (a), in the entry for Manatee County, the second paragraph would be revised to read as follows:

§ 301.75–4 Quarantined areas.

(a) * * *

Florida

* * * * *

Manatee County. * * *

That portion of the county bounded by a line drawn as follows: Beginning at the northwest corner of sec. 24, T. 33 S., R. 17 E.; then east along the northern boundary of sec. 24, T. 33. S., R. 17 E. (Bishop Harbor Road) until it becomes SR 683 (Moccasin Wallow Road); then east on SR 683 to the northeast boundary of sec. 22, T. 33 S., R. 18 E., then south along the eastern boundary of sec. 22, T. 33 S., R. 18 E. to 69th Street East; then east on 69th Street East to Erie Road; then south on Erie Road to U.S. Highway 301; then south on U.S. Highway 301 to Interstate 75; then south on Interstate 75 to the southern boundary of sec. 24, T. 35 S., R. 18 E.; then west along the southern boundaries of secs. 24, 23, and 22 to where the southern boundary of sec. 22 meets Whitfield Avenue; then west on Whitfield Avenue to U.S. Highway 301; then north on U.S. Highway 301 to SR 70; then west on SR 70 to U.S. Highway 41; then north on U.S. Highway 41 to where it becomes 14th Street West; then north on 14th Street West to 1st Avenue West; then east on 1st Avenue West to 9th Street West; then north on 9th Street West to the north bank of the Manatee River; then west along the north bank of the Manatee River to Terra Ceia Bay; then north along the western boundaries of secs. 25 and 24 to the point of the beginning.

* * * * *

Done in Washington, DC, this 15th day of November 2001.

W. Ron DeHaven,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 01–29473 Filed 11–26–01; 8:45 am]

BILLING CODE 3410–34–P

FEDERAL RESERVE SYSTEM

12 CFR Parts 208 and 225

[Regulations H and Y; Docket No. R–1117]

Risk-Based Capital Guidelines; Supplementary Capital Elements (Tier 2 Capital); Deferred Tax Assets

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Proposed rule with request for comment.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is proposing to amend its risk-based capital guidelines to clarify that deferred tax assets in excess of the allowable amount (disallowed deferred tax assets) are included in the items that are deducted from tier 1 capital for the purpose of determining the maximum allowable amount of tier 2 capital that a banking organization may include in qualifying total capital and the maximum allowable amount of term subordinated debt and intermediate-term preferred stock that may be treated as supplementary capital. The proposed rule would reduce the maximum allowable amount of tier 2 capital for institutions that have disallowed deferred tax assets, as well as the amount of term subordinated debt and intermediate-term preferred stock that those institutions could include in supplementary capital. This clarification will make the Federal Reserve's capital guidelines consistent with those of the Office of the Comptroller of the Currency (OCC), the Federal Deposit Insurance Corporation (FDIC), and the Office of Thrift Supervision (OTS).

DATES: Comments must be received by December 27, 2001.

ADDRESSES: Comments should refer to Docket No. R–1117 and should be mailed to Ms. Jennifer J. Johnson, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, NW., Washington, DC 20551, or mailed electronically to *regs.comments@federalreserve.gov*. Comments addressed to Ms. Johnson may also be delivered to the Board's mail facility in the West Courtyard between 8:45 a.m. and 5:15 p.m., located on 21st Street between Constitution Avenue and C Street, NW. Members of the public may inspect comments in Room MP–500 of the Martin Building between 9:00 a.m. and 5:00 p.m. on weekdays pursuant to § 261.12, except as provided in § 261.14, of the Board's Rules Regarding Availability of Information, 12 CFR 261.12 and 261.14.

FOR FURTHER INFORMATION CONTACT: Barbara Bouchard, Associate Director (202/452–3072), or David Adkins, Supervisory Financial Analyst (202/452–5259), Division of Banking Supervision and Regulation. For users of Telecommunications Device for the Deaf (''TDD'') only, contact 202/263–4869.

SUPPLEMENTARY INFORMATION: Under the Board's risk-based capital guidelines, banking organizations must deduct disallowed deferred tax assets from tier 1 capital, along with goodwill and certain other intangible assets.[1] As a general rule, the maximum amount of tier 2 capital that may be included in an organization's qualifying total capital is limited to 100 percent of tier 1 capital. In addition, the aggregate amount of term subordinated debt (excluding mandatory convertible debt) and intermediate-term preferred stock that may be treated as supplementary capital is limited to 50 percent of tier 1 capital. However, for purposes of these two limitations, the Board's current guidelines define tier 1 capital as net of goodwill and certain other intangible assets but not of disallowed deferred tax assets. This treatment is inconsistent with that of the OCC, the FDIC, and the OTS (the other federal banking agencies), whose capital guidelines specifically require disallowed deferred tax assets to be deducted from tier 1 capital in determining these limitations. The Board is proposing to amend its risk-based capital guidelines so that, in addition to goodwill and certain other intangible assets, disallowed deferred tax assets will also be netted out of tier 1 capital for the purpose of determining these two limitations. These changes are being proposed in order to make the Federal Reserve's risk-based capital guidelines consistent with current market practice, and, in keeping with the mandate of section 303(a)(1) of the Riegle Community Development and Regulatory Improvement Act of 1994, to make the Federal Reserve's risk-based capital rules consistent with those of the other Federal banking agencies.

Regulatory Flexibility Act Analysis

Pursuant to section 605(b) of the Regulatory Flexibility Act, the Board has determined that this rule would not have a significant impact on a substantial number of small entities in accord with the spirit and purposes of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). An analysis of recent Call Report data indicates that less than four percent of banks with assets of $100 million or less carry disallowed deferred tax assets on their balance sheets. In addition, many of these banks may already be making the proper deduction of these disallowed deferred tax assets from tier 1 capital. Accordingly, a regulatory flexibility analysis is not required.

Paperwork Reduction Act

The Board has determined that this proposed rule does not involve a collection of information pursuant to the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Solicitation of Comments Regarding the Use of ''Plain Language''

Section 722 of the Gramm-Leach-Bliley Act of 1999 requires the Board to use ''plain language'' in all proposed and final rules published after January 1, 2000. The Board invites comments about how to make the rule easier to understand, including answers to the following questions:

(1) Is the material organized in an effective manner? If not, how could the material be better organized?

(2) Are the terms of the proposed rule clearly stated? If not, how could the terms be more clearly stated?

(3) Does the proposed rule contain technical language or jargon that is unclear? If not, which language requires clarification?

(4) Would a different format (with respect to the grouping and order of sections and use of headings) make the proposed rule easier to understand? If so, what changes to the format would make the proposed rule easier to understand?

(5) Would increasing the number of sections (and making each section shorter) clarify the proposed rule? If so, which portions of the proposed rule should be changed in this respect?

(6) What additional changes would make the proposed rule easier to understand?

List of Subjects

12 CFR Part 208

Accounting, Agriculture, Banks, banking, Confidential business information, Crime, Currency, Federal Reserve System, Mortgages, Reporting and recordkeeping requirements, Securities.

12 CFR Part 225

Administrative practice and procedure, Banks, banking, Federal Reserve System, Holding companies, Reporting and recordkeeping requirements, Securities.

For the reasons set forth in the preamble, part 208 and part 225 of chapter II of title 12 of the Code of Federal Regulations are proposed to be amended as set forth below:

[1] The amount of deferred tax assets that may be included in a banking organization's capital may not exceed the lesser of (i) the amount of deferred tax assets that the banking organization is expected to realize within one year, or (ii) 10 percent of tier 1 capital. Amounts in excess of this threshold represent disallowed deferred tax assets and must be deducted from a banking organization's core capital elements in determining tier 1 capital.

PART 208—MEMBERSHIP OF STATE BANKING INSTITUTIONS IN THE FEDERAL RESERVE SYSTEM (REGULATION H)

1. The authority citation for part 208 continues to read as follows:

Authority: 12 U.S.C. 24, 36, 92a, 93a, 248(a), 248(c), 321–338a, 371d, 461, 481–486, 601, 611, 1814, 1816, 1818, 1820(d)(9), 1823(j), 1828(o), 1831, 1831o, 1831p-1, 1831r-1, 1835a, 1882, 2901–2907, 3105, 3310, 3331–3351, and 3906–3909; 15 U.S.C. 78b, 78l(b), 78l(g), 78l(i), 78o-4(c)(5), 78q, 78q-1, and 78w, 6801, and 6805; 31 U.S.C. 5318; 42 U.S.C. 4012a, 4104a, 4104b, 4106, and 4128.

2. In appendix A to part 208, section *II.*A.2. is amended by revising the first undesignated paragraph following paragraph (v), and section II.A.2.d. is amended by revising paragraph (i) to read as follows:

Appendix A to Part 208—Capital Adequacy Guidelines for State Member Banks: Risk-Based Measure

II. * * *
A. * * *
2. * * *
(v) * * *

The maximum amount of Tier 2 capital that may be included in a bank's qualifying total capital is limited to 100 percent of Tier 1 capital (net of goodwill, other intangible assets required to be deducted in accordance with section II.B.1.b. of this appendix, and deferred tax assets required to be deducted in accordance with section II.B.4. of this appendix).

* * * * *

(d) *Subordinated debt and intermediate term preferred stock.* (i) The aggregate amount of term subordinated debt (excluding mandatory convertible debt) and intermediate-term preferred stock that may be treated as supplementary capital is limited to 50 percent of Tier 1 capital (net of goodwill, other intangible assets required to be deducted in accordance with section II.B.1.b. of this appendix, and deferred tax assets required to be deducted in accordance with section II.B.4. of this appendix).

* * * * *

PART 225—BANK HOLDING COMPANIES AND CHANGE IN BANK CONTROL (REGULATION Y)

1. The authority citation for part 225 continues to read as follows:

Authority: 12 U.S.C. 1817(j)(13), 1818, 1828(o), 1831i, 1831p–1, 1843(c)(8), 1844(b), 1972(1), 3106, 3108, 3310, 3331–3351, 3907, and 3909; 15 U.S.C. 6801 and 6805.

2. In appendix A to part 225, section II.A.2. is amended by revising the first undesignated paragraph following paragraph (v), and section II.A.2.d. is amended by revising paragraph (i) to read as follows:

Appendix A to Part 225—Capital Adequacy Guidelines for Bank Holding Companies: Risk-Based Measure

II. * * *
A. * * *
2. * * *
(v) * * *

The maximum amount of Tier 2 capital that may be included in an organization's qualifying total capital is limited to 100 percent of Tier 1 capital (net of goodwill, other intangible assets required to be deducted in accordance with section II.B.1.b. of this appendix, and deferred tax assets required to be deducted in accordance with section II.B.4. of this appendix).

* * * * *

(d) *Subordinated debt and intermediate term preferred stock.* (i) The aggregate amount of term subordinated debt (excluding mandatory convertible debt) and intermediate-term preferred stock that may be treated as supplementary capital is limited to 50 percent of tier 1 capital (net of goodwill, other intangible assets required to be deducted in accordance with section II.B.1.b. of this appendix, and deferred tax assets required to be deducted in accordance with section II.B.4. of this appendix).

* * * * *

By order of the Board of Governors of the Federal Reserve System, November 19, 2001.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 01–29331 Filed 11–26–01; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–CE–31–AD]

RIN 2120–AA64

Airworthiness Directives; Pilatus Britten-Norman Limited BN–2, BN–2A, BN–2B, BN–2T, and BN2A MK. III Series 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 Pilatus Britten-Norman Limited (Pilatus Britten-Norman) Limited BN–2, BN–2A, BN–2B, BN–2T, and BN2A MK. III series airplanes. This proposed AD would require you to replace the emergency exit window sealant. This proposed AD is the result of mandatory continuing airworthiness information (MCAI) issued by the airworthiness authority for the United Kingdom. The actions specified by this proposed AD are intended to correct the problems with emergency exit windows failing to open. Such failure could lead to the inability to exit the airplane in an emergency.

DATES: The Federal Aviation Administration (FAA) must receive any comments on this proposed rule on or before January 3, 2002.

ADDRESSES: Submit comments to FAA, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 2001–CE–31–AD, 901 Locust, Room 506, Kansas City, Missouri 64106. You may view any comments at this location between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

You may get service information that applies to this proposed AD from Pilatus Britten-Norman Limited, Bembridge, Isle of Wight, United Kingdom PO35 5PR; telephone: +44 (0) 1983 872511; facsimile: +44 (0) 1983 873246. You may also view this information at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; facsimile: (816) 329–4090.

SUPPLEMENTARY INFORMATION:

Comments Invited

How do I comment on this proposed AD? The FAA invites comments on this proposed rule. You may submit whatever written data, views, or arguments you choose. You need to include the rule's docket number and submit your comments to the address specified under the caption **ADDRESSES.** We will consider all comments received on or before the closing date. We may amend this proposed rule in light of comments received. Factual information that supports your ideas and suggestions is extremely helpful in evaluating the effectiveness of this proposed AD action and determining whether we need to take additional rulemaking action.

Are there any specific portions of this proposed AD I should pay attention to? The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of this proposed rule that might suggest a need to modify the rule. You may view all comments we receive before and after the closing date of the rule in the Rules Docket. We will file a report in the Rules Docket that summarizes each contact we have with the public that concerns the substantive parts of this proposed AD.

How can I be sure FAA receives my comment? If you want FAA to acknowledge the receipt of your comments, you must include a self-addressed, stamped postcard. On the postcard, write ''Comments to Docket No. 2001–CE–31–AD.'' We will date stamp and mail the postcard back to you.

Discussion

What events have caused this proposed AD? The Civil Aviation Authority (CAA), which is the airworthiness authority for the United Kingdom, recently notified FAA that an unsafe condition may exist on all Pilatus Britten-Norman BN–2, BN–2A, BN–2B, BN–2T, and BN2A MK. III series airplanes. The CAA reports an incident where an emergency exit window could not be opened. The CAA determined that the emergency exit windows were not properly installed with the correct sealant.

What are the consequences if the condition is not corrected? This condition, if not corrected, could lead to the inability to exit the airplane in an emergency.

Is there service information that applies to this subject? Pilatus Britten-Norman has issued BN Service Bulletin SB 277, Issue 1, dated 03/08/2001.

What are the provisions of this service information? The service bulletin includes procedures for replacing the emergency exit window sealant.

What action did the CAA take? The CAA classified this service bulletin as mandatory and issued British AD Number 001–08–2001, dated August 3, 2001, in order to ensure the continued airworthiness of these airplanes in the United Kingdom.

Was this in accordance with the bilateral airworthiness agreement? These airplane models are manufactured in the United Kingdom and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement.

Pursuant to this bilateral airworthiness agreement, the CAA has kept FAA informed of the situation described above.

The FAA's Determination and an Explanation of the Provisions of this Proposed AD What has FAA decided? The FAA has examined the findings of the CAA; reviewed all available information, including the service information referenced above; and determined that:

—The unsafe condition referenced in this document exists or could develop on Pilatus Britten-Norman BN–2, BN–2A, BN–2B, BN–2T, and BN2A MK. III series airplanes of the same type design that are on the U.S. registry;

—The actions specified in the previously-referenced service information should be accomplished on the affected airplanes; and

—AD action should be taken in order to correct this unsafe condition.

What would this proposed AD require? This proposed AD would require you to incorporate the actions in the previously-referenced service bulletin.

Cost Impact

How many airplanes would this proposed AD impact? We estimate that this proposed AD affects 118 airplanes in the U.S. registry.

What would be the cost impact of this proposed AD on owners/operators of the affected airplanes? We estimate the following costs to accomplish the necessary replacement:

Labor cost	Parts cost	Total cost per airplane	Total cost on U.S. operators
2 workhours × $60 per hour = $120	$40	$160	118 × $160 per airplane = $18,880.

Regulatory Impact

Would this proposed AD impact various entities? 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.

Would this proposed AD involve a significant rule or regulatory action? For the reasons discussed above, I certify that this proposed 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, under 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. FAA amends § 39.13 by adding a new airworthiness directive (AD) to read as follows:

Pilatus Britten-Norman Limited: Docket No. 2001–CE–31–AD

(a) *What airplanes are affected by this AD?* This AD affects all serial numbers of Models BN–2, BN–2A, BN–2A–2, BN–2A–3, BN–2A–6, BN–2A–8, BN–2A–9, BN–2A–20, BN–2A–21, BN–2A–26, BN–2A–27, BN–2B–20, BN–2B–21, BN–2B–26, BN–2B–27, BN–2T, BN–2T–4R, BN2A MK. III, BN2A MK. III–2, and BN2A MK. III–3 airplanes that are certificated in any category.

(b) *Who must comply with this AD?* Anyone who wishes to operate any of the above airplanes must comply with this AD.

(c) *What problem does this AD address?* The actions specified by this AD are intended to prevent the failure of emergency exit windows to open.

(d) *What actions must I accomplish to address this problem?* To address this problem, you must accomplish the following:

Actions	Compliance	Procedures
Replace emergency exit window sealant	Within the next 50 hours time-in-service after the effective date of this AD, unless already performed.	In accordance with the Action section of BN Service Bulletin SB 277, Issue 1, dated 03/08/2001.

(e) *Can I comply with this AD in any other way?* You may use an alternative method of compliance or adjust the compliance time if:

(1) Your alternative method of compliance provides an equivalent level of safety; and

(2) The Manager, Small Airplane Directorate, approves your alternative. Submit your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Small Airplane Directorate.

Note 1: This AD applies to each airplane identified in paragraph (a) of this AD, 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 (e) 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 you have not eliminated the unsafe condition, specific actions you propose to address it.

(f) *Where can I get information about any already-approved alternative methods of compliance?* Contact Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; facsimile: (816) 329–4090.

(g) *What if I need to fly the airplane to another location to comply with this AD?* The FAA can issue a special flight permit under sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.

(h) *How do I get copies of the documents referenced in this AD?* You may get copies of the documents referenced in this AD from Pilatus Britten-Norman Limited, Bembridge, Isle of Wight, United Kingdom PO35 5PR; telephone: +44 (0) 1983 872511; facsimile: +44 (0) 1983 873246. You may view these documents at FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106.

Note 2: The subject of this AD is addressed in British AD 001–08–2001, dated August 3, 2001.

Issued in Kansas City, Missouri, on November 19, 2001.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–29394 Filed 11–26–01; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NM–355–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 747–100, –200, –300, 747SP, and 747SR Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the supersedure of an existing airworthiness directive (AD), applicable to certain Boeing Model 747–100, –200, –300, 747SP, and 747SR series airplanes, that currently requires repetitive inspections to detect cracks in various areas of the fuselage internal structure, and repair, if necessary. This action would add new repetitive inspections for cracking of certain areas of the upper chord of the upper deck floor beams, and repair, if necessary. This proposal is prompted by the results of fatigue testing that revealed severed upper chords of the upper deck floor beams due to fatigue cracking. The actions specified by the proposed AD are intended to prevent loss of the structural integrity of the fuselage, which could result in rapid depressurization of the airplane.

DATES: Comments must be received by January 11, 2002.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2000–NM–355–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: 9–anm–nprmcomment@faa.gov. Comments sent via fax or the Internet must contain ''Docket No. 2000–NM–355–AD'' in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Rick Kawaguchi, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–1153; fax (425) 227–1181.

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 shall 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 action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (e.g., reasons or data) for each request.

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 summarizing 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 action

must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2000–NM–355–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, Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2000–NM–355–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

On April 22, 1993, the FAA issued AD 93–08–12, amendment 39–8559 (58 FR 27927, May 12, 1993), applicable to certain Boeing Model 747 series airplanes, to require repetitive inspections to detect cracks in various areas of the fuselage internal structure, and repair, if necessary. That action was prompted by results of fatigue tests that identified areas of the fuselage internal structure where fatigue cracks occurred. The requirements of that AD are intended to prevent loss of the structural integrity of the fuselage.

Actions Since Issuance of Previous Rule

Since the issuance of AD 93–08–12, the FAA received a report that, during fatigue testing, severed upper chords were found on the upper deck floor beams on a Boeing Model 747 series airplane. The chords severed as a result of fatigue cracking. Additional reports were received that indicated the detailed internal visual inspections of the upper deck floor beams, mandated by AD 93–08–12 may not detect cracks before they become critical. Such conditions, if not corrected, could result in loss of the structural integrity of the fuselage, and rapid depressurization of the airplane.

Related AD

On February 22, 2000, the FAA issued AD 2000–04–17, amendment 39–11600 (65 FR 10695, February 29, 2000), applicable to certain Boeing Model 747–100, –200, and –300 series airplanes. That AD requires repetitive inspections to detect fatigue cracking in the chords and webs of certain upper deck floor beams, and repair of any cracking found. This proposed AD would require similar inspections of upper deck floor beams that were not addressed in that AD.

Explanation of Relevant Service Information

The FAA has reviewed and approved Boeing Alert Service Bulletin 747–53A2349, Revision 1, dated October 12, 2000, which describes procedures for detailed visual inspections for cracking in the following areas of the fuselage internal structure:

- Sections 41 and 42 upper deck floor beams
- Section 42 frames
- Section 46 frames
- Certain Section 41 bulkhead areas

The service bulletin also describes procedures for repetitive detailed internal and external visual inspections of the main entry doors and door cutouts for cracking, and repetitive open hole high frequency eddy current inspections for cracking in the horizontal flanges of the upper chord of the Sections 41 and 42 upper deck floor beams. The new detailed visual inspection of Area 1 of Sections 41 and 42 would eliminate the need for the existing inspection of those sections. If cracking is found, the service bulletin references the 747 Structural Repair Manual (SRM) for repair instructions, or if the damage is beyond the limits specified in the service bulletin, the service bulletin specifies contacting Boeing for repair data.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would supersede AD 93–08–12 to continue to require repetitive inspections to detect cracks in various areas of the fuselage internal structure, and repair, if necessary. The proposed AD would add new repetitive inspections for cracking of certain areas of the upper chord of the upper deck floor beams, and repair, if necessary. The actions would be required to be accomplished in accordance with the service bulletin described previously, except as discussed below.

Differences Between Proposed AD and Revision 1 of the Alert Service Bulletin

This proposed AD differs from the service bulletin as follows:

- The service bulletin specifies that the manufacturer should be contacted for disposition of certain repair conditions, but this proposed AD would require the repair of those conditions to be accomplished per a method approved by the FAA, or per data meeting the type certification basis of the airplane approved by a Boeing Company Designated Engineering Representative (DER) who has been authorized by the Manager, Seattle Aircraft Certification Office, to make such findings.
- The service bulletin specifies doing a high frequency eddy current inspection of the left and right sides of the upper deck floor beam at body station 380 between buttock lines 40 and 76, but this proposed AD would not require that inspection because it was mandated in AD 2000–04–17, amendment 39–11600 (65 FR 10695, February 29, 2000).
- The service bulletin specifies doing detailed visual and high frequency eddy current inspections of body station (BS) 380 through BS 1000 inclusive, on each upper deck floor beam on Group 3 airplanes. This proposed AD would extend the inspection area from BS 380 through BS 1100 inclusive. The manufacturer has informed the FAA that the upper deck floor beams extend to BS 1100 for Group 3 airplanes, and the service bulletin will be revised to reflect this change.
- The service bulletin also specifies that flight cycles with a cabin pressure differential of less than 2.0 pounds per square inch (psi) are not to be counted, but this proposed AD allows this stipulation only for Area 1 (Sections 41 and 42 upper deck floor beams) inspections. The FAA has determined that flight loads can significantly contribute to fatigue loads in other areas. Flights with less than 2.0 psi cabin differential pressure can still have significant flight loads; therefore, the FAA cannot allow an adjustment to flight cycles for areas other than Area 1.
- Additionally, this proposed AD adds a grace period of 3,000 flight cycles after doing the most recent inspection required by AD 93–08–12 for airplanes that have exceeded the compliance threshold specified in the service bulletin.

Explanation of Additional Changes to Requirements of Existing AD

We have changed the requirements of the existing AD, as restated in this proposed AD, to remove all references to the use of ''FAA-approved procedures.'' This change is consistent with FAA policy in that regard. In place of this language, we have specified accomplishing repairs per a method approved by the FAA, or per data meeting the type certification basis of the airplane approved by a Boeing Company DER. We have determined that this change will not increase the economic burden on any operator, nor will it increase the scope of the proposed AD. A new paragraph (c) has been added to accommodate this change.

Interim Action

This is considered to be interim action until similar action for Boeing Model 747–400 series airplanes and 747

freighter airplanes is identified, at which time the FAA may consider further rulemaking.

Cost Impact

There are approximately 489 airplanes of the affected design in the worldwide fleet.

The FAA estimates that 181 airplanes of U.S. registry are subject to the existing AD. The actions that are currently required by AD 93–08–12 take approximately 1,746 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the currently required actions is estimated to be $104,760 per airplane.

We estimate that 155 airplanes of U.S. registry are subject to the new actions in this proposed AD. The new inspections that are proposed in this AD action would take approximately 255 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the proposed requirements of this AD on U.S. operators is estimated to be $2,371,500, or $15,300 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the current or proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

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 proposal would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) 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 is contained 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 removing amendment 39–8559 (58 FR 27927, May 12, 1993), and by adding a new airworthiness directive (AD), to read as follows:

Boeing: Docket 2000–NM–355–AD. Supersedes AD 93–08–12, Amendment 39–8559.

Applicability: Model 747 series airplanes, as listed in Boeing Service Bulletin 747–53–2349, dated June 27, 1991, or Boeing Alert Service Bulletin 747–53A2349, Revision 1, dated October 12, 2000; 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 (h)(1) 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 the structural integrity of the fuselage, which could result in rapid depressurization of the airplane; do the following:

Restatement of Requirements of AD 93–08–12

Repetitive Inspections

(a) Prior to the accumulation of 22,000 total flight cycles, or within 1,000 flight cycles after June 11, 1993 (the effective date of AD 93–08–12, amendment 39–8559), whichever occurs later, unless accomplished previously within the last 2,000 flight cycles; and thereafter at intervals not to exceed 3,000 flight cycles: Perform a detailed visual internal inspection to detect cracks in the areas of the fuselage internal structure specified in paragraphs (a)(1) through (a)(7) of this AD; in accordance with Boeing Service Bulletin 747–53–2349, dated June 27, 1991.

(1) Sections 41 and 42 upper deck floor beams.

(2) Section 42 upper lobe frames.

(3) Section 46 lower lobe frames.

(4) Section 42 lower lobe frames.

(5) Main entry door cutouts.

(6) Section 41 body station 260, 340, and 400 bulkheads.

(7) Main entry doors.

(b) Prior to the accumulation of 25,000 total flight cycles, or within 1,000 flight cycles after June 11, 1993, whichever occurs later, unless accomplished previously within the last 2,000 flight cycles; and thereafter at intervals not to exceed 3,000 flight cycles: Perform a detailed visual internal inspection to detect cracks in the Section 46 upper lobe frames, in accordance with Boeing Service Bulletin 747–53–2349, dated June 27, 1991.

Repair

(c) Prior to further flight, repair any cracks detected during the inspections done per paragraph (a) or (b) of this AD, per a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA; or per data meeting the type certification basis of the airplane approved by a Boeing Company Designated Engineering Representative (DER) who has been authorized by the Manager, Seattle ACO, to make such findings. For a repair method to be approved by the Manager, Seattle ACO, as required by this paragraph, the approval letter must specifically reference this AD.

New Requirements of This AD

Repetitive Inspections

(d) Before the accumulation of 22,000 total flight cycles, or within 3,000 flight cycles after doing the most recent inspection required by paragraph (a) of this AD, whichever occurs later: Do a detailed visual inspection to find cracking in the areas specified in paragraph (d)(1) or (d)(2) of this AD, as applicable, per Figure 2 of the Accomplishment Instructions of Boeing Alert Service Bulletin 747–53A2349, Revision 1, dated October 12, 2000. Repeat the inspection after that every 3,000 flight cycles. Doing this inspection terminates the inspections required by paragraph (a) of this AD in the area specified in paragraph (a)(1) of this AD only.

(1) For Groups 1, 2, 4, and 5 airplanes: Do the inspections of Area 1 (sections 41 and 42 upper deck floor beams), including existing repairs and modifications.

(2) For Group 3 airplanes: Do the inspections of Area 1 (sections 41 and 42 upper deck floor beams from body stations 380 through 1100 inclusive), including existing repairs and modifications.

Note 2: For the purposes of this AD, a detailed visual inspection is defined as: ''An intensive visual examination of a specific

structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required.''

(e) Before the accumulation of 28,000 total flight cycles, or within 3,000 flight cycles after doing the most recent inspection required by paragraph (a) of this AD, whichever occurs later: Do a high frequency eddy current (HFEC) inspection to find cracking of the open holes in the horizontal flanges of the upper chord of each upper deck floor beam in the areas specified in paragraph (e)(1) or (e)(2) of this AD, as applicable, per the Accomplishment Instructions of Boeing Alert Service Bulletin 747–53A2349, Revision 1, dated October 12, 2000. Do the inspection per ''Inspection Alternatives,'' as specified in Sheet 7 of Figure 2 of the Accomplishment Instructions of the service bulletin. Repeat the applicable inspection according to the ''Repeat Inspection Intervals,'' specified in Sheet 7 of Figure 2 of the Accomplishment Instructions of the service bulletin.

(1) For Group 1, 2, 4, and 5 airplanes: Do the inspections at the applicable locations (BS 380 through BS 780 inclusive for Groups 1, 2, and 4, BS 380 through BS 860 inclusive for Group 5) as specified in Sheet 7 of Figure 2.

(2) For Group 3 airplanes: Do the inspections as specified in Sheet 7 of Figure 2, at the upper deck floor beams from BS 380 through BS 1100 inclusive.

Note 3: HFEC inspections of the left and right sides of the upper deck floor beam at body station 380, between buttock lines 40 and 76, done before the effective date of this AD per AD 2000–04–17, amendment 39–11600, are considered acceptable for compliance with the applicable inspections specified in paragraph (e) of this AD.

Adjustments to Compliance Time: Cabin Differential Pressure

(f) For the purposes of calculating the compliance threshold and repetitive interval for the actions required by paragraphs (d) and (e) of this AD: For Area 1 only, the number of flight cycles in which cabin differential pressure is at 2.0 pounds per square inch (psi) or less need not be counted when determining the number of flight cycles that have occurred on the airplane, provided that flight cycles with momentary spikes in cabin differential pressure above 2.0 psi are included as full pressure cycles. For this provision to apply, all cabin pressure records must be maintained for each airplane: NO fleet-averaging of cabin pressure is allowed.

Repair

(g) Before further flight, repair any cracking found during the inspections done per paragraphs (d) and (e) of this AD, according to Boeing Alert Service Bulletin 747–53A2349, Revision 1, dated October 12, 2000. Where the service bulletin specifies to contact Boeing for repair instructions, repair per a method approved by the Manager, Seattle ACO; or per data meeting the type certification basis of the airplane approved by a Boeing Company DER who has been authorized by the Manager, Seattle ACO, to make such findings. For a repair method to be approved by the Manager, Seattle ACO, as required by this paragraph, the approval letter must specifically reference this AD.

Alternative Methods of Compliance

(h)(1) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle ACO. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

(2) Alternative methods of compliance, approved previously in accordance with AD 93–08–12, amendment 39–8559, are approved as alternative methods of compliance with this AD.

Note 4: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

Special Flight Permits

(i) 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.

Issued in Renton, Washington, on November 20, 2001.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–29426 Filed 11–26–01; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–NM–37–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 737–600, –700, –700C, and –800 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Boeing Model 737–600, –700, –700C, and –800 series airplanes. This proposal would require a one-time inspection of certain fasteners in rudder pedal housings to determine if pan-head fasteners are installed, and replacement of existing fasteners with improved fasteners, if necessary. This action is necessary to prevent loss of free movement of the rudder pedals, which could result in reduced controllability of the airplane. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by January 11, 2002.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2001–NM–37–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: *9–anm–nprmcomment@faa.gov.* Comments sent via fax or the Internet must contain ''Docket No. 2001–NM–37–AD'' in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Barbara Mudrovich, Aerospace Engineer, Systems and Equipment Branch, ANM–130S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2983; fax (425) 227–1181.

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 shall 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 action may be changed in light of the comments received.

Submit comments using the following format:

• Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.

• For each issue, state what specific change to the proposed AD is being requested.

• Include justification (e.g., reasons or data) for each request.

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 summarizing 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 action must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2001–NM–37–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, Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2001–NM–37–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The FAA has received a report indicating that, during a check of the flight controls by the captain, a rudder pedal on a Boeing Model 737–800 series airplane caught on a pan-head fastener on the upper cover assembly of the rudder pedal housing. Further investigation revealed that this condition may occur when the rudder pedal for either the captain or first officer is adjusted to the full-forward position and a side load is applied to the rudder pedal. This condition, if not corrected, could prevent free movement of the pedal, and result in reduced controllability of the airplane.

The fasteners on the upper cover assembly of the rudder pedal housing on certain Boeing Model 737–600, –700, and –700C series airplanes may be the same as those installed on Model 737–800 series airplanes. Therefore, those airplanes may also be subject to the same unsafe condition described above.

Airplanes after line number 295 have been delivered with flush-head fasteners installed in the subject area, and are not subject to this unsafe condition.

Explanation of Relevant Service Information

We have reviewed and approved Boeing Alert Service Bulletin 737–25A1383, Revision 1, dated December 2, 1999, which describes procedures for a one-time inspection of fasteners on the upper cover assembly of the housing for the captain's and first officer's rudder pedals to determine if pan-head fasteners are installed, and replacement of all pan-head fasteners with improved (flush-head) fasteners, including countersink-drilling of the fastener holes. Accomplishment of the actions specified in the service bulletin is intended to adequately address the identified unsafe condition.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require accomplishment of the actions specified in the service bulletin described previously, except as discussed below.

Difference Between Proposed AD and Service Bulletin

The proposed AD differs from the service bulletin in the following ways:

• The service bulletin recommends that the actions therein be done as soon as manpower and materials are available. However, we find that such a compliance time may not ensure that the necessary actions are completed in a timely manner. Therefore, this proposed AD would require the replacement of all pan-head bolts with improved bolts within 12 months after the effective date of this AD.

• The effectivity listing of the service bulletin identifies only Model 737–600, –700, and –800 series airplanes as being subject to the actions described therein. However, in reviewing the effectivity listing, the FAA finds that Model 737–700C series airplanes are also included. Therefore, Model 737–700C series airplanes are included in the applicability statement in this proposed AD.

• The service bulletin does not specify what type of inspection is needed to determine if pan-head fasteners are installed on the upper cover assembly of the housing for the captain's and first officer's rudder pedals. The FAA has determined that the procedures in the service bulletin describe a general visual inspection. Note 2 of this proposed AD defines that type of inspection.

Cost Impact

There are approximately 264 airplanes of the affected design in the worldwide fleet. The FAA estimates that 123 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 1 work hour per airplane to accomplish the proposed inspection, and that the average labor rate is $60 per work hour. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $7,380, or $60 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this proposed AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Should an operator be required to accomplish the replacement of fasteners, it would take approximately 2 work hours per airplane to accomplish the repair, at an average labor rate of $60 per work hour. Required parts would be provided by the manufacturer at no cost to the operator. Based on these figures, the cost impact of any repair action is estimated to be $120 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 proposal would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) 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 is contained 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 the following new airworthiness directive:

Boeing: Docket 2001–NM–37–AD.

Applicability: Model 737–600, –700, –700C, and –800 series airplanes; line numbers 1 through 295 inclusive; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (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 loss of free movement of the rudder pedals, which could result in reduced controllability of the airplane, accomplish the following:

Replacement of Fasteners

(a) Within 12 months after the effective date of this AD, do a one-time general visual inspection of the fasteners on the upper cover assembly of the housing for the captain's and first officer's rudder pedals to determine if pan-head fasteners are installed, according to Boeing Alert Service Bulletin 737–25A1383, Revision 1, dated December 2, 1999. Replace all pan-head fasteners on the upper cover assembly of the housing for the captain's and first officer's rudder pedals with improved (flush-head) fasteners, including countersink-drilling the fastener holes, according to the service bulletin.

Note 2: For the purposes of this AD, a general visual inspection is defined as: ''A visual examination of an interior or exterior area, installation, or assembly to detect obvious damage, failure, or irregularity. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or drop-light, and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being checked.''

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

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

Special Flight Permits

(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 requirements of this AD can be accomplished.

Issued in Renton, Washington, on November 20, 2001.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–29427 Filed 11–26–01; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–NM–75–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 757–200, –200CB, and –200PF; and 767–200, –300, and –300F Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Boeing Model 757–200, 200CB, and –200PF; and 767–200, –300, and –300F series airplanes. This proposal would require modification of the right main landing gear and auto-speedbrake control system to provide an air/ground signal to the system. This action is necessary to prevent uncommanded deployment of the auto-speedbrake spoilers during flight, which could result in reduced controllability of the airplane. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by January 11, 2002.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2001–NM–75–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: *9-anm-nprmcomment@faa.gov.* Comments sent via fax or the Internet must contain ''Docket No. 2001–NM–75–AD'' in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Barbara Mudrovich, Aerospace Engineer, Systems and Equipment Branch, ANM–130S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2983; fax (425) 227–1181.

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 shall 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 action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.

• For each issue, state what specific change to the proposed AD is being requested.

• Include justification (e.g., reasons or data) for each request.

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 summarizing 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 action must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2001–NM–75–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, Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2001–NM–75–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The FAA has received a report of two incidents of in-flight auto-speedbrake deployment during landing approach on a Boeing Model 767 series airplane. In one incident, the airplane was at approximately 1,500 feet altitude with the landing gear down and the auto-speedbrake spoilers armed. There was a vibration and the spoilers automatically deployed to 20 degrees during flap extension. Investigation revealed that an incorrect air/ground data input from the proximity switch electronics unit (PSEU) can deploy the auto-speedbrake spoilers. The auto-speedbrake system uses only input from the PSEU as its source for air/ground data, but this single source of air/ground data may not be adequate, in that incorrect data could result in uncommanded deployment of the auto-speedbrake spoilers in flight. Uncommanded deployment of the auto-speedbrake spoilers during flight, if not corrected, could result in reduced controllability of the airplane.

Boeing Model 757 series airplanes have a similar auto-speedbrake control system, therefore, those airplanes may also be subject to the same unsafe condition described above.

Explanation of Relevant Service Information

The FAA has reviewed and approved Boeing Alert Service Bulletins 757–27A0130, dated August 31, 2000, and 767–27A0160, dated December 20, 2000, which describe the following modification procedures:

Work package	Boeing Alert Service Bulletin 757–27A0130
1	Install the truck tilt sensor wire bundle between the main equipment compartment and the right main landing gear (MLG).
2	Install a truck tilt sensor and target on the right MLG. Replace the terminal rail in the forward junction box and the electrical conduits between the box and the truck tilt sensor. Install sensor wires to the truck tilt sensor.
3	Install a wire between the P36 and P37 panel assemblies in the main equipment compartment. The tilt sensor wires are installed in the P36 and P37 panel assemblies, and the tilt sensor relay is installed in the P37 panel assembly. Do the system functional tests. (The service bulletin specifies that each work package can be done independently or at the same time, in any sequence, but the functional tests in Work Package 3 should be done last.)

Work package	Boeing Alert Service Bulletin 767–27A0160
1	Install the truck tilt sensor wiring between the main electronic equipment center disconnect to the right MLG of the forward cargo compartment.
2	Replace the J2 and J4 junction boxes and conduit on the right MLG. Install new truck tilt sensor wiring.
3	Install new truck tilt proximity sensor and target on the right MLG.
4	Install truck tilt sensor wiring to the P33 forward miscellaneous electronic equipment panel of the main electronic equipment center. Do the wiring changes to the P36 left miscellaneous electronic equipment panel. Install a new gear tilt relay in the P33 panel. Do a system checkout test to make sure the truck tilt sensor and auto-speedbrake, engine probe heat, pitot probe heat, auto ice detection, antiskid, tire pressure indication, brake temperature monitoring, and brake cooling fan systems operate properly. (The service bulletin specifies that each work package can be done independently or at the same time, in any sequence, but Work Package 4 should be done last.)

Accomplishment of the actions specified in the service bulletins is intended to adequately address the identified unsafe condition.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require accomplishment of the actions specified in the service bulletins described previously, except as discussed below.

Related Rulemaking

Boeing Alert Service Bulletin 767–27A0160, is cited in this proposed AD as the correct source of service information for doing certain actions. That service bulletin references five other related service bulletins that should be done before, or concurrently, with this proposed AD. Those service bulletins have been addressed in the previously issued ADs listed below:

• On July 28, 1994, the FAA issued AD 94–16–03, amendment 39–8993 (59 FR 41229, August 11, 1994), applicable to certain Boeing Model 767 series airplanes equipped with Pratt & Whitney JT9D–7R4 or General Electric CF6–80A series engines, which requires inspections, adjustments, and functional tests of the thrust reverser system. That AD also requires installation of an additional thrust reverser system locking feature, periodic functional tests of that locking feature following its

installation, and repair of any discrepancy found. (The service bulletins cited in that AD are Boeing Service Bulletins 767–78–0061, Revision 1, and 767–78–0060, Revision 2, both dated August 5, 1993.)

• On February 27, 1996, the FAA issued AD 95–13–12 R1, amendment 39–9528 (61 FR 9092, March 7, 1996), applicable to certain Boeing Model 767 series airplanes equipped with General Electric CF6–80C2 series engines, which requires tests, inspections, and adjustments of the thrust reverser system. That AD also requires installation of a terminating modification and repetitive follow-on actions. (The service bulletin cited in that AD is Boeing Service Bulletin 767–78–0063, Revision 1, dated April 29, 1993.

• On June 3, 1994, the FAA issued AD 94–12–10, amendment 39–8938 (59 FR 31508, June 20, 1994), applicable to certain Boeing Model 767 series airplanes equipped with Pratt & Whitney PW4000 series engines, which requires repetitive inspections, tests, adjustments, and functional checks of the thrust reverser system and of selected engine wiring. That AD also requires installation of a terminating modification, repetitive operational checks of that installation, and repair of any discrepancy found. (The service bulletin cited in that AD is Boeing Service Bulletin 767–78–0062, Revision 1, dated December 17, 1992.)

• On August 4, 1994, the FAA issued AD 94–17–03, amendment 39–8998 (59 FR 41647, August 16, 1994), applicable to certain Boeing Model 767 series airplanes equipped with Rolls-Royce RB211–524 series engines, which requires inspections, adjustments, and functional checks of the thrust reverser system, installation of a terminating modification, and repetitive operational checks of the gearbox locks and the air motor brake following accomplishment of the modification. (The service bulletin cited in that AD is Boeing Service Bulletin 767–78–0059, Revision 1, dated September 24, 1992.)

Difference Between the Proposed AD and Alert Service Bulletins

The alert service bulletins recommend incorporation of the specified actions ''at the earliest maintenance opportunity when manpower, materials, and facilities are available,'' the FAA finds that such a compliance time will not ensure that the modification is accomplished in a timely manner. In developing an appropriate compliance time for this AD, the FAA considered not only the manufacturer's recommendation, but the degree of urgency associated with addressing the subject unsafe condition, the average utilization of the affected fleet, and the time necessary to perform the modifications. In light of all of these factors, the FAA finds a 36-month compliance time for accomplishing the modifications on all affected airplanes to be warranted, in that it represents an appropriate interval of time allowable for affected airplanes to continue to operate without compromising safety.

Cost Impact

There are approximately 1,654 airplanes of the affected design in the worldwide fleet. The FAA estimates that 583 Model 757 series airplanes and 292 Model 767 series airplanes of U.S. registry would be affected by this proposed AD. The work hours and cost estimates for the proposed modifications are listed below:

*BOEING ALERT SERVICE BULLETIN 757–27A0130

Work package	Work hours @ $60/WH	Cost per airplane without parts	Fleet cost without parts
1	50	$3,000	$1,749,000
2	32	1,920	1,119,360
3	12	720	419,760

*Parts cost for Model 757 series airplanes is between $8,953 and $10,630 per airplane.

*BOEING ALERT SERVICE BULLETIN 767–27A0160

Work package	Work hours @ $60/WH	Cost per airplane without parts	Fleet cost without parts
1	11	$660	$192,720
2	18	1,080	315,360
3	2	120	35,040
4	15	900	262,800

*Parts cost for Model 767 series airplanes is between $7,132 and $8,224 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this proposed AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

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 proposal would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) 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 is contained 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 the following new airworthiness directive:

Boeing: Docket 2001–NM–75–AD.

Applicability: Model 757–200, –200CB, and –200PF series airplanes, line numbers 1 through 895 inclusive; and Model 767–200, –300, and –300F series airplanes, line numbers 1 through 759 inclusive; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (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 provide a second air/ground signal to the auto-speedbrake control system to prevent uncommanded deployment of the auto-speedbrake spoilers during flight, which could result in reduced controllability of the airplane, accomplish the following:

Modifications

(a) Within 36 months after the effective date of this AD: Modify the right main landing gear and auto-speedbrake control system according to Work Packages 1 through 3 of the Accomplishment Instructions of Boeing Alert Service Bulletin 757–27A0130, dated August 31, 2000 (for Model 757 series airplanes), or Work Packages 1 through 4 of the Accomplishment Instructions of Boeing Alert Service Bulletin 767–27A0160, dated December 20, 2000 (for Model 767 series airplanes), as applicable.

Note 2: Boeing Alert Service Bulletin 757–27A0130 specifies that each work package can be done independently or at the same time, in any sequence, but the functional tests in Work Package 3 should be done last. Boeing Alert Service Bulletin 767–27A0160 specifies that each work package can be done independently or at the same time, in any sequence, but Work Package 4 should be done last.

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

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

Special Flight Permit

(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 requirements of this AD can be accomplished.

Issued in Renton, Washington, on November 20, 2001.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–29428 Filed 11–26–01; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 420

[FHWA Docket No. FHWA–2001–8874]

RIN 2125–AE84

Planning and Research Program Administration

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of proposed rulemaking (NPRM); request for comments.

SUMMARY: This document proposes to amend the regulation on planning and research program administration to reflect legislative changes due to enactment of the Transportation Equity Act for the 21st Century (TEA–21); remove provisions that are no longer necessary; and make several changes in terminology. Most notable among the changes are renumbering of the State planning and research (SPR) funds section in title 23, United States Code, Highways (title 23, U.S.C.) from section 307(c) to section 505; revisions to 23 U.S.C. 302 that now allow a State transportation department to be reimbursed for indirect costs; and changes in the Federal-aid highway program categories from which SPR funds are set aside.

DATES: Comments must be received on or before January 28, 2002.

ADDRESSES: Mail or hand deliver comments to the U.S. Department of Transportation, Dockets Management Facility, Room PL–401, 400 Seventh Street, SW., Washington, DC 20590, or submit electronically at *http://dmses.dot.gov/submit.* All comments should include the docket number that appears in the heading of this document. All comments received will be available for examination and copying at the above address from 9 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard or you may print the acknowledgment page that appears after submitting comments electronically.

FOR FURTHER INFORMATION CONTACT: For 23 CFR part 420, subpart A: Mr. Tony Solury, (202) 366–5003, Planning and Environment Core Business Unit, HEP–2, Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590; for 23 CFR part 420, subpart B: Jowell Parks or William Zaccagnino, Office of Program Development and Evaluation, HRPD–1, (202) 493–3166, Federal Highway Administration, Research, Development, and Technology Service Business Unit, 6300 Georgetown Pike, McLean, VA 22101. For legal questions: Reid Alsop, Office of the Chief Counsel, HCC–30, (202) 366–1371. Office hours are from 7 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

You may submit or retrieve comments online through the Document Management System (DMS) at: http://dmses.dot.gov/submit. Acceptable formats include: MS Word (versions 95 to 97), MS Word for Mac (versions 6 to 8), Rich Text File (RTF), American Standard Code Information Interchange (ASCII)(TXT), Portable Document Format (PDF), and WordPerfect (versions 7 to 8). The DMS is available 24 hours each day, 365 days each year. Electronic submission and retrieval help and guidelines are available under the help section of the web site.

An electronic copy of this document may also be downloaded from the

Government Printing Office's Electronic Bulletin Board Service at (202) 512–1661 by using a computer, modem, and suitable communications software. Internet users may also reach the Office of the Federal Register's home page at: http://www.nara.gov/fedreg and the Government Printing Office's web page at: http://www.access.gpo.gov/nara.

Background

The FHWA's regulations for Planning and Research Program Administration were last revised on July 22, 1994, (59 FR 37548) prior to the enactment of the TEA–21 (Pub. L. 105–178, 112 Stat.107(1998)). Section 5119(b) of TEA–21 repealed the SPR funds section in 23 U.S.C. 307(c) and section 5105 of TEA–21 added a new SPR funds section 505 to title 23, United States Code. Changes in the Federal-aid highway program in TEA–21 also resulted in changes in the Federal-aid highway program categories from which SPR funds are set aside. Section 1212 of TEA–21 revised 23 U.S.C. 302 to allow a State transportation department (STD) to be reimbursed for indirect costs.

Based on experience since the 1994 revision, we are proposing revisions to clarify the meaning and applicability of several sections of the regulation, and to replace the phrase ''peer review'' with ''peer exchange'' to describe the transfer of research, development, and technology transfer (RD&T) related information and best practices between STDs, the FHWA, universities and public and private sector transportation organizations. In addition, we propose to add a definition of ''transportation pooled fund study'' to reflect current practice and the conditions under which the non-Federal share of an SPR or metropolitan planning (PL) funded project may be waived would be clarified.

General Discussion of the Proposal

We propose to reword the title of each section of the regulation into a question format to better indicate the content of the sections. In addition, this action proposes to add references to 49 CFR part 19, Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations, in appropriate sections throughout the regulation since FHWA planning and research funds are often passed through to entities covered by Part 19. Furthermore, in all appropriate places throughout the regulation where an approval action or review is required by an FHWA Division Office, we propose to replace the term ''FHWA'' with ''FHWA Division Administrator'' to clarify which FHWA office has the approval responsibility.

Section-by-Section Discussion

Section 420.101 What Is the Purpose of This Part?

This section would be revised to more clearly indicate the applicability of 23 CFR part 420 and subparts A and B.

Section 420.103 How Does the FHWA Define the Terms Used in This Part?

In the definition of FHWA planning and research funds, references to 23 U.S.C. 307(c) would be changed to 23 U.S.C. 505. In the definition of FHWA planning and research funds under item 1, the words ''or allocated'' would be added after ''apportioned'' since under the TEA–21, SPR funds are now also derived from funds allocated under the minimum guarantee program. The reference to minimum allocation funds would be deleted, since such funds were not continued under the TEA–21, and the new TEA–21 category of minimum guarantee funds would be added.

We propose to revise the wording of the definition of ''grant agreement'' to be more consistent with the definition in the Federal Grant and Cooperative Agreement Act (31 U.S.C. 6301 *et seq.*) and ''subrecipient'' would be added to help clarify when a subaward by a recipient is considered to be a subgrant.

The FHWA proposes to revise the definition of ''metropolitan planning area'' to update the reference to the metropolitan transportation planning requirements from ''section 8 of the Federal Transit Act'' to ''49 U.S.C. 5303–5305.''

We propose to move the definition of National Cooperative Highway Research Program (NCHRP) currently in § 420.203 to § 420.103 since that term is now used in subpart A.

We propose to replace the definitions of ''national pooled fund study'' and ''regional pooled fund study'' with a definition of ''transportation pooled fund study'' to reflect current pooled fund study practices and the elimination of FHWA regional offices.

The FHWA proposes to slightly revise the definition of ''procurement contract'' to be more consistent with the definition in the Federal Grant and Cooperative Agreement Act and ''subrecipient'' would be added to help clarify when a subaward by a recipient is considered to be a subcontract.

This action proposes to delete the definition of ''State transportation agency (STA)'' and to replace the term throughout part 420 with ''State transportation department (STD)'' which is defined in section 101(a) of title 23, U.S.C.

We further propose to add a definition of ''Transportation management area'' since the term is used in the regulation.

This action also proposes to delete the phrase ''during the next 1 or 2-year period'' from the definition of ''work program'' to allow STDs and metropolitan planning organizations (MPOs) greater flexibility to follow procedures that best meet their own needs.

Section 420.105 What Is the FHWA's Policy on Use of FHWA Planning and Research Funds?

In this section, the FHWA proposes to make the following changes:

Paragraph (a) would be reworded for clarity and the reference ''23 U.S.C. 307(c)'' would be changed to ''23 U.S.C. 505.''

The word ''multimodal'' in paragraph (a)(1) would be changed to ''intermodal'' for consistency with current usage within the FHWA.

A new paragraph (c) would be added to more clearly indicate that the FHWA has the authority and responsibility to determine which activities are eligible for Federal funding.

Section 420.107 What Is the Minimum Required Expenditure of State Planning and Research Funds for Research, Development and Technology Transfer?

We propose the following amendments to this section:

The reference ''23 U.S.C. 307(c)'' in paragraph (a) would be changed to ''23 U.S.C. 505.''

Paragraph (b)(1) would be revised to update the reference to Federal Transit Act State planning and research funds from ''Section 26(a)(2)'' to ''49 U.S.C. 5313(b).''

In paragraph (c), the title ''Associate Administrator'' would be changed to ''Director'' to reflect organizational changes in the FHWA. In paragraph (c)(2), and all other places where it is in the existing regulation, ''pooled fund'' would be changed to ''transportation pooled fund'' to reflect the revised definition discussed above. Since data on expenditures for RD&T prior to enactment of the Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA), Pub. L. 102–240, 105 Stat. 1914, is no longer readily available, paragraph (c)(4) would be removed and paragraphs (5) and (6) would be renumbered (4) and (5), respectively. The language in renumbered paragraphs (c)(4)'(5) and in (d) would be revised for clarity.

Section 420.109 What Are the Requirements for Distribution of Metropolitan Planning Funds?

The FHWA proposes to make the following changes in this section:

Paragraph (a) would be revised by adding language that recognizes that a State's PL fund distribution formula, which must be developed in cooperation with the MPOs, may include provisions that allow funds to be used for activities that benefit all MPOs in the State or for discretionary awards to those MPOs to supplement their allocated share of the funds.

Paragraph (f) would be revised to require that a State's PL fund distribution formula be in compliance with the provisions of paragraphs (a) and (b) before distribution of any new apportionment of PL funds to MPOs.

Section 420.111 What Are the Documentation Requirements for Use of FHWA Planning and Research Funds?

We propose to add the language ''or other document that describes the work to be accomplished'' in paragraph (a) to clarify the FHWA's long-standing practice of allowing projects to be funded separately from a work program if such projects can be better administered separately. For example, if a project is expected to take several years to complete and is funded under a consultant contract, it may be easier to administer if funds needed during each year of the contract did not need to be shown in each corresponding annual work program. If funded as a separate Federal-aid project, the project would stay open until all work has been completed, as for highway construction projects. The third sentence of the existing paragraph, which discussed separate or combined planning and RD&T projects, would be removed since it is a fiscal issue that is covered in § 420.115.

Existing paragraph (b) would be amended by moving the requirement for each work program to include a summary of the amounts and sources of funds from existing paragraph (c)(1) through (c)(4) to revised paragraph (b)(1)(i) through (iv) and the remainder of existing paragraph (c) would become revised paragraph (d).

The provisions in 23 CFR part 450 that allow metropolitan areas that are not TMAs to used simplified statements of work in lieu of a more detailed work program would be included in new paragraph (c) to clearly indicate this option.

Existing paragraph (d) would become paragraph (e) and the reference to 23 CFR Part 450 would be removed since it is not necessary.

Section 420.113 What Costs Are Eligible?

Prior to revision of 23 U.S.C. 302 by section 1212(a) of the TEA–21, STDs were not allowed to charge indirect costs to title 23, U.S.C., funded projects. However, STDs were allowed to charge salaries of certain planning and research unit administrative staff directly to SPR funds on a prorata basis. The MPOs and other subgrantees could charge indirect costs in accordance with the Office of Management and Budget (OMB) cost principles applicable to those subgrantees. Paragraphs (b)–(d) of existing § 420.113 specify the allowability of indirect costs for each of these types of grantee and subgrantee. With the amendment to 23 U.S.C. 302, STDs can now also claim reimbursement for indirect costs in compliance with OMB Circular A–87, Cost Principles for Grants, and Cooperative Agreements with State, Local, and Indian Tribal Governments. Therefore, existing paragraphs (b) through (d) would be deleted and replaced with a new paragraph (b) that covers indirect costs of the STDs and their subgrantees.

Section 420.115 What Are the FHWA Approval and Authorization Requirements?

We propose to add the words ''or other documents that describe the work to be performed'' after ''work program'' in paragraph (a) for consistency with the change to § 420.111(a) described above and a reference to 49 CFR 19.25 would be added to indicate where the provisions for changes can be found when the subrecipient is a non-profit organization or institution of higher education.

Section 420.117 What Are the Program Monitoring and Reporting Requirements?

In order to indicate where the provisions for reporting can be found when the subrecipient is a non-profit organization or institution of higher education, we propose to add a reference to 49 CFR 19.14 to paragraph (c).

Paragraph (e), which requires preparation of reports to document work performed with FHWA planning and research funds, would be revised to remove the reference to the Federal-aid project agreement since this report requirement is no longer in the agreement.

Section 420.119 What Are the Fiscal Requirements?

We propose to delete existing paragraphs (a) and (b) because they include internal FHWA fiscal procedures that do not apply to grantees.

Existing paragraph (d) would be split into a new paragraph (a) and revised paragraph (d) and revised for clarity. Existing paragraph (e), which includes a reference to matching provisions in 49 CFR 18.24 would be moved to new paragraph (a) and a citation to the matching provision for non-profits and institutions of higher education in 49 CFR 19.23 would be added.

We propose to add a new paragraph (b) to incorporate the requirements in 49 CFR 18.24 and 49 CFR 19.23 that apply to use of the value of in kind services as a match for FHWA planning and research funds.

A new paragraph (c) would be added to address additional options, such as toll credits, for matching FHWA planning and research funds.

In revised paragraph (d) we propose to more clearly indicate the applicability and procedures for FHWA waiver of the non-Federal fund matching requirements for SPR and PL funds. This provision does not apply to other 23 U.S.C funds that may be used for planning and research. The reference to 23 U.S.C. 307(c)(3) would be updated to 23 U.S.C. 505(c). Minimum Guarantee (MG) funds would be added to the list of funds that this provision does not apply to. The titles of the FHWA officials who may approve the matching fund waiver would be updated to reflect the previously mentioned FHWA reorganization.

Existing paragraph (c) would become (e) and would be revised for clarity by replacing the term ''optional'' with the specific categories of funds, by removing the reference to minimum allocation funds because they no longer exist, and by adding MG funds. The reference to 23 CFR part 450 would be replaced with the specific transportation improvement program provisions in part 450.

We propose to revise existing paragraph (f) by adding a reference to the payment provisions for non-profits and institutions of higher education in 49 CFR 19.22.

Section 420.121 What Other Requirements Apply to the Administration of FHWA Planning and Research Funds?

For ease of finding specific requirements, we propose to put the provisions in existing § 420.121 into alphabetical order by subject.

Existing paragraph (c) on audits would become paragraph (a) and would be revised by deleting the reference to

49 CFR part 90 because this part has been rescinded.

Existing paragraph (g) on procurement would become paragraph (j) and would be revised by adding ''and (i)'' after ''49 CFR 18.36(a)'' to clarify that the provisions in 49 CFR 18.36(i) are applicable to STD procurements with FHWA planning and research funds. We further propose to move the provisions regarding suspension and debarment to a new paragraph (o) that would more clearly indicate the restrictions on awards of Federal funds to suspended or debarred parties.

Existing paragraph (n) would become paragraph (c) and would be revised to reference the most recent disadvantaged business enterprise legislative and regulatory provisions that are applicable to FHWA planning and research funds.

We propose to delete paragraph (p) because it specified that reports produced with FHWA planning and research funds were to be in metric and we believe that is unnecessary.

Section 420.201 What Is the Purpose of This Subpart?

We propose to rewrite this section for clarity.

Section 420.203 How Does the FHWA Define the Terms Used in This Subpart?

The FHWA proposes to amend this section in the following manner:

The terms ''applied research,'' ''basic research,'' and ''development'' would be revised to be more consistent with definitions used by the National Science Foundation.

The term ''cooperatively funded study'' would be removed since it would not be used in the revised regulation.

The term ''peer review'' would be replaced with ''peer exchange'' to describe the transfer of RD&T related information and best practices between STDs, the FHWA, universities and public and private sector transportation organizations.

The term ''RD&T activity'' would be revised for clarity.

The term ''research'' would be removed to avoid redundancy in light of the definitions for applied research and basic research.

The Term ''Transportation Research Information Service'' would be revised to reflect the partnership between the Transportation Research Board and the National Transportation Library.

Section 420.205 What Is the FHWA's Policy for Research, Development, and Technology Transfer Funding?

In paragraph (b) peer review would be replaced with peer exchange.

New language would be added to paragraph (c) to encourage STDs to include technology transfer programs to share the results of research efforts and promote the use of new technology. The second sentence in paragraph (c) would become new paragraph (d) and language would be added to new paragraph (d) encouraging STDs to pool their funds as a means to leverage resources.

Existing paragraphs (d) through (g) would be renumbered (e) through (h), respectively, and the reference to the FHWA Regional offices in existing paragraph (g) would be amended to Resource Center.

Section 420.207 What Are the Requirements for Research, Development, and Technology Transfer Work Programs?

We propose to redesignate existing § 420.209 as § 420.207 and in this section we propose to replace ''national'' and ''regional'' with ''transportation'' in reference to pooled fund studies in paragraph (a). Language would be added to indicate that a previously funded study needs to be included in the work program until the final report for the study is completed.

In addition, we propose adding language to paragraph (a) that would require that studies funded under previous work programs be shown in subsequent work programs until a final report has been completed for the studies. This provision will enable the FHWA to track work performed under previous grants so that closing of those grants can proceed in a timely manner.

Section 420.209 What Are the Conditions for Approval?

Because of the overlap or redundancy among the provisions in existing §§ 420.207, 420.211, and 420.213, we are proposing to combine and revise these three sections into new § 420.209. The following changes are proposed:

''National'' and ''regional'' would be replaced with ''transportation'' in reference to pooled fund studies in paragraph (a)(2).

The reference to ''peer reviews'' in paragraph (a)(5) would be changed to ''peer exchanges.''

Former paragraph (c) would be revised for clarity and redesignated as paragraph (a)(7).

Former paragraph (c) would be redesignated as paragraph (b) and the reference to ''peer reviews'' would be changed to ''peer exchanges.''

Former paragraph (b) would be redesignated (c) and reworded for clarity. The provisions regarding the FHWA selection of reviewers would be removed.

Former § 420.113, Certification requirements, would be rewritten to remove outdated material and consolidated in new paragraph 420.209 (c). The STDs would still need to certify that it is in compliance with the requirements of 23 CFR part 420, subpart B.

Former § 420.115, Procedure for withdrawal of approval, would be rewritten to remove outdated material and consolidated in new § 420.209 (c).

Distribution Table

For ease of reference, a distribution table is provided for the current sections and the proposed sections as follows:

DISTRIBUTION TABLE

Old section	New section
420.101	420.101 Revised.
420.103	420.103 Revised.
FHWA planning and research funds	Revised.
Grant agreement	Revised.
Metropolitan planning area	Revised.
Metropolitan planning organization	Unchanged.
National Cooperative Highway Research Program (NCHRP)	Added.
National pooled-fund study	Removed.
Procurement contract	Revised.
Regional pooled-fund study	Removed.
State transportation agency	Removed.
Transportation management area	Added.
Transportation pooled-fund study	Added.

DISTRIBUTION TABLE—Continued

Old section	New section
Work program	Revised.
420.105(a) Introductory Paragraph	420.105(a) Introductory Paragraph Revised.
420.105(a)(1)	420.105(a)(1) Revised.
420.105(a)(2)	420.105(a)(2) Unchanged.
420.105(b)	420.105(b) Revised.
None	420.105(c) Added.
420.107(a)	420.107(a) Revised.
420.107(b)	420.107(b) Revised.
420.107(c)(1) through (3)	420.107(c)(1) through (3) Revised.
420.107(c)(4)	Removed.
420.107(c)(5)	420.107(c)(4) Revised.
420.107(c)(6)	420.107(c)(5) Revised.
420.107(d)	420.107(d) Revised.
420.109	420.109 Revised.
420.111(a)	420.111(a) Revised.
420.111(b) 1st Sentence	420.111(b)(1) Revised.
420.111(b) 2d Sentence	420.111(b)(2) Revised.
420.111(c)(1) through (4)	420.111(b)(1)(i) through (iv).
None	420.111(c) Added.
420.111(c) introductory paragraph	420.111(d) Revised.
420.111(d)	420.111(e) Revised.
420.113(a)(1)	420.113(a)(1) Unchanged.
420.113(a)(2)	420.113(a)(2) Revised.
420.113(a)(3) to (a)(5)	420.113(a)(3) to (a)(5) Unchanged.
420.113(b)	420.113(b) Revised.
420.113(c)	420.113(b) Revised.
420.113(d)	420.113(b) Revised.
420.115(a)	420.115(a) Revised.
420.115(b)	420.115(b) Revised.
420.115(c)	420.115(c) Revised.
420.117(a)	420.117(a) Revised.
420.117(b)(1)	420.117(b)(1) Revised.
420.117(b)(2)	420.117(b)(2) Unchanged.
420.117(c)	420.117(c) Revised.
420.117(d)	420.117(d) Revised.
420.117(e)	420.117(e) Revised.
420.119(a)	Removed.
420.119(b)	Removed.
420.119(c)	420.119(d) Revised.
None	420.119(c).
420.119(d), 1st Sentence	420.119(a) Revised.
420.119(d), 2nd and 3rd Sentences	420.119(b) Revised.
420.119(e)	420.119(a) Revised.
420.119(f)	420.119(f) Revised.
420.121(a)	420.121(f) Revised.
420.121(b)	420.121(k) Revised.
420.121(c)	420.121(a) Revised.
420.121(d)	420.121(e) Revised.
420.121(e)	420.121(p) Revised.
420.121(f)	420.121(b) Revised.
420.121(g), 1st Sentence	420.121(j) Revised.
420.121(g), 2nd Sentence	420.121(o) Revised.
420.121(h)	420.121(m) Revised.
420.121(i)	420.121(l) Revised.
420.121(j)	420.121(i) Revised.
420.121(k)	420.121(d) Revised.
420.121(l)	420.121(g) Revised.
420.121(m)	420.121(h) Revised.
420.121(n)	420.121(c) Revised.
420.121(o)	420.121(n) Revised.
420.121(p)	Removed.
420.201	420.201 Revised.
420.203	420.203 Revised.
Applied research	Revised.
Basic research	Revised.
Cooperatively funded study	Removed.
Development	Revised.
Final report	Unchanged.
Intermodal RD&T	Unchanged.
National Cooperative Highway Research Program (NCHRP)	420.103 Revised.
Peer review	Peer exchange. Revised.
RD&T activity	Revised.

DISTRIBUTION TABLE—Continued

Old section	New section
Research	Revised.
Technology transfer	Unchanged.
Transportation Research Information Services (TRIS)	Revised.
420.205(a)	420.205(a).
420.205(b)	420.205(b) Revised.
420.205(c)	420.205(c) Revised.
420.205(c), 2nd Sentence	420.205(d) Revised.
420.205 (d) through (g)	420.205(e) through (h) Revised.
420.207(a)	420.209(a) Revised.
420.207(a)(1)	420.209(a)(1) Revised.
420.207(a)(2)	420.209(a)(2) Revised.
420.207(a)(3)–(4)	420.209(a)(3)–(4).
420.207(a)(5)	420.209(a)(5) Revised.
420.207(a)(6)	420.209(a)(6).
420.207(b)	420.209(a)(7) Revised.
420.207(c)	420.209(b) Revised.
420.209(a)–(c)	420.207(a)–(c) Revised.
420.211	Removed.
420.213(a)–(c)	420.209(c) Revised.
420.215(a)–(d)	420.209(d) Revised.

Rulemaking Analyses and Notices

All comments received before the close of business on the comment closing date indicated above will be considered and will be available for examination in the docket at the above address. Comments received after the comment closing date will be filed in the docket and will be considered to the extent practicable. In addition to late comments, the FHWA will also continue to file relevant information in the docket as it becomes available after the comment period closing date, and interested persons should continue to examine the docket for new material. A final rule may be published at any time after close of the comment period.

Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures

The FHWA has determined that this action would not be a significant regulatory action within the meaning of Executive Order 12866 and would not be significant within the meaning of U.S. Department of Transportation regulatory policies and procedures. It is anticipated that the economic impact of this rulemaking would be minimal. The proposed changes would update the existing rule to conform to changes included in the TEA–21 and amend the current rule to make it clearer and easier to understand. These proposed changes would not adversely affect, in a material way, any sector of the economy. In addition, these changes would not interfere with any action taken or planned by another agency and would not materially alter the budgetary impact of any entitlements, grants, user fees, or loan programs. Consequently, a full regulatory evaluation is not required.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601–612) the FHWA has evaluated the effects of this proposed action on small entities. This rule addresses the administrative procedures and requirements that STDs must comply with when using FHWA planning and research funds provided under title 23, U.S.C. This rule would not impose any direct requirement on small entities that would result in increased economic costs. The proposed changes would update the existing rule to conform to provisions in the TEA–21 and make it clearer and easier to understand. Based on this evaluation, the FHWA certifies that this rule would not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This proposed rule would not impose unfunded mandates as defined by the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, March 22, 1995, 109 Stat. 48). This proposed rule would not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year (2 U.S.C. 1532). The proposed changes will update the existing rule to conform to provisions in the TEA–21 and make it clearer and easier to understand. The costs of compliance with the provisions of this rule are minor and are eligible for Federal funding.

Executive Order 13132 (Federalism Assessment)

This proposed action has been analyzed in accordance with the principles and criteria contained in Executive Order 13132, and the FHWA has determined that this action would not have sufficient Federalism implications to warrant the preparation of a Federalism assessment. The FHWA has also determined that this proposed action would not preempt any State law or State regulation or affect the States' ability to discharge traditional State governmental functions. The rule provides STDs the authority and flexibility to manage their federally assisted State planning and research programs using their own procedures to the extent permitted under the principles and criteria contained in OMB Circular A–102, Grants and Cooperative Agreements with State and Local Governments. Accordingly, the FHWA certifies that this rule does not have sufficient Federalism implications to warrant the preparation of a full Federalism Assessment under the principles and criteria contained in Executive Order 13132.

Executive Order 12372 (Intergovernmental Review)

Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to FHWA planning and research fund grants. Accordingly, the FHWA solicits comments on this issue.

Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501, *et seq.*), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct, sponsor, or require through regulations. Although 23 CFR part 420 also includes administrative requirements and procedures for funds provided for Metropolitan Planning Organizations (MPOs) to carry out the requirements of 23 U.S.C. 134, the FHWA clearance only covers transportation planning and research, development and technology (RD&T) work performed by State Departments of Transportation (State DOTs) with funds provided under the provisions of 23 U.S.C. 505 or, at a State DOT's option, other 23 U.S.C. sections as identified in the definition of FHWA planning and research funds in 23 CFR 420.103. The FHWA has determined that this proposal contains collection of information requirements for the purposes of the PRA. The information collection requirements referenced in § 420.105(b) have been approved by the OMB and have been assigned OMB control numbers 2125–0028 (expiration date, February 28, 2003) and 2125–0032 (expiration date, March 31, 2003). The information collection requirements in §§ 420.111, 420.117, and 420.213 for State planning and RD&T activities have been have been approved by the OMB and assigned control number 2125–0039 (expiration date, April 30, 2004). The information collection requirements in §§ 420.111, and 420.117 for work performed by the MPOs is a joint FHWA/FTA requirement that is covered under the FTA OMB Control Number 2132–0529 (expiration date, March 31, 2004). The information collection requirements in § 420.115, Preparation and Execution of the Project Agreement and Modifications, for project agreements has been approved by the OMB and have been assigned OMB control number 2125–0529 (expiration date June 30, 2204).

Executive Order 12630 (Taking of Private Property)

This proposed rule would not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Executive Order 12988 (Civil Justice Reform)

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

Executive Order 13045 (Protection of Children)

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

Executive Order 13175 (Tribal Consultation)

The FHWA has analyzed this proposal under Executive Order 13175, dated November 6, 2000, and believes that the proposed action will not have substantial direct effects on one or more Indian tribes; will not impose substantial direct compliance costs on Indian tribal governments; and will not preempt tribal law. Therefore, a tribal summary impact statement is not required.

Executive Order 13211 (Energy Effects)

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a significant energy action under that order because it is not a significant regulatory action under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution or use of energy. Therefore, a Statement of Energy Effects under Executive Order 13211 is not required.

National Environmental Policy Act

The agency has analyzed this proposed action for the purpose of the National Environmental Policy Act of 1969 (42 U.S.C. 4321) and has determined that this proposed action would not have any effect on the quality of the environment.

Regulation Identification Number

A regulation identification number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross reference this action with the Unified Agenda.

List of Subjects in 23 CFR Part 420

Accounting, Grant programs—transportation, Highways and roads, Planning, Reporting and recordkeeping requirements, Research.

Issued on: November 19, 2001

Mary E. Peters,

Federal Highway Administrator.

In consideration of the foregoing, the FHWA proposes to amend, title 23, Code of Federal Regulations by revising, part 420 to read as set forth below:

PART 420—PLANNING AND RESEARCH PROGRAM ADMINISTRATION

Subpart A—Administration of FHWA Planning and Research Funds

Sec.
420.101 What is the purpose of this part?
420.103 How does the FHWA define the terms used in this part?
420.105 What is the FHWA's policy on use of FHWA planning and research funds?
420.107 What is the minimum required expenditure of State planning and research funds for research development and technology transfer?
420.109 What are the requirements for distribution of metropolitan planning funds?
420.111 What are the documentation requirements for use of FHWA planning and research funds?
420.113 What costs are eligible?
420.115 What are the FHWA approval and authorization requirements?
420.117 What are the program monitoring and reporting requirements?
420.119 What are the fiscal requirements?
420.121 What other requirements apply to the administration of FHWA planning and research funds?

Subpart B—Research, Development, and Technology Transfer Program Management

Sec.
420.201 What is the purpose of this subpart?
420.203 How does the FHWA define the terms used in this subpart?
420.205 What is FHWA's for policy research development and technology transfer funding?
420.207 What are the requirements for research, development, and technology transfer work programs?
420.209 What are the conditions for approval?

Authority: 23 U.S.C. 103(b)(6), 104(f), 115, 120, 133(b), 134(n), 303(g), 505, and 315; and 49 CFR 1.48(b).

Subpart A—Administration of FHWA Planning and Research Funds

§ 420.101 What is the purpose of this part?

This part prescribes the Federal Highway Administration (FHWA) policies and procedures for the administration of activities undertaken

by State transportation departments (STDs) and their subrecipients, including metropolitan planning organizations (MPOs), with FHWA planning and research funds. This subpart A identifies the administrative requirements that apply to use of FHWA planning and research funds both for planning and for research, development, and technology transfer (RD&T) activities. Subpart B of this part describes the policies and procedures that relate to the approval and authorization of RD&T work programs. The requirements in this part supplement those in 49 CFR part 18, Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments and 49 CFR part 19, Uniform Administrative Requirements for Grants and Cooperative Agreements with Institutions of Higher Education, Hospitals and Other Non-Profit Organizations.

§ 420.103 How does FHWA define the terms used in this part?

Unless otherwise specified in this part, the definitions in 23 U.S.C. 101(a) are applicable to this part. As used in this part:

FHWA planning and research funds include:

(1) State planning and research (SPR) funds (the two percent set aside of funds apportioned or allocated to a STD for activities authorized under 23 U.S.C. 505);

(2) Metropolitan planning (PL) funds (the one percent of funds authorized under 23 U.S.C. 104(f) to carry out the provisions of 23 U.S.C. 134);

(3) National highway system (NHS) funds authorized under 23 U.S.C. 104(b)(1) used for transportation planning in accordance with 23 U.S.C. 134 and 135, highway research and planning in accordance with 23 U.S.C. 505, highway-related technology transfer activities, or development and establishment of management systems under 23 U.S.C. 303;

(4) Surface transportation program (STP) funds authorized under 23 U.S.C. 104(b)(3) used for highway and transit research and development and technology transfer programs, surface transportation planning programs, or development and establishment of management systems under 23 U.S.C. 303; and

(5) Minimum guarantee (MG) funds authorized under 23 U.S.C. 505 used for transportation planning and research, development and technology transfer activities that are eligible under title 23, U.S.C.

Grant agreement means a legal instrument reflecting a relationship between an awarding agency and a recipient or subrecipient when the principal purpose of the relationship is to transfer a thing of value to the recipient or subrecipient to carry out a public purpose of support or stimulation authorized by a law instead of acquiring (by purchase, lease, or barter) property or services for the direct benefit or use of the awarding agency.

Metropolitan planning area means the geographic area in which the metropolitan transportation planning process required by 23 U.S.C. 134 and 49 U.S.C. 5303–5305 must be carried out.

Metropolitan planning organization (MPO) means the forum for cooperative transportation decisionmaking for a metropolitan planning area.

National Cooperative Highway Research Program (NCHRP) means the cooperative RD&T program directed toward solving problems of national or regional significance identified by STDs and the FHWA, and administered by the Transportation Research Board, National Academy of Sciences.

Procurement contract means a legal instrument reflecting a relationship between an awarding agency and a recipient or subrecipient when the principal purpose of the instrument is to acquire (by purchase, lease, or barter) property or services for the direct benefit or use of the awarding agency.

Transportation management area (TMA) means an urbanized area with a population over 200,000 (as determined by the latest decennial census) or other area when TMA designation is requested by the Governor and the MPO (or affected local officials), and officially designated by the Administrators of the FHWA and the Federal Transit Administration (FTA).

Transportation pooled fund study means a planning, research, development, or technology transfer activity administered by the FHWA, a lead STD, or other organization that is supported by two or more participants and that addresses an issue of significant or widespread interest related to highway, public, or intermodal transportation. A transportation pooled fund study is intended to address a new area or provide information that will complement or advance previous investigations of the subject matter.

Work program means a periodic statement of proposed work and estimated costs that document eligible activities to be undertaken by STDs and/or their subrecipients with FHWA planning and research funds.

§ 420.105 What is the FHWA's policy on use of FHWA planning and research funds?

(a) If the FHWA determines that planning activities of national significance, identified in paragraph (b) of this section, and the requirements of 23 U.S.C. 134, 135, 303, and 505 are being adequately addressed, the FHWA will allow STDs and MPOs:

(1) Maximum possible flexibility in the use of FHWA planning and research funds to meet highway and intermodal transportation planning and RD&T needs at the national, State, and local levels while ensuring legal use of such funds and avoiding unnecessary duplication of efforts; and

(2) To determine which eligible planning and RD&T activities they desire to support with FHWA planning and research funds and at what funding level.

(b) The STDs must provide data that support the FHWA's responsibilities to the Congress and to the public. These data include, but are not limited to, information required for: preparing proposed legislation and reports to the Congress; evaluating the extent, performance, condition, and use of the Nation's transportation systems; analyzing existing and proposed Federal-aid funding methods and levels and the assignment of user cost responsibility; maintaining a critical information base on fuel availability, use, and revenues generated; and calculating apportionment factors.

(c) The policy in paragraph (a) of this section does not remove the FHWA's responsibility and authority to determine which activities are eligible for funding. Activities proposed to be funded with FHWA planning and research funds by the STDs and their subrecipients shall be documented and submitted for FHWA approval and authorization as prescribed in §§ 420.111 and 420.113.

(The information collection requirements in paragraph (b) of § 420.105 have been approved by the Office of Management and Budget (OMB) under control numbers 2125–0028 and 2125–0032.)

§ 420.107 What is the minimum required expenditure of State planning and research funds for research development and technology transfer?

(a) An STD must expend no less than 25 percent of its annual SPR funds on RD&T activities relating to highway, public transportation, and intermodal transportation systems in accordance with the provisions of 23 U.S.C. 505(b), unless a STD certifies, and the FHWA accepts the STD's certification, that total expenditures by the STD during the

fiscal year for transportation planning under 23 U.S.C. 134 and 135 will exceed 75 percent of the amount apportioned for the fiscal year.

(b) Prior to submitting a request for an exception to the 25 percent requirement, the STD must ensure that:

(1) The additional planning activities are essential, and there are no other reasonable options available for funding these planning activities (including the use of NHS, STP, MG, or FTA State planning and research funds (49 U.S.C. 5313(b)) or by deferment of lower priority planning activities);

(2) The planning activities have a higher priority than RD&T activities in the overall needs of the STD for a given fiscal year; and

(3) The total level of effort by the STD in RD&T (using both Federal and State funds) is adequate.

(c) If the STD chooses to pursue an exception, it must send the request, along with supporting justification, to the FHWA Division Administrator for action by the FHWA Director of Research, Development, and Technology. The Director's decision will be based upon the following considerations:

(1) Whether the STD has a process for identifying RD&T needs and for implementing a viable RD&T program.

(2) Whether the STD is contributing to cooperative RD&T programs or activities, such as the National Cooperative Highway Research Program, the Transportation Research Board, and transportation pooled fund studies.

(3) Whether the STD is using SPR funds for technology transfer and for transit or intermodal research and development to help meet the 25 percent minimum requirement.

(4) Whether the STD can demonstrate that it will meet the requirement or substantially increase its RD&T expenditures over a multi-year period, if an exception is granted for the fiscal year.

(5) Whether Federal funds needed for planning exceed the 75 percent limit for the fiscal year and whether any unused planning funds are available from previous fiscal years.

(d) If the FHWA Director of Research, Development and Technology approves the STD's request for an exception, the exception is valid only for that fiscal year's funds. A new request must be submitted and approved for subsequent fiscal year funds.

§ 420.109 What are the requirements for distribution of metropolitan planning funds?

(a) The STDs shall make all PL funds authorized by 23 U.S.C. 104(f) available to the MPOs in accordance with a formula developed by the STD, in consultation with the MPOs, and approved by the FHWA Division Administrator. The formula may allow for a portion of the PL funds to be used by the STD, or other agency agreed to by the STD and the MPOs, for activities that benefit all MPOs in the State, but STDs shall not use any PL funds for grant or subgrant administration. The formula may also provide for a portion of the funds to be made available for discretionary grants to MPOs to supplement their annual amount received under the distribution formula.

(b) In developing the formula for distributing PL funds, the STD shall consider population, status of planning, attainment of air quality standards, metropolitan area transportation needs, and other factors necessary to provide for an appropriate distribution of funds to carry out the requirements of 23 U.S.C. 134 and other applicable requirements of Federal law.

(c) The STDs shall inform the MPOs and the FHWA Division Office of the amounts allocated to each MPO as soon as possible after PL funds have been apportioned by the FHWA to the STDs.

(d) If the STD, in a State receiving the minimum apportionment of PL funds under the provisions of 23 U.S.C. 104(f)(2), determines that the share of funds to be allocated to any MPO results in the MPO receiving more funds than necessary to carry out the provisions of 23 U.S.C. 134, the STD may, after considering the views of the affected MPO(s) and with the approval of the FHWA Division Administrator, use those funds for transportation planning outside of metropolitan planning areas.

(e) In accordance with the provisions of 23 U.S.C. 134(n), any PL funds not needed for carrying out the metropolitan planning provisions of 23 U.S.C. 134 in any State may be made available by the MPO(s) to the STD for funding statewide planning activities under 23 U.S.C. 135, subject to approval by the FHWA Division Administrator.

(f) Any State PL fund distribution formula that does not meet the requirements of paragraphs (a) and (b) of this section shall be brought into conformance with those requirements before distribution on any new apportionment of PL funds.

§ 420.111 What are the documentation requirements for use of FHWA planning and research funds?

(a) Proposed use of FHWA planning and research funds must be documented by the STDs and subrecipients in a work program, or other document that describes the work to be accomplished, that is acceptable to the FHWA Division Administrator. Statewide, metropolitan, other transportation planning activities, and transportation RD&T activities may be documented in separate programs, paired in various combinations, or brought together as a single work program. The expenditure of PL funds for transportation planning outside of metropolitan planning areas under § 420.109(d) may be included in the work program for statewide transportation planning activities or in a separate work program submitted by the STD.

(b)(1) A work program(s) for transportation planning activities must include a description of work to be accomplished and cost estimates by activity or task. In addition, each work program must include a summary that shows:

(i) Federal share by type of fund;

(ii) Matching rate by type of fund;

(iii) State and/or local matching share; and

(iv) Other State or local funds.

(2) Additional information on metropolitan planning area work programs is contained in 23 CFR part 450. Additional information on RD&T work program content and format is contained in subpart B of this part.

(c) In areas not designated as TMAs, a simplified statement of work that describes who will perform the work and the work that will be accomplished using Federal funds may be used in lieu of a work program. If a simplified statement of work is used, it may be submitted separately or as part of the Statewide planning work program.

(d) The STDs that use separate Federal-aid projects in accordance with § 420.111(a) must submit an overall summary that identifies the amounts and sources of FHWA planning and research funds available, matching funds, and the amounts budgeted for each activity (e.g., statewide planning, RD&T, each metropolitan area, contributions to NCHRP and transportation pooled fund studies, etc.).

(e) The STDs and MPOs also are encouraged to include cost estimates for transportation planning, research, development, and technology transfer related activities funded with other Federal or State and/or local funds; particularly for producing the FHWA-required data specified in paragraph (b) of § 420.105, for planning for other transportation modes, and for air quality planning activities in areas designated as non-attainment for transportation-related pollutants in their work programs. The MPOs in TMAs must

include such information in their work programs.

(The information collection requirements in §§ 420.111 have been approved by the OMB and assigned control numbers 2125–0039 for States and 2132–0529 for MPOs.)

§ 420.113 What costs are eligible?

(a) Costs will be eligible for FHWA participation provided that the costs:

(1) Are for work performed for activities eligible under the section of title 23, U.S.C., applicable to the class of funds used for the activities;

(2) Are verifiable from the STD's or the subrecipient's records;

(3) Are necessary and reasonable for proper and efficient accomplishment of project objectives and meet the other criteria for allowable costs in the applicable cost principles cited in 49 CFR 18.22;

(4) Are included in the approved budget, or amendment thereto; and

(5) Were not incurred prior to FHWA authorization.

(b) Indirect costs of STDs and their subrecipients are allowable if supported by a cost allocation plan and indirect cost proposal prepared, submitted (if required), and approved by the cognizant or oversight agency in accordance with the OMB requirements applicable to the STD or subrecipient specified in 49 CFR 18.22(b).

§ 420.115 What are the FHWA approval and authorization requirements?

(a) The STD and its subrecipients must obtain approval and authorization to proceed prior to beginning work on activities to be undertaken with FHWA planning and research funds. Such approvals and authorizations should be based on final work programs or other documents that describe the work to be performed. The STD and its subrecipients also must obtain prior approval for budget and programmatic changes as specified in 49 CFR 18.30 or 49 CFR 19.25 and for those items of allowable costs which require approval in accordance with the cost principles specified in 49 CFR 18.22(b) applicable to the entity expending the funds.

(b) Authorization to proceed with the FHWA funded work in whole or in part is a contractual obligation of the Federal Government pursuant to 23 U.S.C. 106 and requires that appropriate funds be available for the full Federal share of the cost of work authorized. Those STDs that do not have sufficient FHWA planning and research funds or obligation authority available to obligate the full Federal share of a work program or project may utilize the advance construction provisions of 23 U.S.C. 115(a) in accordance with the requirements of 23 CFR Part 630, subpart G. The STDs that do not meet the advance construction provisions, or do not wish to utilize them, may request authorization to proceed with that portion of the work for which FHWA planning and research funds are available. In the latter case, authorization to proceed may be given for either selected work activities or for a portion of the program period, but such authorization does not constitute a commitment by the FHWA to fund the remaining portion of the work if additional funds do become available.

(c) A project agreement must be executed by the STD and the FHWA Division Office for each statewide transportation planning, metropolitan planning area, or RD&T work program, individual activity or study, or any combination administered as a single Federal-aid project. The project agreement may be executed concurrent with or after authorization has been given by the FHWA Division Administrator to proceed with the work in whole or in part. In the event that the project agreement is executed for only part of the work, the project agreement must be amended when authorization is given to proceed with additional work.

(The information collection requirements in §§ 420.115(c) have been approved by the OMB and assigned control numbers 2125–0529.)

§ 420.117 What are the program monitoring and reporting requirements?

(a) In accordance with 49 CFR 18.40, the STD shall monitor all activities performed by its staff or by subrecipients with FHWA planning and research funds to assure that the work is being managed and performed satisfactorily and that time schedules are being met.

(b)(1) The STD must submit performance and expenditure reports, including a report from each subrecipient, that contain as a minimum:

(i) Comparison of actual performance with established goals;

(ii) Progress in meeting schedules;

(iii) Status of expenditures in a format compatible with the work program, including a comparison of budgeted (approved) amounts and actual costs incurred;

(iv) Cost overruns or underruns;

(v) Approved work program revisions; and

(vi) Other pertinent supporting data.

(2) Additional information on reporting requirements for individual RD&T studies is contained in subpart B of this part.

(c) Reports required by paragraph (b) of this section shall be annual unless more frequent reporting is determined to be necessary by the FHWA Division Administrator. The FHWA may not require more frequent than quarterly reporting unless the criteria in 49 CFR 18.12 or 49 CFR 19.14 are met. Reports are due 90 days after the end of the reporting period for annual and final reports and no later than 30 days after the end of the reporting period for other reports.

(d) Events that have significant impact on the work must be reported as soon as they become known. The types of events or conditions that require reporting include: problems, delays, or adverse conditions that will materially affect the ability to attain program objectives. This disclosure must be accompanied by a statement of the action taken, or contemplated, and any Federal assistance needed to resolve the situation.

(e) Suitable reports that document the results of activities performed with FHWA planning and research funds must be prepared by the STD or subrecipient and submitted for approval by the FHWA Division Administrator prior to publication. The FHWA Division Administrator may waive this requirement for prior approval. The FHWA's approval of reports constitutes acceptance of such reports as evidence of work performed but does not imply endorsement of a report's findings or recommendations. Reports prepared for FHWA-funded work must include appropriate credit references and disclaimer statements.

(The information collection requirements in §§ 420.117 have been approved by the OMB and assigned control numbers 2125–0039 for States and 2132–0529 for MPOs.)

§ 420.119 What are the fiscal requirements?

(a) The maximum rate of Federal participation for FHWA planning and research funds shall be as prescribed in title 23, U.S.C., for the specific class of funds used (i.e., SPR, PL, NHS, STP, or MG) except is specified in paragraph (d) of this section. The provisions of 49 CFR 18.24 or 49 CFR 19.23 are applicable to any necessary matching of FHWA planning and research funds.

(b) The value of third party in-kind contributions may be accepted as the match for FHWA planning and research funds, in accordance with the provisions of 49 CFR 18.24(a)(2) or 49 CFR 19.23(a) and may be on either a total planning work program basis or for specific line items or projects. The use of third party in-kind contributions

must be identified in the original work program/scope of work and the grant/subgrant agreement, or amendments thereto. The use of third-party in-kind contributions must be approved in advance by the FHWA Division Administrator and may not be made retroactive prior to approval of the work program/scope of work or an amendment thereto. The STD or subrecipient is responsible for ensuring that the following additional criteria are met:

(1) The third party performing the work agrees to allow the value of the work to be used as the match;

(2) The cost of the third party work is not paid for by other Federal funds or used as a match for other federally funded grants/subgrants;

(3) The work performed by the third party is an eligible transportation planning or RD&T related activity that benefits the federally funded work;

(4) The third party costs (i.e., salaries, fringe benefits, etc.) are allowable under the applicable Office of Management and Budget (OMB) cost principles (i.e., OMB Circular A–21, A–87, or A–122).[1]

(5) The third party work is performed during the period to which the matching requirement applies;

(6) The third party in-kind contributions are verifiable from the records of the STD or subrecipient and these records show how the value placed on third party in-kind contributions was derived; and

(7) If the total amount of third party expenditures at the end of the program period is not sufficient to match the total expenditure of Federal funds by the a recipient/subrecipient, the recipient/subrecipient will need to make up any shortfall with its own funds.

(c) In accordance with the provisions of 23 U.S.C. 120(j), toll revenues that are generated and used by public, quasi-public, and private agencies to build, improve, or maintain highways, bridges, or tunnels that serve the public purpose of interstate commerce may be used as a credit for the non-Federal share of an FHWA planning and research funded project.

(d) In accordance with 23 U.S.C. 505(c) or 23 U.S.C. 104(f)(3), the requirement for matching SPR or PL funds may be waived if the FHWA determines the interests of the Federal-aid highway program would be best served. Waiver of the matching requirement is intended to encourage STDs and/or MPOs to pool SPR and/or PL funds to address national or regional high priority planning or RD&T problems that would benefit multiple States and/or MPOs. Requests for waiver of matching requirements must be submitted to the FHWA headquarters office for approval by the Program Manager for Planning and Environment (for planning activities) or the Director of Research, Development, and Technology (for RD&T activities). The matching requirement may not be waived for NHS, STP, or MG funds.

(e) NHS, STP, or MG funds used for eligible planning and RD&T purposes must be identified separately from SPR or PL funds in the work program(s) and must be administered and accounted for separately for fiscal purposes. In accordance with the statewide and metropolitan planning process requirements for fiscally constrained transportation improvement program (TIPs) planning or RD&T activities funded with NHS, STP, or MG funds must be included in the Statewide and/or metropolitan TIP(s) unless the STD and MPO (for a metropolitan area) agree that they may be excluded from the TIP.

(f) Payment shall be made in accordance with the provisions of 49 CFR 18.21 or 49 CFR 19.22.

§ 420.121 What other requirements apply to the administration of planning and research funds?

(a) *Audits.* Audits of the STDs and their subrecipients shall be performed in accordance with OMB Circular A–133, Audits of States, Local Governments, and Non-Profit Organizations.[2] Audits of for-profit contractors are to be performed in accordance with STD or subrecipient contract administration procedures.

(b) *Copyrights.* The STDs and their subrecipients may copyright any books, publications, or other copyrightable materials developed in the course of the FHWA planning and research funded project. The FHWA reserves a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use, and to authorize others to use, the work for Government purposes.

(c) *Disadvantaged business enterprises.* The STDs must administer the transportation planning and RD&T program(s) consistent with their overall efforts to implement section 1001(b) of the Transportation Equity Act for the 21st Century (Pub. L. 105–178) and 49 CFR part 26 regarding disadvantaged business enterprises.

(d) *Drug free workplace.* In accordance with the provisions of 49 CFR part 29, subpart F, STDs must certify to the FHWA that they will provide a drug free workplace. This requirement may be satisfied through the annual certification for the Federal-aid highway program.

(e) *Equipment.* Acquisition, use, and disposition of equipment purchased with FHWA planning and research funds by the STDs must be in accordance with 49 CFR 18.32(b). Local government subrecipients of STDs must follow the procedures specified by the STD. Universities, hospitals, and other non-profit organizations must follow the procedures in 49 CFR 19.34.

(f) *Financial management systems.* The financial management systems of the STDs and their local government subrecipients must be in accordance with the provisions of 49 CFR 18.20(a). The financial management systems of universities, hospitals, and other non-profit organizations must be in accordance with 49 CFR 19.21.

(g) *Lobbying.* The provisions of 49 CFR part 20 regarding restrictions on influencing certain Federal activities are applicable to all tiers of recipients of FHWA planning and research funds.

(h) *Nondiscrimination.* The nondiscrimination provisions of 23 CFR parts 200 and 230 and 49 CFR part 21, with respect to Title VI of the Civil Rights Act of 1964 and the Civil Rights Restoration Act of 1987, apply to all programs and activities of recipients, subrecipients, and contractors receiving FHWA planning and research funds whether or not those programs or activities are federally funded.

(i) *Patents.* The STDs and their subrecipients are subject to the provisions of 37 CFR part 401 governing patents and inventions and must include, the standard patent rights clause at 37 CFR 401.14, except for § 401.14(g), in all subgrants or contracts. In addition, STDs and their subrecipients must include the following clause, suitably modified to identify the parties, in all subgrants or contracts, regardless of tier, for experimental, developmental or research work: ''The subgrantee or contractor will retain all rights provided for the State in this clause, and the State will not, as part of the consideration for awarding the subgrant or contract, obtain rights in the subgrantee's or contractor's subject inventions.''

(j) *Procurement.* Procedures for the procurement of property and services with FHWA planning and research funds by the STDs must be in accordance with 49 CFR 18.36(a) and (i) and, if applicable, 18.36(t). Local government subrecipients of STDs must follow the procedures specified by the STD. Universities, hospitals, and other

[1] OMB Circulars are available on the Internet at *http://www.whitehouse.gov/omb/circulars/index.html.*

[2] See footnote 1.

non-profit organizations must follow the procedures in 49 CFR 19.40 to 19.48. The STDs and their subrecipients must not use FHWA funds for procurements from persons (as defined in 49 CFR 29.105) who have been debarred or suspended in accordance with the provisions of 49 CFR part 29, subparts A through E.

(k) *Program income.* Program income, as defined in 49 CFR 18.25(b) or 49 CFR 19.24, must be shown and deducted from total expenditures to determine the Federal share to be reimbursed, unless the FHWA Division Administrator has given prior approval to use the program income to perform additional eligible work or as the non-Federal match.

(l) *Record retention.* Recordkeeping and retention requirements must be in accordance with 49 CFR 18.42 or 49 CFR 19.53.

(m) *Subgrants to local governments.* The STDs and subrecipients are responsible for administering FHWA planning and research funds passed through to MPOs and local governments, for ensuring that such funds are expended for eligible activities, and for ensuring that the funds are administered in accordance with this part, 49 CFR part 18, Uniform Administrative Requirements for Grants and Agreements to State and Local Governments, and applicable OMB cost principles. The STDs shall follow State laws and procedures when awarding and administering subgrants to MPOs and local governments and must ensure that the requirements of 49 CFR 18.37(a) have been satisfied.

(n) *Subgrants to universities, hospitals, and other non-profit organizations.* The STDs and subrecipients are responsible for ensuring that FHWA planning and research funds passed through to universities, hospitals, and other non-profit organizations are expended for eligible activities and for ensuring that the funds are administered in accordance with this part, 49 CFR part 19, Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations, and applicable OMB cost principles.

(o) *Suspension and debarment.* (1) The STDs and their subrecipients shall not award grants or cooperative agreements to entities who are debarred or suspended, or otherwise excluded from or ineligible for participation in Federal assistance programs under Executive Order 12549; and

(2) The STDs and their subrecipients shall comply with the provisions of 49 CFR part 29, subparts A through E, for procurements from persons (as defined in 49 CFR 29.105) who have been debarred or suspended.

(p) *Supplies.* Acquisition and disposition of supplies acquired by the STDs and their subrecipients with FHWA planning and research funds must be in accordance with 49 CFR 18.33 or 49 CFR 19.35.

Subpart B—Research, Development and Technology Transfer Program Management

§ 420.201 What is the purpose of this subpart?

The purpose of this subpart is to prescribe requirements for research, development, and technology transfer (RD&T) activities, programs, and studies undertaken by State transportation departments (STDs) and their subrecipients with FHWA planning and research funds.

§ 420.203 How does the FHWA define the terms used in this subpart?

Unless otherwise specified in this part, the definitions in 23 U.S.C. 101(a) and subpart A of this part, are applicable to this subpart. As used in this subpart:

Applied research means the study of phenomena to gain knowledge or understanding necessary for determining the means by which a recognized need may be met; the primary purpose of this kind of research is to answer a question or solve a problem.

Basic research means the study of phenomena, and of observable facts, without specific applications towards processes or products in mind; the primary purpose of this kind of research is to increase knowledge.

Development means the systematic use of the knowledge or understanding gained from research, directed toward the production of useful materials, devices, systems or methods, including design and development of prototypes and processes.

Final report means a report documenting a completed RD&T study or activity.

Intermodal RD&T means research, development, and technology transfer activities involving more than one mode of transportation, including transfer facilities between modes.

Peer exchange means a periodic review of an STD's RD&T program, or portion thereof, by representatives of other STD's, for the purpose of exchange of information or best practices. The STD may also invite the participation of the FHWA, and other Federal, State, regional or local transportation agencies, the Transportation Research Board, academic institutions, foundations or private firms that support transportation research, development or technology transfer activities.

RD&T activity means a basic or applied research project or study, development or technology transfer activity.

Research means a systematic study directed toward fuller scientific knowledge or understanding of the subject studied. Research can be basic or applied.

Technology transfer means those activities that lead to the adoption of a new technique or product by users and involves dissemination, demonstration, training, and other activities that lead to eventual innovation.

Transportation Research Information Services (TRIS) means the database produced and maintained by the Transportation Research Board and available online through the National Transportation Library. TRIS includes bibliographic records and abstracts of on-going and completed RD&T activities. TRIS Online also includes links to the full text of public-domain documents.

§ 420.205 What is the FHWA's policy for research, development, and technology transfer funding?

(a) It is the FHWA's policy to administer the RD&T program activities utilizing FHWA planning and research funds consistent with the policy specified in § 420.105 and the following general principles in paragraphs (b) through (g) of this section.

(b) The STDs must provide information necessary for peer exchanges.

(c) The STDs are encouraged to develop, establish, and implement an RD&T program, funded with Federal and STD resources that anticipates and addresses transportation concerns before they become critical problems. Further, the STDs are encouraged to include in this program development and technology transfer programs to share the results of their own research efforts and promote the use of new technology.

(d) To promote effective use of available resources, the STDs are encouraged to cooperate with other STDs, the FHWA, and other appropriate agencies to achieve RD&T objectives established at the national level and to develop a technology transfer program to promote and use those results. This includes contributing to cooperative RD&T programs such as the NCHRP, the TRB, and transportation pooled fund studies as a means of addressing

national and regional issues and as a means of leveraging funds.

(e) The STDs will be allowed the authority and flexibility to manage and direct their RD&T activities as presented in their work programs, and to initiate RD&T activities supported by FHWA planning and research funds, subject to the limitation of Federal funds and to compliance with program conditions set forth in subpart A of this part and § 420.207.

(f) The STDs will have primary responsibility for managing RD&T activities supported with FHWA planning and research funds carried out by other State agencies and organizations and for ensuring that such funds are expended for purposes consistent with this subpart.

(g) Each STD must develop, establish, and implement a management process that ensures effective use of available FHWA planning and research funds for RD&T activities on a statewide basis. Each STD is permitted to tailor its management process to meet State or local needs; however, the process must comply with the minimum requirements and conditions of this subpart.

(h) The STDs are encouraged to make effective use of the FHWA Division, Resource Center, and Headquarters office expertise in developing and carrying out their RD&T activities. Participation of the FHWA on advisory panels and in program exchange meetings is encouraged.

§ 420.207 What are the requirements for research, development, and technology transfer work programs?

(a) The STD's RD&T work program must, as a minimum, consist of a description of RD&T activities to be accomplished during the program period, estimated costs for each eligible activity, and a description of any cooperative activities including the STD's participation in any transportation pooled fund studies and the NCHRP. The STD's work program should include a list of the major items with a cost estimate for each item. The work program should also include any study funded under a previous work program until a final report has been completed for the study.

(b) The STD's RD&T work program must include financial summaries showing the funding levels and share (Federal, State, and other sources) for RD&T activities for the program year. STDs are encouraged to include any activity funded 100 percent with State or other funds for information purposes.

(c) Approval and authorization procedures in § 420.115 are applicable to the STD's RD&T work program.

§ 420.209 What are the conditions for approval?

(a) As a condition for approval of FHWA planning and research funds for RD&T activities, a STD must develop, establish, and implement a management process that identifies and results in implementation of RD&T activities expected to address high priority transportation issues. The management process must include:

(1) An interactive process for identification and prioritization of RD&T activities for inclusion in an RD&T work program;

(2) Use of all FHWA planning and research funds set aside for RD&T activities, either internally or for participation in transportation pooled fund studies or other cooperative RD&T programs, to the maximum extent possible;

(3) Procedures for tracking program activities, schedules, accomplishments, and fiscal commitments;

(4) Support and use of the TRIS database for program development, reporting of active RD&T activities, and input of the final report information;

(5) Procedures to determine the effectiveness of the STD's management process in implementing the RD&T program, to determine the utilization of the STD's RD&T outputs, and to facilitate peer exchanges of its RD&T Program on a periodic basis;

(6) Procedures for documenting RD&T activities through the preparation of final reports. As a minimum, the documentation must include the data collected, analyses performed, conclusions, and recommendations. The STD must actively implement appropriate research findings and should document benefits; and

(7) Participation in peer exchanges of its RD&T management process and of other STDs' programs on a periodic basis. To assist peer exchange teams in conducting an effective exchange, the STD must provide to them the information and documentation required to be collected and maintained under this subpart. Travel and other costs associated with the STD's peer exchange may be identified as a line item in the STD's work program and will be eligible for 100 percent Federal funding. The peer exchange team must prepare a written report of the exchange.

(b) Documentation that describes the STD's management process and the procedures for selecting and implementing RD&T activities must be developed by the STD and submitted to the FHWA Division office for approval. Significant changes in the management process also must be submitted by the STD to the FHWA for approval. The STD must make the documentation available, as necessary, to facilitate peer exchanges.

(c) The STD must include a certification that it is in full compliance with the requirements of this subpart in each RD&T work program. If the STD is unable to certify full compliance, the FHWA Division Administrator may grant conditional approval of the STD's work program. A conditional approval must cite those areas of the STD's management process that are deficient and require that the deficiencies be corrected within 6 months of conditional approval. The certification must consist of a statement signed by the Administrator, or an official designated by the Administrator, of the STD certifying as follows: I (name of certifying official), (position title), of the State (Commonwealth) of_____, do hereby certify that the State (Commonwealth) is in compliance with all requirements of 23 U.S.C. 505 and its implementing regulations with respect to the research, development, and technology transfer program, and contemplate no changes in statutes, regulations, or administrative procedures which would affect such compliance.

(d) The FHWA Division Administrator shall periodically review the STD's management process to determine if the State is in compliance with the requirements of this subpart. If the Division Administrator determines that a STD is not complying with the requirements of this subpart, or is not performing in accordance with its RD&T management process, the FHWA Division Administrator shall issue a written notice of proposed determination of noncompliance to the STD. The notice will set forth the reasons for the proposed determination and inform the STD that it may reply in writing within 30 calendar days from the date of the notice. The STD's reply should address the deficiencies cited in the notice and provide documentation as necessary. If the STD and the Division Administrator cannot resolve the differences set forth in the determination of nonconformity, the STD may appeal to the Federal Highway Administrator whose action shall constitute the final decision of the FHWA. An adverse decision shall result in immediate withdrawal of approval of FHWA planning and research funds for

the STD's RD&T activities until the STD is in full compliance.

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 913

[SPATS No. IL–101–FOR]

Illinois Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) is announcing receipt of a proposed amendment to the Illinois regulatory program (Illinois program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). The Illinois Department of Natural Resources, Office of Mines and Minerals (Illinois or Department) proposes revisions to and additions of regulations concerning regulatory coordination with requirements under other laws, permit processing requirements, permit fees, right of entry, performance bonds, revegetation timing, standards for measuring revegetation success of herbaceous wildlife, affected acreage, use of explosives, high capability lands, suspension or revocation of permits, and public and administrative hearings. Illinois also proposes to correct or remove outdated references in several regulations. Illinois intends to revise its program to be consistent with the corresponding Federal regulations, to clarify ambiguities, and to improve operational efficiency.

This document gives the times and locations that the Illinois program and the proposed amendment to that program are available for your inspection, the comment period during which you may submit written comments on the amendment, and the procedures that we will follow for the public hearing, if one is requested.

DATES: Written comments must be received by 4 p.m., e.s.t., December 27, 2001. If requested, we will hold a public hearing on the amendment on December 24, 2001. We will accept requests to speak at the hearing until 4 p.m., e.s.t. on December 12, 2001.

ADDRESSES: You should mail or hand deliver written comments and requests to speak at the hearing to Andrew R. Gilmore, Director, Indianapolis Field Office, at the address listed below.

You may review copies of the Illinois program, the amendment, a listing of any scheduled public hearings, and all written comments received in response to this document at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSM's Indianapolis Field Office.

Andrew R. Gilmore, Director, Indianapolis Field Office, Office of Surface Mining, Minton-Capehart Federal Building, 575 North Pennsylvania Street, Room 301, Indianapolis, IN 46204, Telephone: (317) 226–6700.

Illinois Department of Natural Resources, Office of Mines and Minerals, Land Reclamation Division, 300 W. Jefferson Street, Suite 300, Springfield, IL 62701, Telephone (217) 782–4970.

FOR FURTHER INFORMATION CONTACT: Andrew R. Gilmore, Director, Indianapolis Field Office. Telephone: (317) 226–6700. Internet: IFOMAIL@osmre.gov.

SUPPLEMENTARY INFORMATION:

I. Background on the Illinois Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its program includes, among other things, ''* * * a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of this Act * * *; and rules and regulations consistent with regulations issued by the Secretary pursuant to this Act.'' *See* 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Illinois program on June 1, 1982. You can find background information on the Illinois program, including the Secretary's findings, the disposition of comments, and the conditions of approval in the June 1, 1982, **Federal Register** (47 FR 23883). You can find later actions concerning the Illinois program at 30 CFR 913.15, 913.16, and 913.17.

II. Description of the Proposed Amendment

By letter dated October 15, 2001 (Administrative Record No. IL–5073), Illinois sent us an amendment to its program under SMCRA and the Federal regulations at 30 CFR 732.17(b). Illinois sent the amendment at its own initiative. Illinois proposes to amend its surface coal mining and reclamation regulations at Title 62 of the Illinois Administrative Code (IAC). Below is a summary of the changes proposed by Illinois. The full text of the program amendment is available for your inspection at the locations listed above under **ADDRESSES.**

A. Miscellaneous Revisions

1. Illinois proposes to delete references to the ''interagency committee'' from 62 IAC 1700.11(b), 1773.12, 1780.21(f)(3)(D)(v), 1784.14(e)(3)(C)(v), and 1785.23(d)(4). Illinois is removing these references because the interagency committee was abolished by Illinois Public Act 90–0490 in 1997.

2. Illinois is removing its current office address from and adding a reference to the ''Department's Springfield office'' in 62 IAC 1700.12(a), 1780.21(a), 1784.14(a), 1816.116(a)(2)(C) and (5)(A), 1817.116(a)(2)(C) and (5)(A), and 1846.17(b)(1). Illinois is proposing these revisions so the regulations will not have to be corrected because of future address changes.

3. Illinois is correcting citation references and simplifying its use of numbers in 62 IAC 1700.11, 1700.12, 1773.13, 1777.17, 1780.21, 1785.23, 1825.14, 1843.13, and 1846.17.

B. 62 IAC 1773.12 Regulatory Coordination With Requirements Under Other Laws

Illinois proposes to remove the language from 62 IAC 1773.12 that required the Interagency Committee on Surface Mining Control to review permit applications and provide comments and recommendations for coordination with requirements under other laws. Illinois proposes to add the following provision to address how it currently provides for the coordination of review and issuance of permits with requirements under other laws.

The Department shall, to avoid duplication, provide for the coordination of review and issuance of permits for surface coal mining and reclamation operations with applicable requirements of State laws and regulations and the requirements of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*); the Fish and Wildlife Coordination Act, as amended (16 U.S.C. 661 *et seq.*); the Migratory Bird Treaty Act of 1918, as amended (16 U.S.C. 703 *et seq.*); the National Historic Preservation Act of 1966, as amended (16 U.S.C. 470 *et seq.*); the Bald Eagle Protection Act, as amended (16 U.S.C. 668a); and Executive Order 11593.

C. 62 IAC 1773.13 Public Participation in Permit Processing

1. Illinois is revising 62 IAC 1773.13(a)(1)(B) to require the applicant for a permit or revision application to include a map or description in the newspaper advertisement required under paragraph (1) that clearly shows or describes the precise location and boundaries of the proposed permit area and shadow area for underground mines, if applicable. If the application includes a shadow area, the map or description must differentiate between the permit area and shadow area.

2. Illinois is proposing to revise 62 IAC 1773.13(a)(2) to require the applicant to file an additional copy of any changes to the permit application with the Department. The Department will forward this copy to the clerk at the courthouse of the county where the mining is proposed to occur.

D. 62 IAC 1773.15 Review of Permit Applications

Illinois is revising 62 IAC 1773.15(a)(1) to read as follows:

(1) The Department shall review the application for a permit, revision, or renewal; written comments and objections submitted; and records of any informal conference or hearing held on the application and, either

(A) Issue a written decision, in accordance with Section 1773.19, either granting or denying the application. If a public hearing is held under Section 1773.14, the decision shall be made within 60 days after the close of the public hearing, unless a later time is necessary to provide an opportunity for a hearing under subsection (b)(3) below; or

(B) Issue a written decision requiring modification of the application. If a public hearing is held under Section 1773.14, the decision to require modifications shall be made within 60 days after the close of the public hearing.

(i) If the applicant does not submit the required modifications to the Department within one year of the date of receipt of notification of the need for modifications, the Department shall issue a written finding in accordance with Section 1773.19 denying the application. The Department may issue an extension to this time limit if the applicant can demonstrate just cause for doing so.

(ii) Upon receipt of the applicant's responses to the required modifications, the Department shall review the responses and issue a written decision, in accordance with Section 1773.19, either granting or denying the application.

E. 62 IAC 1777.17 Permit Fees

1. Illinois is redesignating the existing provisions at subsections (a) through (d) as new subsections (b) through (e). Illinois is then adding the following new provision at subsection (a):

(a) After a permit application under 62 Ill. Adm. Code 1772 through 1785 has been deemed approvable, but before a permit is issued in accordance with Section 1773.19, the Department shall notify the applicant in writing of the amount of fee required for the permit.

2. Illinois is proposing to revise the introductory paragraph of newly designated subsection (c) by adding the language ''are payable as a lump sum or in equal annual increments for the permit term and.'' Illinois is removing similar language from subsection (c)(1). As proposed revised subsections (c) and (c)(1) read as follows:

(c) Permit fees are payable as a lump sum or in equal annual increments for the permit term and shall be determined as follows:

(1) The permit fee for areas to be surface mined is $125.00 per bonded acre;

3. Illinois proposes to revise newly designated subsection (e) to read as follows:

(e) Failure to submit permit fees within 1 year after notification of the required fee amount shall result in the application being deemed null and void. The Department may issue an extension to this time limit if the applicant can demonstrate just cause for doing so.

F. 62 IAC 1778.15 Right of Entry Information

Illinois proposes to remove a reference to planned subsidence operations from subsection (e).

G. 62 IAC 1785.23 Minor Underground Mine Facilities Not at or Adjacent to the Processing or Preparation Facility or Area

Illinois proposes to revise 62 IAC 1785.23(d)(4) to read as following:

Other state agencies deemed appropriate by the Department shall be given copies of the application and provided 30 days from the date of receipt to submit comments.

H. 62 IAC 1800.11 Requirement To File a Bond

Illinois is revising 62 IAC 1800.11(a) to require the Department to notify a permit applicant in writing of the amount of bond required to ensure reclamation of the permit area. The permit applicant then has one year to submit a performance bond. The Department will consider the permit application null and void if the applicant does not submit the bond within the time specified. The Department may issue an extension of the time limit if the applicant can demonstrate just cause for doing so.

I. 62 IAC 1800.40 Requirement To Release Performance Bonds

Illinois proposes to revise 62 IAC 1800.40 by reversing the order of the provisions in existing subsections (d) and (e).

1. Redesignated subsection (d) concerns the right that specified persons have to file objections to a proposed bond release. Illinois is revising this subsection by adding language to clarify that these persons also have the right to request a public hearing.

2. Redesignated subsection (e) concerns the right that specified persons have to request a hearing if the Department disapproves an application for release of bond. Illinois is revising this subsection by removing the language that allowed an opportunity for a public hearing and replacing it with the following language that allows an administrative hearing:

The permittee, the surety, and any person with an interest in collateral as provided for in Section 1800.21(e) may request an administrative hearing on the disapproval of bond release by filing a request for hearing in accordance with the procedures set forth in 62 Ill. Adm. Code 1847.3.

J. 62 IAC 1816.113 (Surface Mining) and 62 IAC 1817.113 (Underground Mining) Revegetation Timing

Illinois is adding a new provision at subsection (b) to establish a time frame for the planting of trees and shrubs. Illinois is requiring trees and shrubs to be planted within two years after replacement of the plant-growth medium.

K. 62 IAC 1816.117 (Surface Mining) and 62 IAC 1817.117 (Underground Mining) Revegetation-Tree, Shrub, and Herbaceous Wildlife Vegetation

Illinois proposes to revise 62 IAC 1816.117 and 1817.117 by adding the following standard for measuring revegetation success for areas reclaimed to herbaceous wildlife to new subsection (e):

(e) For areas where herbaceous vegetation plants are used for fish and wildlife habitat (including shelter belts), or recreation land uses, vegetative ground cover of approved species shall not be less than required to achieve the approved post-mining land use and shall be adequate to control erosion and shall not be less than 70% during the last year of the responsibility period. Planting arrangements such as hedgerows, border plantings, clump plantings, shelterbelts, and open herbaceous areas which increase diversity within wildlife areas may be approved by the Department on a case-by-case basis prior to planting such areas.

L. 62 IAC 1816.1907 Affected Acreage Map

Illinois is revising 62 IAC 1816.190(b) to require that areas affected by auger mining must be shown on the annual affected acreage map.

M. 62 IAC 1817.64 Use of Explosives—General Performance Standards

Illinois is revising 62 IAC 1817.64(c) by replacing the existing language with the following language:

(c) All blasting shall be conducted between sunrise and sunset unless nighttime blasting is approved by the Department based upon a showing by the operator that the public will be protected from adverse noise and other impacts. Protection from adverse noise may include alternatives to the audible warning requirement specified in Section 1817.66(b). The Department may specify more restrictive time periods for blasting.

N. 62 IAC 1817.66 Use of Explosives-Blasting Signs, Warnings, and Access Control

Illinois is revising 62 IAC 1817.66(b) by removing the following sentence: ''The requirement to supply daily notice may be fulfilled by the audible warning signals.''

O. 62 IAC 1825.14 High Capability Lands

Illinois is revising 62 IAC 1825.14(e)(2) to require permittees to do soil compaction alleviation on lands reclaimed to high capability standards unless it can be shown that the productivity standards of 62 IAC 1816.116(a)(3)(C) have been, or could be met, without compaction alleviation on areas reclaimed in a similar manner.

P. 62 IAC 1843.13 Suspension or Revocation of Permits

Illinois is revising 62 IAC 1843.13(c) by adding a new paragraph at (c)(3) that requires the Department to notify the surety or other bond holder in writing when it issues a show cause order to the permittee.

Q. 62 IAC 1847.3 Permit and Related Administrative Hearings

Illinois is revising 62 IAC 1847.3(a) to clarify that the procedures outlined in this section apply to, among other things, review of bond release decisions under 62 IAC 1847.9(i). Illinois is also adding the following provision at the end of the paragraph: ''A request for hearing is deemed filed the day it is received by the Department.''

R. 62 IAC 1847.9 Bond Release Public Hearings

Illinois is revising 62 IAC 1847.9 to clearly differentiate between a public hearing and an administrative review hearing for bond release decisions. The Department will use the provisions in this section for public hearings on proposed bond releases.

1. At subsection (b), Illinois added the word ''public'' between the words ''bond release'' and ''hearings.''

2. Illinois removed the provision at existing subsection (c) concerning a pre-hearing conference and redesignated existing subsection (d) as new subsection (c).

3. Illinois removed the provision at existing subsection (e) concerning a settlement agreement and added the following new provision at new subsection (d):

(d) The Department shall appoint a hearing officer to conduct the hearing. The hearing officer shall be a licensed attorney or an employee of the Department. The hearing officer shall conduct a fair hearing and shall take all necessary action to avoid delay, to maintain order, and to develop a clear and complete record. He or she shall have all powers necessary to these ends, including but not limited to the power to change the time and place of the hearing and adjourn the hearing from time to time or from place to place within the county of the surface coal mining and reclamation operation and to give due notice of such action consistent with the notice requirement of subsection (c).

4. Illinois removed the provision at existing subsection (f) concerning a summary disposition and added the following new provision at new subsection (e):

(e) The hearing shall be informal.

(1) All participants in the public hearing shall have the right to be represented by counsel, or by some other authorized representative.

(2) The hearing officer shall allow the applicant and any interested persons to present data, views or arguments relevant to the bond release application.

(3) Where necessary in order to prevent undue prolongation of the hearing, the hearing officer shall establish a time period during which the participants shall be heard. Every effort will be made to allow all persons who wish to make a statement to do so.

(4) A verbatim transcript of the hearing shall be maintained by a court reporter appointed by the Department, and shall constitute a part of the record. Copies of the transcript shall be furnished, at cost, upon request to the court reporter. Such record shall be maintained by the Department and shall be accessible to the public at the Department's Springfield Office until final release of the applicant's reclamation performance bond.

(5) The record shall remain open for additional written statements responsive to statements or other documents for 10 days following the close of the hearing, or for such other reasonable time as the hearing officer may direct.

5. Illinois removed the provision at existing subsection (g) concerning burden of proof and added a new provision at new subsection (f) to provide that the hearing need not be held if the hearing request is withdrawn.

6. Illinois is redesignating existing subsection (h) as new subsection (g). Illinois is revising the second sentence to require the record of a public hearing to be maintained and available to the public until at least 60 days after the Department's final decision on the bond release application.

7. Illinois is redesignating existing subsection (i) as new subsection (h) and revising the provision to require the Department to issue and serve its bond release decision, by certified mail, to each party who participated in the hearing.

8. Illinois is removing the provisions in existing subsections (j) and (k).

9. Illinois is redesignating existing subsection (l) as new subsection (i) and revising it to read as follows:

(i) Any person with a valid legal interest who either filed written objections to the bond release or were a party to the public hearing may request an administrative hearing on the Department's final decision on the bond release application by filing a request for hearing in accordance with the procedures set forth in 62 Ill. Adm. Code 1847.3.

III. Public Comment Procedures

Under the provisions of 30 CFR 732.17(h), we are seeking comments on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If we approve the amendment, it will become part of the Illinois program.

Written Comments: If you submit written or electronic comments on the proposed rule during the 30-day comment period, they should be specific, should be confined to issues pertinent to the notice, and should explain the reason for your recommendation(s). We may not be able to consider or include in the Administrative Record comments delivered to an address other than the one listed above (*see* **ADDRESSES**).

Electronic Comments: Please submit Internet comments as an ASCII, WordPerfect, or Word file avoiding the use of special characters and any form of encryption. Please also include ''Attn: SPATS NO. IL–101–FOR'' and your name and return address in your Internet message. If you do not receive a confirmation that we have received your Internet message, contact the Indianapolis Field Office at (317) 226–6700.

Availability of Comments: Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours at OSM's Indianapolis Field Office (*see* **ADDRESSES**). Individual respondents may request that we withhold their home address from the administrative

record, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold from the administrative record a respondent's identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

Public Hearing: If you wish to speak at the public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4 p.m., e.s.t. on December 12, 2001. We will arrange the location and time of the hearing with those persons requesting the hearing. If no one requests an opportunity to speak at the public hearing, the hearing will not be held.

To assist the transcriber and ensure an accurate record, we request, if possible, that each person who speaks at a public hearing provide us with a written copy of his or her testimony. The public hearing will continue on the specified date until all persons scheduled to speak have been heard. If you are in the audience and have not been scheduled to speak and wish to do so, you will be allowed to speak after those who have been scheduled. We will end the hearing after all persons scheduled to speak and persons present in the audience who wish to speak have been heard.

If you are disabled and need a special accommodation to attend a public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

Public Meeting: If only one person requests an opportunity to speak at a hearing, a public meeting, rather than a public hearing, may be held. If you wish to meet with us to discuss the proposed amendment, you may request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT.** All such meetings are open to the public and, if possible, we will post notices of meetings at the locations listed under **ADDRESSES.** We will also make a written summary of each meeting a part of the Administrative Record.

IV. Procedural Determinations

Executive Order 12866—Regulatory Planning and Review

This rule is exempt from review by the Office of Management and Budget under Executive Order 12866.

Executive Order 12630—Takings

This rule does not have takings implications. This determination is based on the analysis performed for the counterpart Federal regulations.

Executive Order 13132—Federalism

This rule does not have federalism implications. SMCRA delineates the roles of the Federal and State governments with regard to the regulation of surface coal mining and reclamation operations. One of the purposes of SMCRA is to ''establish a nationwide program to protect society and the environment from the adverse effects of surface coal mining operations.'' Section 503(a)(1) of SMCRA requires that State laws regulating surface coal mining and reclamation operations be ''in accordance with'' the requirements of SMCRA, and section 503(a)(7) requires that State programs contain rules and regulations ''consistent with'' regulations issued by the Secretary under SMCRA.

Executive Order 12988—Civil Justice Reform

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments because each program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR parts 730, 731, and 732 have been met.

Executive Order 13211—Regulations That Significantly Affect The Supply, Distribution, or Use of Energy

On May 18, 2001, the President issued Executive Order 13211 which requires agencies to prepare a Statement of Energy Effects for a rule that is (1) considered significant under Executive Order 12866 and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy. Because this rule is exempt from review under Executive Order 12866 and is not expected to have a significant adverse effect on the supply, distribution, or use of energy, a Statement of Energy Effects is not required.

National Environmental Policy Act

Section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that a decision on a proposed State regulatory program provision does not constitute a major Federal action within the meaning of section 102(2)(C) of the National Environmental Policy Act (NEPA) (42 U.S.C. 4332(2)(C)). A determination has been made that such decisions are categorically excluded from the NEPA process (516 DM 8.4.A).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

a. Does not have an annual effect on the economy of $100 million.

b. Will not cause a major increase in costs or prices for consumers, individual industries, federal, state, or local government agencies, or geographic regions.

c. Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

This determination is based upon the fact that the State submittal which is the

subject of this rule is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation was not considered a major rule.

Unfunded Mandates

This rule will not impose a cost of $100 million or more in any given year on any governmental entity or the private sector.

List of Subjects in 30 CFR Part 913

Intergovernmental relations, Surface mining, Underground mining.

Dated: October 25, 2001.

John W. Coleman,

Acting Regional Director, Mid-Continent Regional Coordinating Center.

[FR Doc. 01–29452 Filed 11–26–01; 8:45 am]

BILLING CODE 4310–05–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[WV059–6017; FRL–7108–4]

Approval and Promulgation of Air Quality Implementation Plans; West Virginia; Revisions to the Ozone Maintenance Plan for the Huntington-Ashland Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of West Virginia. This revision amends West Virginia's ten-year plan to maintain the national ambient air quality standard (NAAQS) for ozone in the Huntington-Ashland area. The maintenance plan is being amended to implement contingency measures in response to recorded violations of the 1-hour ozone NAAQS, and to revise the motor vehicle emission sub-budgets for the West Virginia counties (Cabell and Wayne) that are located in the Huntington-Ashland area. This action is being taken under the Clean Air Act (the Act).

DATES: Written comments must be received on or before December 27, 2001.

ADDRESSES: Written comments may be mailed to David L. Arnold, Chief, Air Quality Planning and Information Services Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103; and West Virginia Department of Environmental Protection, Office of Air Quality, 1558 Washington Street, East, Charleston, West Virginia, 25311.

FOR FURTHER INFORMATION CONTACT: Christopher Cripps, (215) 814–2179, or via e-mail at *cripps.christopher@epa.gov.* While clarifying questions may be posed via e-mail, formal comments must be submitted, in writing, as indicated in the **ADDRESSES** section of this document.

SUPPLEMENTARY INFORMATION:

I. Background

The Huntington-Ashland area includes Wayne and Cabell Counties in West Virginia, and Boyd County and a portion of Greenup County in Kentucky. On December 21, 1994 (59 FR 65719), EPA approved the State of West Virginia's request to redesignate the Huntington-Ashland moderate ozone nonattainment area to attainment, and also approved West Virginia's 10-year plan for continued maintenance of the 1-hour ozone NAAQS in the Huntington-Ashland area as a revision to the West Virginia SIP. On June 29, 1995 (60 FR 33748), EPA approved the Commonwealth of Kentucky's request to redesignate the Huntington-Ashland moderate ozone nonattainment area to attainment, and also approved the Commonwealth's 10-year plan for continued maintenance of the 1-hour ozone NAAQS in the Huntington-Ashland area as a revision to the Kentucky SIP. While the maintenance plans submitted and approved for these two states cover the entire nonattainment area, each plan contains its own set of contingency measures.

Each state's maintenance plan also identifies and establishes the applicable motor vehicle emission budgets (MVEBs) for its portion of the Huntington-Ashland area to which the area's transportation improvement program and long range transportation plan must conform. Conformity to MVEBs in the SIP means that transportation activities will not produce new air quality violations, worsen existing violations, or delay timely attainment of the NAAQS. The Huntington-Ashland maintenance plan identifies and establishes the applicable MVEBs for Cabell and Wayne Counties for both volatile organic compounds (VOC) and nitrogen oxides (NO_X), which are precursors of ground level ozone, for the years 1996, 1999, 2002 and 2005.

A provision of the West Virginia maintenance plan requires the state to adopt contingency measures in the event of a violation of the 1-hour ozone NAAQS. In 1998, the West Virginia side of the Huntington-Ashland area violated the 1-hour ozone NAAQS. In 1998, however, at the time of the violation, the 1-hour ozone NAAQS had been revoked (or made not applicable) by EPA in all areas that had attained the standard, including the Huntington-Ashland area. In July 2000 (65 FR 45181), EPA reinstated the 1-hour ozone NAAQS and notified West Virginia that it is required to implement the contingency measures contained in the SIP-approved maintenance plan to address the violation that occurred in 1998.

On September 25, 2001, the West Virginia Department of Environmental Protection (WVDEP) submitted a request that EPA parallel process revisions to the West Virginia SIP's 1-hour ozone maintenance plan for the Huntington-Ashland area. West Virginia's maintenance plan is being amended to implement contingency measures in response to recorded violations of the 1-hour ozone NAAQS, and to revise the applicable MVEBs for Cabell and Wayne Counties. The proposed SIP revision consists of new requirements to control VOC emissions from marine tank vessel loading operations and revised MVEBs for VOC and NO_X for the years 2002 and 2005. This rulemaking does not propose to amend Kentucky's maintenance plan for the Huntington-Ashland area.

II. Summary of West Virginia's SIP Revision Submittal

A. Control of VOC Emissions from Marine Tank Vessels

West Virginia is implementing controls on marine tank vessel loading operations as a new control measure to prevent against future violations of the 1-hour ozone NAAQS. The National Emission Standards for Hazardous Air Pollutants (NESHAP) for Marine Tank Vessel Loading Operations [40 CFR part 63, subpart Y] was adopted and effective in September 1995, and sources were required to comply with the emission limits by September 1999. These standards establish and require reasonably available control technology (RACT) to limit VOC emissions and maximum achievable control technology (MACT) standards to limit hazardous air pollutants from new and existing marine tank vessel loading operations. West Virginia has adopted these federal requirements into its state code at Code of State Regulation 45–34–

4. The marine tank vessel standards are both Federally and State enforceable. The purpose of the September 25, 2001 SIP revision is to incorporate the requirements to control VOC from marine tank vessel loading operations into the SIP. These control requirements are a contingency measure to prevent future violations of the 1-hour ozone NAAQS in the Huntington-Ashland area.

B. Revisions to the Motor Vehicle Emission Budgets

The September 25, 2001 SIP revision, increases the MVEBs for the years 2002 and 2005. In the original maintenance plan for Huntington-Ashland, emissions growth was projected for all source categories (point, area, and highway mobile) at three-year intervals starting with the year that the area attained the NAAQS (1993). Long term maintenance of the NAAQS is deemed to be demonstrated when total projected growth in emissions in all categories remains below the level of emissions that occurred in the attainment year. The amount of projected future emissions that is both below and beyond the level of the attainment year emissions is called the ''safety margin''. In its September 25, 2001 SIP revision, West Virginia is proposing to reallocate a portion of the safety margins from the point and area source categories to the highway mobile category to increase the existing MVEBs for NO_X and VOC for 2002 and 2005.

III. EPA's Evaluation of West Virginia's SIP Revision

Because the Huntington-Ashland area violated the ozone NAAQS, West Virginia is required to adopt and implement contingency measures to reduce emissions. The contingency measure from its approved maintenance plan that West Virginia has adopted and implemented is RACT for the control of VOC emissions from marine tank vessel loading operations. One major source in the Huntington area is subject to these requirements, the Marathon Ashland Kenova Marine Terminal. The WVDEP estimates that compliance with the marine vessel standards results in an approximate 66 percent reduction of the total VOC point source emissions, and an additional 18 percent reduction in overall VOC emissions in the West Virginia portion of the Huntington-Ashland area.

Five exceedances of the 1-hour ozone NAAQS were recorded at the Huntington monitor in 1998 and one exceedance occurred in 1999. Since the time of full implementation of the marine vessel loading requirements (September 1999), no exceedances of the ozone NAAQS have been recorded. Ozone data monitored for the years 1999, 2000, and 2001 indicate that the Huntington-Ashland area is now once again attaining the 1-hour ozone NAAQS. The control requirements for marine tank vessel loading operations have provided a sufficient level of emission reductions to maintain the 1-hour NAAQS and have strengthened the SIP. Therefore, EPA believes that adequate contingency measures have been adopted and implemented for the Huntington-Ashland area to prevent future violations of the 1-hour ozone NAAQS.

The SIP revision also revises the MVEBs applicable in Cabell and Wayne Counties for 2002 and 2005 by reallocating some of the projected excess emission reductions from the point and area sources located in those counties. In the originally approved maintenance plan, total VOC emissions in 2002 are projected to be 2.47 tons per day (TPD) below the 1993 attainment year inventory, and total NO_X emissions in 2002 are projected to be 2.31 TPD lower than the 1993 attainment inventory. In this SIP revision, West Virginia proposes to use a portion of these excess emission reductions (2.22 TPD for VOC and 2.08 TPD for NO_X) to increase the MVEBs. For the year 2002, the MVEB will be increased from 8.98 TPD to 11.2 TPD for VOC and from 9.48 TPD to 11.56 TPD for NO_X.

As previously stated, the SIP revision also revises the MVEBs applicable in Cabell and Wayne Counties for 2005 by reallocating some of the projected excess emission reductions from the point and area sources located in those counties. In its originally approved maintenance plan, total VOC emissions for 2005 are projected to be 2.20 TPD below the 1993 attainment year inventory, and total NO_X emissions are projected to be 1.96 TPD lower than the 1993 attainment inventory. In this SIP revision, West Virginia proposes to use a portion of these excess emission reductions (1.98 TPD for VOC and 1.76 TPD for NO_X) to increase the MVEBs applicable in Cabell and Wayne Counties. For the year 2005, the MVEB for VOC will be increased from 9.02 TPD to 11.0 TPD and for NO_X the MVEB will be increased from 9.66 TPD to 11.43 TPD.

EPA's review of this material indicates West Virginia has adopted adequate control measures such that the Huntington-Ashland area is once again attaining the 1-hour ozone standard. The adjustments being made to the 2002 and 2005 MVEBs continue to stay below the level of the 1993 attainment year inventory and do not take any credit from the VOC emission reductions associated with the adoption and implementation of RACT to control VOC from marine tank vessel loading operations. Therefore, the reductions being implemented for contingency purposes are not being used to increase the MVEBs, and should yield an additional margin of safety. EPA believes that the proposed revisions to the Huntington-Ashland maintenance plan will continue to provide attainment of the 1-hour ozone NAAQS in the future.

The relationship between determining the adequacy of MVEBs in a SIP versus approval of a SIP with motor vehicle emission budgets is delineated in the EPA's May 14, 1999 memorandum titled ''Conformity Guidance on Implementation of March 2, 1999 Conformity Court Decision.'' The MVEBs are actually approved, or disapproved, at the time EPA takes final action to approve or disapprove the SIP revision which identifies and establishes those budgets. West Virginia's September 25, 2001 SIP revision submittal of revised MVEBs for Cabell and Wayne Counties for the years 2002 and 2005 is posted on EPA's conformity Web site (http://www.epa.gov/oms/transp/conform/currsips.htm) noting that EPA is taking comment on the adequacy and approvability of these budgets via notice and comment rulemaking on the SIP revision. This is that proposed rulemaking. We are forgoing the standard adequacy process because the State has requested that we expedite the processing of this SIP revision. We have reviewed the revised MVEBs for 2002 and 2005 submitted by West Virginia on September 25, 2001. Based upon our review, we conclude that the revised MVEBs meet the adequacy criteria set out at 40 CFR part 93, section 93.118, the Transportation Conformity Regulations. Therefore we are proposing to find the budgets adequate as well as proposing to approve them. A final action approving the revision to West Virginia's maintenance plan for the Huntington-Ashland area would have the effect of approving these revised MVEBs into the SIP and would negate the need for a separate finding of adequacy.

We are seeking public comments on this proposed rulemaking including the adequacy of the revised MVEBs for Cabell and Wayne Counties and will accept such comments provided they are submitted as specified in the **DATES** and **ADDRESSES** sections of this document. We will not hold a separate comment period on the adequacy of

these budgets through the conformity web process. We will address all comments in our final rulemaking on the revisions to West Virginia's maintenance plan. Because the final rule on the revised maintenance plan will promulgate our final determination regarding both the approvability and adequacy of the SIP's MVEBs, we will not publish a separate **Federal Register** notice announcing our adequacy findings.

EPA is proposing to approve the September 25, 2001 SIP revision to West Virginia's 1-hour ozone maintenance plan for the Huntington-Ashland area. EPA is soliciting public comments on the issues discussed in this notice or on other relevant matters. These comments will be considered before taking final action. Interested parties may participate in the Federal rulemaking procedure by submitting written comments to the EPA Regional office listed in the **ADDRESSES** section of this document.

This revision is being proposed under a procedure called parallel processing, whereby EPA proposes rulemaking action concurrently with the state's procedures for amending its SIP. If the state's proposed revision is substantially changed in areas other than those identified in this notice, EPA will evaluate those changes and may publish another notice of proposed rulemaking. If no substantial changes are made other than those areas cited in this notice, EPA will publish a Final Rulemaking Notice on the revisions. The final rulemaking action by EPA will occur only after the SIP revision has been adopted by West Virginia and submitted formally to EPA for incorporation into the SIP.

IV. Proposed Action

EPA is proposing to approve the revisions to West Virginia's 1-hour ozone maintenance plan for the Huntington-Ashland area submitted by the WVDEP on September 25, 2001.

V. Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this proposed action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This proposed action merely proposes to approve state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule proposes to approve pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). This proposed rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does 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 (64 FR 43255, August 10, 1999). This action merely proposes to approve a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This proposed rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant. In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply.

This rulemaking proposing approval of revisions to West Virginia's 1-hour ozone maintenance plan for the Huntington-Ashland area does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Nitrogen dioxide, Ozone.

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

Dated: November 16, 2001.

Donald S. Welsh,

Regional Administrator, Region III.

[FR Doc. 01–29471 Filed 11–26–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 194

[FRL–7108–3]

RIN 2060–AG85

Waste Characterization Program Documents Applicable to Transuranic Radioactive Waste From the Savannah River Site for Disposal at the Waste Isolation Pilot Plant

AGENCY: Environmental Protection Agency.

ACTION: Notice of availability; opening of public comment period.

SUMMARY: The Environmental Protection Agency (EPA, or ''we'') is announcing the availability of, and soliciting public comments for 30 days on, Department of Energy (DOE) documents applicable to characterization of transuranic (TRU) radioactive waste at the Savannah River Site proposed for disposal at the Waste Isolation Pilot Plant (WIPP). The documents are entitled: ''Savannah River Site WIPP Disposal Program Quality Assurance Project Plan, WSRC–RP–99–01097''; ''Savannah River Site WIPP Disposal Program Quality Assurance Program Document, WSRC–RP–99–01119''; and ''Savannah River Site WIPP Disposal Program Waste Certification Plan, WSRC–RP–99–01095.'' They are available for review in the public dockets listed in **ADDRESSES.** We will conduct an inspection of waste characterization systems and processes and the quality assurance program for waste characterization at the Savannah River Site to verify that the site can characterize transuranic debris waste in accordance with EPA's WIPP compliance criteria. We will perform this inspection during the week of December 10, 2001. This notice of the inspection and comment period accords with 40 CFR 194.8.

DATES: EPA requests public comment on the documents. Comments must be received by EPA's official Air Docket on or before December 27, 2001.

ADDRESSES: Comments should be submitted to: Docket No. A–98–49, Air Docket, Room M–1500, U.S. Environmental Protection Agency, 401 M Street, SW., Mail Code 6102, Washington, DC 20460. The DOE documents are available for review in the official EPA Air Docket in Washington, DC, Docket No. A–98–49, Category II–A2, and at the following three EPA WIPP informational docket locations in New Mexico: in Carlsbad at the Municipal Library, Hours: Monday-Thursday, 10 a.m.–9 p.m., Friday-Saturday, 10 a.m.–6 p.m., and Sunday 1 p.m.–5 p.m.; in Albuquerque at the Government Publications Department, Zimmerman Library, University of New Mexico, Hours: vary by semester; and in Santa Fe at the New Mexico State Library, Hours: Monday–Friday, 9 a.m.–5 p.m.

As provided in EPA's regulations at 40 CFR part 2, and in accordance with normal EPA docket procedures, if copies of any docket materials are requested, a reasonable fee may be charged for photocopying. Air Docket A–98–49 in Washington, DC, accepts comments sent electronically or by fax (fax: 202–260–4400; e-mail: *a-and-r-docket@epa.gov*).

FOR FURTHER INFORMATION CONTACT: Ed Feltcorn, Office of Radiation and Indoor Air, (202) 564–9422. You can also call EPA's toll-free WIPP Information Line, 1–800–331–WIPP or visit our website at http://www.epa/gov/radiation/wipp.

SUPPLEMENTARY INFORMATION:

Background

DOE operates the WIPP near Carlsbad in southeastern New Mexico as a deep geologic repository for disposal of TRU radioactive waste. As defined by the WIPP Land Withdrawal Act (LWA) of 1992 (Pub. L. No. 102–579), as amended (Pub. L. No. 104–201), TRU waste consists of materials containing elements having atomic numbers greater than 92 (with half-lives greater than twenty years), in concentrations greater than 100 nanocuries of alpha-emitting TRU isotopes per gram of waste. Much of the existing TRU waste consists of items contaminated during the production of nuclear weapons, such as rags, equipment, tools, and sludges.

On May 13, 1998, we announced our final compliance certification decision to the Secretary of Energy (published May 18, 1998, 63 FR 27354). This decision stated that the WIPP will comply with EPA's radioactive waste disposal regulations at 40 CFR part 191, subparts B and C.

The final WIPP certification decision includes conditions that: (1) prohibit shipment of TRU waste for disposal at WIPP from any site other than the Los Alamos National Laboratory (LANL) until EPA determines that the site has established and executed a quality assurance program, in accordance with §§ 194.22(a)(2)(i), 194.24(c)(3), and 194.24(c)(5) for waste characterization activities and assumptions (Condition 2 of Appendix A to 40 CFR part 194); and (2) prohibit shipment of TRU waste for disposal at WIPP from any site other than LANL until EPA has approved the procedures developed to comply with the waste characterization requirements of § 194.22(c)(4) (Condition 3 of Appendix A to 40 CFR part 194). EPA's approval process for waste generator sites is described in § 194.8. As part of our decision-making process, the DOE is required to submit to EPA appropriate documentation of quality assurance and waste characterization programs at each DOE waste generator site seeking approval for shipment of TRU radioactive waste to WIPP. In accordance with § 194.8, we will place such documentation in the official Air Docket in Washington, DC, and informational dockets in the State of New Mexico for public review and comment.

EPA will perform an inspection of the Savannah River Site's technical and quality assurance programs for waste characterization in accordance with Conditions 2 and 3 of the WIPP certification. The inspection is scheduled to take place the week of December 10, 2001.

EPA has placed two documents pertinent to the inspection in the public docket described in **ADDRESSES.** The documents are entitled: ''Savannah River Site WIPP Disposal Program Quality Assurance Project Plan, WSRC–RP–99–01097,'' ''Savannah River Site WIPP Disposal Program Quality Assurance Program Document, WSRC–RP–99–01119''; and ''Savannah River Site WIPP Disposal Program Waste Certification Plan, WSRC–RP–99–01095'' (Item II–A2–28). In accordance with 40 CFR 194.8, as amended by the final certification decision, we are providing the public 30 days to comment on these documents.

If we determine as a result of the inspection that the proposed processes and programs at the Savannah River Site adequately control the characterization of transuranic waste, we will notify DOE by letter and place the letter in the official Air Docket in Washington, DC, as well as in the informational docket locations in New Mexico. A letter of approval will allow DOE to ship transuranic debris waste belonging to approved waste streams from the Savannah River Site to the WIPP. We will not make a determination of compliance prior to the inspection or before the 30-day comment period has closed.

Information on the certification decision is filed in the official EPA Air Docket, Docket No. A–93–02 and is available for review in Washington, DC, and at three EPA WIPP informational docket locations in New Mexico. The dockets in New Mexico contain only major items from the official Air Docket in Washington, DC, plus those documents added to the official Air Docket since the October 1992 enactment of the WIPP LWA.

Dated: November 20, 2001.

Robert D. Brenner,

Acting Assistant Administrator for Air and Radiation.

[FR Doc. 01–29455 Filed 11–26–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 194

[FRL–7108–2]

RIN 2060–AG85

Waste Characterization Program Documents Applicable to Transuranic Radioactive Waste From the Hanford Site for Disposal at the Waste Isolation Pilot Plant

AGENCY: Environmental Protection Agency.

ACTION: Notice of availability; opening of public comment period.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of, and soliciting public comments for 30 days on, Department of Energy (DOE) documents applicable to characterization of transuranic (TRU) radioactive waste at the Hanford site proposed for disposal at the Waste Isolation Pilot Plant (WIPP). The documents (Item II–A2–36, Docket A–98–49) are available for review in the public dockets listed in **ADDRESSES.** EPA will conduct an inspection of waste characterization systems and processes and the quality assurance program for waste characterization at Hanford to verify that the site can characterize transuranic waste in accordance with EPA's WIPP compliance criteria. EPA will perform this inspection the week of December 17, 2001. This notice of the

inspection and comment period accords with 40 CFR 194.8.

DATES: EPA is requesting public comment on the documents. Comments must be received by EPA's official Air Docket on or before December 27, 2001.

ADDRESSES: Comments should be submitted to: Docket No. A–98–49, Air Docket, Room M–1500, U.S. Environmental Protection Agency, 401 M Street, SW., Mail Code 6102, Washington, DC 20460. The DOE documents are available for review in the official EPA Air Docket in Washington, DC, Docket No. A–98–49, Category II–A2, and at the following three EPA WIPP informational docket locations in New Mexico: in Carlsbad at the Municipal Library, Hours: Monday-Thursday, 10 a.m.–9 p.m., Friday-Saturday, 10 a.m.–6 p.m., and Sunday 1 p.m.–5 p.m.; in Albuquerque at the Government Publications Department, Zimmerman Library, University of New Mexico, Hours: vary by semester; and in Santa Fe at the New Mexico State Library, Hours: Monday-Friday, 9 a.m.–5 p.m.

As provided in EPA's regulations at 40 CFR part 2, and in accordance with normal EPA docket procedures, if copies of any docket materials are requested, a reasonable fee may be charged for photocopying. Air Docket A–98–49 in Washington, DC, accepts comments sent electronically or by fax (fax: 202–260–4400; e-mail: *a-and-r-docket@epa.gov*).

FOR FURTHER INFORMATION CONTACT: Ed Feltcorn, Office of Radiation and Indoor Air, (202) 564–9422. You can also call EPA's toll-free WIPP Information Line, 1–800–331–WIPP or visit our website at *http://www.epa/gov/radiation/wipp*.

SUPPLEMENTARY INFORMATION:

Background

DOE is developing the WIPP near Carlsbad in southeastern New Mexico as a deep geologic repository for disposal of TRU radioactive waste. As defined by the WIPP Land Withdrawal Act (LWA) of 1992 (Pub. L. No. 102–579), as amended (Pub. L. No. 104–201), TRU waste consists of materials containing elements having atomic numbers greater than 92 (with half-lives greater than twenty years), in concentrations greater than 100 nanocuries of alpha-emitting TRU isotopes per gram of waste. Much of the existing TRU waste consists of items contaminated during the production of nuclear weapons, such as rags, equipment, tools, and sludges.

On May 13, 1998, EPA announced its final compliance certification decision to the Secretary of Energy (published May 18, 1998, 63 FR 27354). This decision stated that the WIPP will comply with EPA's radioactive waste disposal regulations at 40 CFR part 191, subparts B and C.

The final WIPP certification decision includes conditions that (1) prohibit shipment of TRU waste for disposal at WIPP from any site other than the Los Alamos National Laboratory (LANL) until the EPA determines that the site has established and executed a quality assurance program, in accordance with §§ 194.22(a)(2)(i), 194.24(c)(3), and 194.24(c)(5) for waste characterization activities and assumptions (Condition 2 of appendix A to 40 CFR part 194); and (2) prohibit shipment of TRU waste for disposal at WIPP from any site other than LANL until the EPA has approved the procedures developed to comply with the waste characterization requirements of § 194.22(c)(4) (Condition 3 of appendix A to 40 CFR part 194). The EPA's approval process for waste generator sites is described in § 194.8. As part of EPA's decision-making process, the DOE is required to submit to EPA appropriate documentation of quality assurance and waste characterization programs at each DOE waste generator site seeking approval for shipment of TRU radioactive waste to WIPP. In accordance with § 194.8, EPA will place such documentation in the official Air Docket in Washington, DC, and informational dockets in the State of New Mexico for public review and comment.

EPA will perform an inspection of Hanford's technical and quality assurance programs for waste characterization in accordance with Conditions 2 and 3 of the WIPP certification. More specifically, we will be focusing on CH-debris and solid waste streams. The inspection is scheduled to take place the week of December 17, 2001.

EPA has placed a number of documents pertinent to the inspection in the public docket described in **ADDRESSES.** The documents are listed as Item II–A2–36 in Docket A–98–49. In accordance with 40 CFR 194.8, as amended by the final certification decision, EPA is providing the public 30 days to comment on these documents.

If EPA determines as a result of the inspection that the proposed processes and programs at Hanford adequately control the characterization of transuranic waste, we will notify DOE by letter and place the letter in the official Air Docket in Washington, DC, as well as in the informational docket locations in New Mexico. A letter of approval will allow DOE to ship transuranic waste from Hanford to the WIPP. The EPA will not make a determination of compliance prior to the inspection or before the 30-day comment period has closed. Information on the certification decision is filed in the official EPA Air Docket, Docket No. A–93–02 and is available for review in Washington, DC, and at three EPA WIPP informational docket locations in New Mexico. The dockets in New Mexico contain only major items from the official Air Docket in Washington, DC, plus those documents added to the official Air Docket since the October 1992 enactment of the WIPP LWA.

Dated: November 20, 2001.

Robert D. Brenner,

Acting Assistant Administrator for Air and Radiation.

[FR Doc. 01–29454 Filed 11–26–01; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 2, 15, 18 and 90

[ET Docket No. 01–278; FCC 01–290]

Radio Frequency Rules (Part 15) Biennial Review

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document proposes to review and update certain rules. We are proposing to modify limits and restrictions on emissions from certain unlicensed, devices above 2 GHz; require that radar detectors be subject to emission limits in order to prevent interference to certain satellite operations; eliminate the prohibition on data transmissions and make other changes to rules governing remote control devices; modify the rules for radio frequency identification systems to harmonize our rules with those in other parts of the world and to allow for improved operation; simplify the labeling requirement for manufacturer self-authorized equipment; and make other changes to update and correct our rules. This item responds to two petitions for rule making, a filing pursuant to the Regulatory Flexibility Act of 1980 and recommendations contained in the *Biennial Regulatory Review 2000 Updated Staff Report.*

DATES: Comments must be filed on or before February 12, 2002; and reply comments must be filed on or before March 12, 2002.

ADDRESSES: All filings must be sent to the Commission's Secretary, Magalie Roman Salas, Office of the Secretary,

Federal Communications Commission, 415 12th Street, SW, TW–A325, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Hugh Van Tuyl, Office of Engineering and Technology, (202) 418–7506.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Notice of Proposed Rule Making and Order*, ET Docket—01–278, FCC 01–290, adopted October 2, 2001, and released October 15, 2001. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Information Center, Room CY–A257, 445 12th Street, SW, Washington, DC, and also may be purchased from the Commission's duplication contractor, Qualex International (202) 863–2893, Room CY–B402, 445 12th Street, SW, Washington, DC 20554.

Summary of the Notice of Proposed Rule Making

1. This Notice of Proposed Rule Making (NPRM) proposes to review and update certain rules sections contained in parts 2, 15 and 18 of our rules. Specifically, we are proposing to: (1) modify limits and restrictions on emissions from certain unlicensed or part 15 devices above 2 GHz; (2) require that radar detectors be subject to emission limits in order to prevent interference to certain satellite operations; (3) eliminate the prohibition on data transmissions and make other changes to rules governing part 15 remote control devices; (4) modify the rules for radio frequency identification systems to harmonize our rules with those in other parts of the world and to allow for improved operation; (5) simplify the labeling requirement for manufacturer self-authorized equipment; and (6) make other changes to update and correct our rules. This item responds to two petitions for rule making, a filing pursuant to the Regulatory Flexibility Act of 1980 and recommendations contained in the *Biennial Regulatory Review 2000 Updated Staff Report.*

2. On September 19, 2000, the Commission issued a staff report summarizing an extensive review of the Commission's rules undertaken as part of the 2000 Biennial Review. On January 17, 2001, the Commission released an updated report (''Updated Staff Report'') taking into account comments received in response to the initial report. In developing the reports, the staff from each Commission Bureau and Office reviewed all rules pertinent to its operations to determine whether to recommend that the Commission modify or eliminate any rules. The review was not limited to the rules implicated by section 11 and section 202(h). Accordingly, the staff reviewed part 15 to determine whether there were any rules that could be modified or eliminated, even though a review of that part was not required by statute. Updated Staff Report recommended that the Commission consider a number of changes to part 15 and other parts of the rules. Specifically, it recommended that the Commission:

- Review the limits for radio frequency emissions above 2 GHz.
- Permit data transmission by transmitters operating under § 15.231.
- Simplify the labeling requirements for equipment approved under the Declaration of Conformity procedure.
- Incorporate a new test procedure for unlicensed Personal Communication Services (PCS) transmitters into the rules.
- Clarify the measurement requirements in 47 CFR part 2 of the rules for Family Radio Service transmitters.
- Clarify the requirements for scanning receivers to prevent the reception of cellular telephone frequencies.

3. In addition, the National Council for Information Technology Standardization Technical Committee B10 (NCTIS B10) and SAVI Technology, Inc. (SAVI) filed petitions for rule making requesting changes to the part 15 requirements for radio frequency identification systems.

Proposed Revisions to Part 15

1. Part 15 Emission Limits Above 2 GHz

4. 47 CFR part 15 of the rules contains the technical requirements for radiofrequency devices that may be operated without individual licenses. The requirements include radiated emission limits for intentional radiators, such as transmitters, and for unintentional radiators, such as radio receivers, computers and VCRs. The limits are intended to minimize the possibility of unlicensed part 15 devices causing interference to licensed radio services. The last significant change to these limits was made in 1989, so they have been essentially unchanged for over ten years. During this period, the commercial use of spectrum above 2 GHz has increased significantly. Licensed and unlicensed devices operating above 2 GHz have proliferated, in part because advances in technology have made such devices more affordable.

5. The *Updated Staff Report* recommends that we review the emission limits above 2 GHz to determine whether any changes are warranted. We have identified two specific areas where we believe changes may be warranted. The first concerns emission limits in the frequency range above 38.6 GHz, and the second concerns certain types of receivers operating above 960 MHz that are exempt from equipment authorization and from complying with the emission limits for unintentional radiators.

6. *Restricted frequency bands above 38.6 GHz.* The entire frequency range above 38.6 GHz is currently listed as a restricted band of operation under part 15. Frequency bands are designated as restricted to protect certain sensitive radio services, such as those that protect safety-of-life or those that use very low received levels, such as satellite downlinks or radio astronomy. With certain exceptions, part 15 permits only spurious emissions in restricted frequency bands, and the emissions must comply with the limits in section 15.209. These limits are lower than the out-of-band emission limits permitted by some other rule sections in part 15. For this reason, compliance with the rules may be more difficult to achieve for devices that produce harmonic emissions above 38.6 GHz, including field disturbance sensors operating in the 10.5 and 24 GHz bands and other transmitters operating in the 24 GHz band. The maximum permitted level of harmonics from these devices would be significantly higher if they did not fall in restricted bands. The rules allow some relaxation of the harmonic limits for field disturbance sensors under certain conditions, but the limits are still lower than they would be if the emissions were not in restricted bands.

7. There are a number of sensitive radio services operating above 38.6 GHz, but we believe it is not necessary to restrict the entire spectrum above this frequency. At the time the entire frequency range above 38.6 GHz was designated as a restricted band, there was no requirement in our rules to make measurements above 40 GHz because of limitations in measurement technology. Designating the entire band above 38.6 GHz as restricted, rather than restricting designated segments, was simply a matter of administrative convenience and had no impact on manufacturers because measurements were not required at those frequencies. However, due to advancements in measurement technology, the Commission now requires measurements above 40 GHz for some devices, which means these devices must now comply with the restricted band limits. In light of this, we believe the strict limits of section

15.209 are not appropriate for all frequency bands above 38.6 GHz. We seek comments on the need for changes to the restricted bands above 38.6 GHz and the potential benefits to manufacturers of such changes. We also seek comment on whether there are any other part 15 rules designed to protect sensitive services such as government operations that should be modified.

8. *Receivers operating above 960 MHz.* In addition to possible changes in the restricted bands, we believe that changes to the requirements for radio receivers operating above 960 MHz may be warranted. Most receivers contain one or more oscillators that generate radio frequency signals used in tuning the received signal. This generated signal can radiate from the receiver and could interfere with other nearby receivers. For this reason, part 15 requires certain receivers to meet radiated emission limits to minimize the possibility of interference. The rules currently require only receivers that tune in the range of 30–960 MHz and Citizen's Band receivers to comply with the limits. Other receivers are not required to comply with the limits, but the rules require the operation of any receiver to cease if it causes interference. In the past, most receivers used in the home only tuned below 960 MHz and were subject to emission limits to minimize the possibility of interference to other radio equipment. Above 960 MHz, the emissions generated by radio receivers tend to be more directional and the propagation losses are higher. There is less probability of such receivers causing interference, so the rules have not required receivers that tune above 960 MHz to meet emission limits or to receive an equipment authorization. Historically, these rules have generally worked well.

9. Radar detectors are currently exempt from complying with the part 15 emission limits because they tune above 960 MHz. They are designed to monitor for the presence of police radar in several frequency bands, including the 10.50–10.55 GHz, 24.05–24.25 GHz and 33.4–36.0 GHz bands. The oscillator signals internally generated by some radar detectors' tuning circuitry are being radiated and causing interference to VSATs. The level of these signals is typically far above the Part 15 limits. The potential for interference to VSATs caused by radar detectors has recently increased because manufacturers have begun using swept frequency oscillators at different frequencies than previously used. The purpose of these changes is to enhance detection of police radar while making it more difficult for police to detect the presence of radar detectors in vehicles.

10. We invite comment on whether there is a need to require radar detectors to comply with emission limits to minimize the possibility of interference, and if so, what are the appropriate limits. We also seek comments on whether there are any other receivers that tune above 960 MHz that should be required to comply with emission limits. If so, we seek comments on the appropriate limits, and whether the limits should apply in all frequency bands or only certain bands where interference may be more likely to occur, such as the VSAT bands. Furthermore, we seek comment, especially from small entities, concerning the timeframe that should be required to comply with any new emission limits.

Data Transmission by Remote Control Devices

11. Section 15.231 of the rules allows the operation of remote control devices in the 40 MHz band and above 70 MHz. There are two separate provisions for operation under this section. Paragraph (a) contains field strength limits for transmitters that transmit control signals, such as those used with alarm systems, door openers and remote switches. A transmitter operated under this paragraph must cease transmission within 5 seconds after being activated automatically or after a manually operated switch is released. Continuous transmissions such as voice and video are not permitted, and data transmissions are not permitted except for recognition codes to identify specific transmitters in a system. There is a prohibition on periodic transmissions at regular predetermined intervals, although transmissions are permitted once per hour to verify the integrity of security transmitters. Paragraph (e) of this section allows any type of transmission, including data and transmissions at regular periodic intervals. However, this paragraph contains lower field strength limits than paragraph (a), and it places strict timing requirements on periodic transmissions.

12. We believe that the prohibition on data transmissions in paragraph (a) is unnecessarily constraining and can be an impediment to the development of new types of devices. We do not believe that removing this restriction will result in an increased potential for interference. Based on the lack of a record of interference complaints from devices operating under this section, we tentatively conclude that the existing limits on field strength and duration of transmissions are sufficient to prevent harmful interference. Because the interference potential of a device is a function of the permitted signal strength and duration of the transmissions rather than the type of information sent, there should be no difference between the interference potential of a device transmitting recognition codes as permitted by paragraph (a) as compared to a device transmitting data that represents other kinds of information. Accordingly, we are proposing to remove the prohibition on the transmission of data in § 15.231(a). We are also proposing to remove the prohibition on voice and video transmissions. Data representing voice or video has no greater interference potential than any other type of data, and the timing requirements in paragraphs (a) and (e) will not allow continuous transmissions, so there is no need to expressly prohibit them.

13. We seek comments on our proposal to allow data transmission under § 15.231(a) and the potential benefits to manufacturers. We also seek comment on whether allowing data transmissions will result in an increased proliferation of devices or in devices transmitting for a greater amount of time, and whether there is a need to modify the timing requirements in paragraphs (a) or (e) to avoid interference to other radio services.

Radio Frequency Identification Systems

14. Radio frequency identification (RFID) systems use radio signals to track and identify items such as shipping containers and merchandise in stores. A system typically consists of a tag mounted on the item to be identified, and a transmitter/receiver unit that interrogates the tag and receives identification data back from the tag. The tag may be a self-powered transmitter, or it may receive power from the interrogating transmitter. RFID systems can operate in a number of frequency bands under part 15 of the rules.

15. *NCITS B10 Petition for Rulemaking.* We believe that the increases in emission levels proposed by NCITS B10 are not likely to create significant interference to other services. Further, although other part 15 RFID systems are not protected from interference from new RFID systems, we believe that the potential for such interference is low and can be mitigated through site engineering techniques if it should occur. Thus, we find that the public interest would be best served by proposing to modify our rules to permit the introduction of these improved RFID devices. Specifically, we are proposing to modify § 15.225 to include the

emission mask sought by NCITS B10. We are also proposing to amend § 15.205 of the rules to allow devices operated pursuant to § 15.255 to place emissions other than spurious emissions into the 13.36–13.41 MHz restricted band. This restricted band was intended to protect radio astronomy operations. However, radio astronomy operations in this band in the United States are limited to one site in Florida. NTIA has stated that they do not object to allowing emissions from RFID devices in this restricted band. Alternatively, we propose to remove the 13.36–13.41 MHz band from the restricted bands listed in § 15.205. We seek comment on these proposals.

16. The NCITS B10 also requests that the Commission clarify that RFID tags may be approved with or without the reader. NCITS B10 states that separate authorizations of the RFID tag and reader could foster competition in the provision of tags designed to work with multiple readers. We agree with NCITS B10 and are proposing to amend § 15.225 to specify that RFID applications equipment authorization for tags and readers can be submitted either together or separately. Tags and readers approved together would both be labeled with the same FCC identification number. We seek comment on this proposal.

17. *SAVI Petition for Rule Making.* We agree with SAVI that changes to part 15 to all more advanced RFID systems in the 433 MHz band would serve the public interest. Accordingly, we are proposing to create a new section that would allow operation of such devices in the 425–435 MHz band. We propose to allow a maximum field strength of 11,000 microvolts per meter measured at a distance of 3 meters using equipment with an average detector function. The maximum peak level permitted would be 110,000 microvolts per meter measured at a distance of 3 meters. This is the same as the current limit in § 15.231(a) at 433 MHz, which we believe will provide an adequate signal for reliable communications while minimizing the potential for interference to other users of the band. As proposed by SAVI, transmissions would be limited to 120 seconds with at least a 10 second silent period between transmissions, except that retransmissions would be permitted in case of data errors. We also propose that powered tags and readers could be approved either separately or under a single application as we proposed for devices operating in the 13.56 MHz band. We seek comments on these proposals. We also seek comments on allowing retransmissions in the event of data errors, and whether we need to more clearly define the circumstances under which retransmissions are permitted.

Declaration of Conformity (DoC) Labeling

18. Many unintentional radiators under part 15 of the rules, including personal computers, VCRs and radio receivers, are authorized through the Declaration of Conformity (DoC) procedure. DoC is a self-approval procedure in which the manufacturer has the equipment tested for compliance at a laboratory accredited to make the required measurements. Once the equipment has been found to comply with the applicable rules, it may be marketed without an approval from the Commission.

19. Equipment authorized through the DoC procedure must be labeled as specified in Section 15.19 of the rules. This section shows illustrations of two variations of the label to be used. One label is for equipment that was tested for compliance as a complete unit, and the other label is for personal computers that were assembled from components that were tested separately for compliance. Either variation of label must include the manufacturer's trade name, the equipment model number, the FCC logo, the phrase ''For Home or Office Use'', and a statement as to whether the complete device was tested for compliance or whether it was assembled from tested components.

20. The DoC procedure was originally established to reduce the burden on manufacturers of Class B personal computers and peripherals by eliminating the delays resulting from the requirement to obtain a Commission approval prior to marketing equipment. The phrase ''For Home or Office Use'' on the DoC label was intended to show that a device meets the more stringent Class B limits and is suitable for use in either residential (Class B) or non-residential (Class A) environments. However, because Class B devices may be used anywhere, this statement on the label is unnecessary, and requiring it to be included means that manufacturers must use a larger label on a device. This could become increasingly burdensome as advancements in technology result in smaller and smaller equipment. We are therefore proposing to delete the requirement for the phrase ''For Home or Office Use'' to simplify the label (The text of labels in § 15.19(b)(1) do not appear in this proposed rule but will appear in full text in the final rule.).

21. We are also proposing to eliminate the statement on the label that the complete device be tested for compliance in order to further simplify the label. We will, however, continue to require that personal computers assembled from tested components contain a statement to that effect on their label. That information could assist us in determining the source of compliance problems when investigating cases of non-compliant equipment. We do not believe requiring this information on the label would be unduly burdensome because the types of computers assembled from tested components generally have more space for the label. We believe these changes will result in a reduced burden on manufacturers while still requiring sufficient information on equipment for enforcement purposes. We seek comment on these proposals. In other proceedings, parties have indicated that electronic labeling may enhance flexibility by permitting equipment to be quickly re-labeled when changes are made to the product identification number. We seek comment on whether electronic labeling should be permitted for devices authorized under the DoC procedure as we proposed for certain other equipment. If so, we seek comment on what would be an appropriate method for electronically labeling equipment such as computers that are authorized through the DoC procedure.

Test Procedure for Unlicensed PCS Equipment

22. Section 15.31 of the rules lists the measurement procedures that the Commission will use to determine whether a part 15 device complies with the applicable technical requirements. In the past the Commission usually developed its own measurement procedures. More recently, the Commission has shifted to incorporating industry-developed measurement procedures into the rules by reference. The American National Standards Institute (ANSI) C63.4–1992 procedure is specified as the procedure the Commission will use for testing most intentional and unintentional radiators for compliance. However, this procedure does not cover certain types of devices, including unlicensed Personal Communication Service (PCS) equipment.

23. Unlicensed PCS equipment has certain unique technical requirements that other Part 15 devices do not have which are intended to prevent interference between devices. For example, there is a clearly defined spectrum etiquette that requires unlicensed PCS equipment to monitor the spectrum before transmitting and to use a specific transmission format.

Ensuring that unlicensed PCS equipment complies with this etiquette requires a highly specialized measurement procedure. The ANSI C63 Committee recently completed work on a measurement procedure for unlicensed PCS equipment, ANSI C63.17–1998. This procedure provides detailed guidance that will assist manufacturers in measuring unlicensed PCS devices to ensure that they comply with the requirements in our rules. We are therefore proposing to incorporate this procedure into our rules by reference as the procedure we will use for testing unlicensed PCS equipment. We request comments on this proposal.

Exemption for Very Low-Powered Devices

24. Part 15 of the rules requires most devices that intentionally emit radiofrequency radiation to be certified before they can be marketed. Phillip Inglis noted that there are a number of devices on the market that transmit signals on low frequencies at extremely low power levels, such as card readers, pens used to write on specialized computer screens, and other devices designed to communicate over distances of inches. All such devices must be certified regardless of how low an operating power they use. Certification requires that the manufacturer have the equipment tested for compliance, submit an application with the test results and other exhibits to the Commission and wait for an approval before marketing the equipment. We believe that the interference potential of such devices is extremely low, and we tentatively conclude that requiring certification is an unnecessary burden on manufacturers. We therefore propose to exempt devices operating below 490 kHz from certification if the maximum field strength emitted is more than 40 dB below the applicable part 15 limits. We seek comment on this proposal. As an alternative, we seek comment on whether all transmitters operating below 490 kHz under the provisions of § 15.209 should be only subject to verification. Verification simply requires the manufacturer to have the equipment tested and to retain certain information on file. No application filing is required for verification and the equipment may be sold as soon as it is found to comply.

Information to the User

25. Manufacturers are required to supply certain information to the users of products operating under part 15 of the rules. Section 15.21 requires the instruction manual for all part 15 devices to contain a statement that unauthorized modifications to a device could void the user's authority to operate it. In addition, § 15.105 requires the manual for a digital device to include a warning of the potential for interference to other devices and a list of some steps that could possibly eliminate the interference. The rules originally envisioned that this information would be included in a paper instruction manual. As manufacturers have moved to provide more of their manuals electronically, the Commission has permitted this warning information to be provided by alternative means, such as a CD–ROM.

26. The Information Technology Industry Council (ITI) states that manufacturers are increasingly providing information over the Internet, rather than on paper or a CD–ROM. ITI recommends that the Commission consider the possibility of allowing the information to users required by the rules to be supplied over the Internet rather than with the product. We do not believe it is burdensome on manufacturers to require this information to be supplied with the product when a paper manual or CD–ROM is supplied with the product. However, this requirement could be burdensome in cases where the instruction manual is only available over the Internet. We therefore propose that manufacturers be permitted to provide the required information to users in the instruction manual in whatever form the manual is supplied. This may be on paper, a computer disk, a CD–ROM or over the Internet. This will ensure that the information is readily available to users while minimizing the burden on manufacturers. We seek comment on this proposal. We seek comment, more particularly, on whether Internet-delivered manuals create accessibility problems for consumers without Internet access or for groups of consumers for whom obtaining Internet access is difficult. Where this is the case, we seek comment on whether allowing important information to be delivered only over the Internet results in certain consumers having insufficient access to information. We also seek comment on whether allowing warnings to be delivered exclusively online will result in a significant reduction in the number of consumers who receive the warnings.

Proposed Revisions to Part 2

Family Radio Service Equipment Measurements

27. In 1996, the Commission established the Family Radio Service (FRS), which is a private, two-way, very short distance voice communications service for facilitating family and group activities. Part 95 of the rules specifies the operating frequencies and a frequency tolerance requirement for transmitters used in the FRS. The temperature ranges over which frequency tolerance measurements for most transmitters must be made are specified in part 2 of the rules. However, at the time the FRS was established, the temperature ranges specified in part 2 only applied to equipment authorized under the now-abolished type-acceptance procedure. Because the rules adopted for the FRS stated that transmitters were to be authorized under the certification procedure, the temperature ranges specified in part 2 for type-accepted equipment did not apply. Therefore, the temperature range over which FRS frequency stability measurements must be made was not clear. Accordingly, we are proposing to amend our rules to specify that FRS frequency stability measurements are to be made from −20 °C to +50 °C. We request comments on this proposal.

Accreditation of Test Laboratories

28. Section 2.948 of the rules require laboratories that submit test data for equipment subject to certification under parts 15 and 18 of the rules to file an up-to-date description of its facility with the Commission. Many of these laboratories are accredited by a recognized accrediting organization such Accreditation Program (NVLAP) that determines the technical competency of the laboratory in accordance with International Organization for Standardization/ International Electrotechnical Commission (ISO/IEC) Standard 17025. Because the accreditation process considers both the test facility and the competency of the laboratory to perform the required measurements, we question whether it is necessary for an accredited laboratory to submit a description of its facility to the Commission as the rules currently require. Therefore, we are tentatively proposing to remove this requirement from § 2.948 of the rules for accredited laboratories, provided the accrediting organization notifies the Commission with certain minimum information about the laboratory. We propose that this information would include the laboratory name, address, contact information, scope of accreditation, date of accreditation and date by which the accreditation must be renewed. In addition, we are proposing to clarify the requirements in § 2.948 for the testing of equipment subject to

Declaration of Conformity, which requires the use of an accredited laboratory. Specifically, we propose that the accreditation of laboratories outside the United States will be recognized by the Commission if one of the following two conditions are met: (1) the laboratory has been designated by a foreign authority and recognized by the Commission under the terms of a government-to-government Mutual Recognition Agreement or Arrangement; or (2) the laboratory has been accredited by an organization whose accreditations are recognized by the Commission. We seek comment on these proposals.

Additional Proposals

29. We believe that there are a number of other changes that can be made to simplify and clarify Parts 2, 15 and 18 of the rules. Our analysis revealed several rule sections that no longer appear to be necessary. In addition, we identified several sections that need to be updated to reflect the availability of more recent industry documents, or that need other minor revisions. The proposed changes are listed below. We request comment on each of these proposals.

- Section 2.202 Bandwidths. The table of necessary bandwidth calculations in paragraph (g) does not contain entries for newer digital modulation types. The *NTIA Manual of Regulations & Procedures for Federal Radio Frequency Management* contains formulas for calculating necessary bandwidths for various digital modulation types, and we are proposing to add them to the table in § 2.202(g).
- Section 2.948 Description of measurement facilities. We are proposing to remove references to expired transition dates and obsolete measurement procedures, update references to reflect the availability of the new ANSI C63.4–2000 measurement procedure, and to correct the Commission's mailing address.
- Section 2.1033 Application for certification. We are proposing to re-designate paragraph 2.1033(c)(17) on composite devices as paragraph 2.1033(d). This proposed change corrects a numbering error that arose in the Report and Order in ET Docket 97–94.
- Sections 2.1061 through 2.1065 Filing for Application Reference. This procedure was developed over 20 years ago to allow manufacturers and licensees to file transmitter measurement data with the Commission. The Commission would retain the test data for future reference by licensees. This procedure is separate from the regular equipment authorization process. There appears to be no current need for this procedure, so we are proposing to remove it from the rules.
- Section 15.31 Measurement standards. We are proposing to remove references to measurement procedures that are no longer used and to correct the Commission's mailing address. In addition we are proposing to update the reference to reflect the new ANSI C63.4–2000 measurement procedure. The rules will continue to indicate that the Commission will not use certain sections of this procedure for determining the compliance of equipment. Also, we are proposing that the rules reflect the Commission's longstanding practice to use loop antennas rather than rod antennas for low frequency measurements.
- Section 15.118 Cable ready consumer electronics equipment. We are proposing to correct the Commission's mailing address.
- Section 15.120 Program blocking technology requirements for television receivers. We are proposing to correct the Commission's mailing address.
- Section 15.255 Operation in the band 59.0–64.0 GHz. We are proposing to correct the wording in paragraph (b)(5) from ''emission limits'' to ''emission levels''.
- Section 18.103 Organization and applicability of the rules. We are proposing to delete this section because it duplicates the table of contents for Part 18.
- Section 18.105 Other applicable rules. We are proposing to delete this section because it provides little information and is not necessary.
- Section 18.119 Importation. We are proposing to delete this section because it duplicates portions of the rules in part 2.
- Section 90.203 Certification required. We are proposing to correct an error in paragraph (k) that occurred when rules streamlining the equipment authorization processes were published in the **Federal Register**.

Initial Regulatory Flexibility Analysis

30. As required by the Regulatory Flexibility Act (RFA),[1] the Commission has prepared this present Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on small entities by the policies and rules proposed in this Notice of Proposed Rule Making (NPRM). Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments provided in paragraph 51 of the NPRM. The Commission will send a copy of the NPRM, including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA).[2]

A. Need for, and Objectives of, the Proposed Rules

31. Section 11 of the Communications Act of 1934, as amended, and Section 202(h) of the Telecommunications Act of 1996 require the Commission: (1) To review biennially its regulations pertaining to telecommunications service providers and broadcast ownership; and (2) to determine whether economic competition has made those regulations no longer necessary in the public interest. The Commission is directed to modify or repeal any such regulations that it finds are no longer in the public interest.

32. As part of the biennial review for the year 2000, the Commission reviewed its regulations pertaining to telecommunications service providers and broadcast ownership and recommended a number of changes to those rules. While not specifically required by statute, the Commission also reviewed parts 2, 15 and 18 as part of this process.

33. The NPRM proposes several changes to part 15 and other parts of the rules. Specifically, it proposes to:

(1) Make certain changes to the part 15 emission limits above 2 GHz. While the part 15 emission limits have been effective at controlling interference, a review is warranted due to the increasing use of frequencies above 2 GHz. These limits appear to restrict unnecessarily certain types of devices such as field disturbance sensors. In addition, radar detectors, which are currently exempt from complying with emission limits, are causing interference to satellite services.

(2) Remove the restriction on data transmissions by remote control device because it may hinder the development of new types of devices, and the distinction between control signals and data signals is becoming increasingly blurred.

(3) Make changes to the requirements for radio frequency identification (RFID) systems to allow faster data transmission. RFID systems use a small transmitter attached to an item that transmits data identifying the item. The Commission received two petitions for

[1] See 5 U.S.C. 603. The RFA, *see* 5 U.S.C. 601 *et. seq.*, has been amended by the Contract With America Advancement Act of 1996, Public Law 104–121, 110 Stat. 847 (1996) (CWAAA). Title II of the CWAAA is the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA).

[2] See 5 U.S.C.603(a).

rule making requesting these changes to the rules.

(4) Streamline the labeling process for equipment authorized under the Declaration of Conformity (DoC) procedure. As equipment becomes smaller, it becomes more difficult to include all the information currently required on the label.

(5) Make minor corrections and updates to part 15 and other parts of the rules.

B. Legal Basis

34. The proposed action is authorized under sections 4(i), 301, 302, 303(e), 303(f), 303(r), 304 and 307 of the Communications Act of 1934, as amended, 47 U.S.C. sections 154(i), 301, 302, 303(e), 303(f), 303(r), 304 and 307.

C. Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply

35. The RFA directs agencies to provide a description of and, where feasible, an estimate of the number of small entities that may be affected by the proposed rules, if adopted.[3] The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.''[4] In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act.[5] A small business concern is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.[6]

36. The Commission has not developed a definition of small entities applicable to Radio Frequency Equipment Manufacturers (RF Manufacturers). Therefore, the applicable definition of small entity is the definition under the SBA rules applicable to manufacturers of ''Radio and Television Broadcasting and Communications Equipment.'' According to the SBA's regulation, an RF manufacturer must have 750 or fewer employees in order to qualify as a small business.[7] Census Bureau data indicates that there are 858 companies in the United States that manufacture radio and television broadcasting and communications equipment, and that 778 of these firms have fewer than 750 employees and would be classified as small entities.[8] We believe that many of the companies that manufacture RF equipment may qualify as small entities.

D. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

37. The NPRM proposes a number of rule changes that will affect reporting, recordkeeping and other compliance requirements. Each of these changes is described below.

38. The NPRM proposes to require radar detectors used by motorists to meet emission limits to prevent interference to satellite services. The tuning circuitry in most receivers, including radar detectors, generates radio frequency signals that can be radiated and cause interference. Part 15 of the rules has limits on the radiated signals from radio receivers that tune up to 960 MHz. Because radar detectors only tune above 960 MHz, they are exempt from complying with emission limits and most or all models currently sold significantly exceed the Part 15 limits. We expect that manufacturers would be required to redesign radar detectors to comply with any emission limit adopted.

39. The NPRM proposes changes to streamline the labeling requirements for equipment authorized under the Declaration of Conformity (DoC) procedure. DoC is a self-approval procedure in which the manufacturer has the equipment tested for compliance at a laboratory accredited to make the required measurements. There is an alternative procedure that allows personal computers to be assembled using compliant motherboards and power supplies with no additional testing required. Equipment that complies with the applicable rules may be marketed without an approval from the Commission, and must be labeled as specified in part 15 of the rules. The NPRM proposes to eliminate the phrase ''For home or office use'' from the label for all equipment subject to DoC. In addition, it proposes to eliminate the phrase ''Tested to comply with FCC standards'' from the label on equipment that was tested as a complete unit, although this phrase will still be required on personal computers that were assembled from tested components. The NPRM also proposes to eliminate the need to place the equipment trade name and model number on the label if that information is already on the equipment in close proximity to the label. These changes will permit smaller labels on equipment. These changes will not be required, and small entities can change labels as they change and upgrade models.

40. The NPRM proposes to incorporate the ANSI C63.17–1998 procedure into the part 15 of the rules by reference as the procedure the Commission will use for testing unlicensed Personal Communication Service (PCS) equipment for compliance. Unlicensed PCS equipment has a number of specialized technical requirements designed to prevent interference between devices. Specifically, there is a defined ''spectrum etiquette'' that requires unlicensed PCS transmitters to monitor the spectrum for other users before transmitting, and to use a defined transmission format. There is currently no procedure listed in the rules for testing unlicensed PCS equipment to these requirements. The American National Standards Institute (ANSI) C63 Committee recently completed work on a procedure for measuring unlicensed PCS equipment, which the NPRM proposes to incorporate into the rules as the procedure that the Commission will use.

41. Part 15 currently references the ANSI C63.4–1992 procedure as the one that will be used for testing most intentional and unintentional radiators for compliance with the rules. The ANSI C63 Committee recently completed a minor revision of the ANSI C63.4–1992 procedure that contains a number of clarifications to the testing procedures. The NPRM proposes to reference the new C63.4–2000 procedure in place of the older version as the procedure that manufacturers should use for compliance testing.

42. The NPRM proposes a change to the temperature range for frequency stability measurements on transmitters used in the Family Radio Service (FRS) under part 95 of the rules. Most transmitters used in licensed services are required to maintain their carrier frequency within a specified tolerance over a range of voltage and temperature variations to minimize the probability of interference to other users. At the time the FRS was established in 1996, a frequency stability limit was specified for transmitters, but no temperature range was specified. The Commission

[3] 5 U.S.C. 603(b)(3).

[4] 5 U.S.C. 601(6).

[5] 5 U.S.C. 601(3) (incorporating by reference the definition of ''small business concern'' in 15 U.S.C.632). Pursuant to the RFA, the statutory definition of a small business applies ''unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the **Federal Register**.'' 5 U.S.C.601(3).

[6] Small Business Act, 15 U.S.C.632 1996).

[7] See 13 CFR 121.201, North American Industrial Classification System (NAICS) Code 33422.

[8] See U.S. Department of Commerce, 1992 Census of Transportation, Communications and Utilities (issued May 1995), NAICS code 33422.

staff informally interpreted that measurements must be made to −20 degrees centigrade. A 1998 rule change to the equipment authorization requirements unintentionally resulted in a new requirement to measure FRS transmitters to −30 degrees centigrade. However, the staff continued requiring measurements to −20 degrees centigrade in the interest of fairness. The NPRM proposes to specifically specify that FRS transmitters are to be measured to −20 degree centigrade as the staff has been requiring since 1996.

E. Steps Taken To Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

43. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.[9]

44. The proposal to require emission limits on radar detectors would have an impact on equipment manufacturers, some of which may be small entities. Paragraphs 10 through 14 in the primary item discuss the need to require certain receivers to meet radiated emission limits to minimize the possibility of interference. We requested comments in the NPRM on the timetable that should be required for compliance with new emission limits, and whether a differing compliance timetable should be required for small entities. The alternative of establishing a different timetable for small manufacturers would allow these small entities additional time to consider how to meet these new emission limits, and, if necessary, an opportunity to redesign or retool manufacturing facilities. We expect that the emission limits would be performance, rather than design standards, in that the Commission would not specify how manufacturers must design their equipment. The Commission seeks additional comment from small entities on what an appropriate time limit for compliance would be, and the resulting costs.

45. The other proposals contained in this NPRM are deregulatory in nature, which we expect will simplify compliance and reporting requirements for all parties, particularly small entities. For example, we proposed to reduce the amount of information required on the label for products authorized through the Declaration of Conformity self-approval process. If this change were adopted, manufacturers would be permitted to use the simplified label as soon as the rules become effective, but would not be required to do so.

F. Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rule

46. None.

List of Subjects

47 CFR Part 2

Communications equipment, Radio, Reporting and recordkeeping requirements.

47 CFR Part 15

Communications equipment, Labeling, Radio, Reporting and recordkeeping requirements.

47 CFR Part 18

Business and industry, Medical devices, Radio, Reporting and recordkeeping requirements, Scientific equipment.

47 CFR Part 90

Communications equipment, Reporting and recordkeeping requirements.

Federal Communications Commission.

William F. Caton,

Deputy Secretary.

Rule Changes

For reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR, parts 2, 15, 18 and 90 as follows:

PART 2—FREQUENCY ALLOCATIONS AND RADIO TREATY MATTERS; GENERAL RULES AND REGULATIONS

1. The authority citation for part 2 continues to read as follows:

Authority: 47 U.S.C. 154, 302a, 303 and 336, unless otherwise noted.

2. In § 2.202(g) table, under III–A. Frequency Modulation the entry 6. Composite Emissions emissions is revised to read as follows:

§ 2.202 Bandwidths.

* * * * *

(g) * * *

Description of emission	Necessary bandwidth		Designation of emission
	Formula	Sample calculation	
* *	* *	* *	*
III–A. Frequency Modulation			
* *	* *	* *	*
6. Composite Emissions			
Radio-relay system	$B_n = 2K/t$ $K = 1.6$	Pulse position modulated by 36 voice channel baseband: pulse width at half amplitude 0.4 μS; $B_n = 8 \times 10^6$ Hz = 8 MHz (Bandwidth independent of the number of voice channels)	8M00M7E

[9] See 5 U.S.C. 603(c).

Description of emission	Necessary bandwidth		Designation of emission
	Formula	Sample calculation	
Composite transmission digital modulation using DSB–AM (Microwave radio relay system).	$B_n = 2RK/\log_2 S$	Digital modulation used to send 5 megabits per second by use of amplitude modulation of the main carrier with 4 signaling states $R = 5 \times 10^6$ bits per second; K = 1; S = 4; B_n = 5 MHz	5M00K7
Binary Frequency Shift Keying	(0.03 < 2D/R < 1.0); $B_n = 3.86D + 0.27R$ (1.0 < 2D/R < 2) $B_n = 2.4D + 1.0R$	Digital modulation used to send 1 megabit per second by frequency shift keying with 2 signaling states and 0.75 MHz peak deviation of the carrier. $R = 1 \times 10^6$ bps;$D = 0.75 \times 10^6$ Hz;B_n = 2.8 MHz	2M80F1D
Multilevel Frequency Shift Keying	$B_n = (R/\log_2 S) + 2DK$	Digital modulation to send 10 megabits per second by use of frequency shift keying with four signaling states and 2 MHz peak deviation of the main carrier. $R = 10 \times 10^6$ bps; D = 2 MHz; K = 1; S = 4; B_n= 9 MHz	9M00F7D
Phase Shift Keying	B_n= $2RK/\log_2 S$	Digital modulation used to send 10 megabits per second by use of phase shift keying with 4 signaling states $R = 10 \times 10^6$ bps; K = 1; S = 4; B_n= 10 MHz	10M0G7D
Quadrature Amplitude Modulation (QAM)	B_n= $2R/\log_2 S$	64 QAM used to send 135 Mbps has the same necessary bandwidth as 64–PSK used to send 135 Mbps; $R = 135 \times 10^6$ bps; S = 64; B_n= 45 MHz	45M0W
Minimum Shift Keying	2-ary: Bn = R(1.18) 4-ary: B_n= R(2.34)	Digital modulation used to send 2 megabits per second using 2-ary minimum shift keying $R = 2.36 \times 10^6$ bps; B_n= 2.36 MHz	2M36G1D

3. Section 2.948 is amended by adding a new sentence to the end of paragraph (a)(2) and by adding paragraphs (a)(2)(i), (a)(2)(ii), (a)(2)(iii) and (e) and, by revising paragraphs (a)(3), (b)(8) and (d) to read as follows:

§ 2.948 Description of measurement facilities.

(a) * * *

(2) * * * A laboratory that has been accredited in accordance with paragraph (d) of this section, is not required to file a description of its facilities with the Commission's laboratory, provided the accrediting organization (or designating authority in the case of foreign laboratories) submits the following information to the Commission's laboratory:

(i) Laboratory name, address and contact information.

(ii) Scope of accreditation.

(iii) Date of accreditation and renewal date of accreditation.

(3) If the equipment is to be authorized under the Declaration of Conformity procedure, the laboratory making the measurements must be accredited in accordance with paragraph (d) of this section.

(b) * * *

(8) For equipment that will be measured on an open field test site, a plot of site attenuation data taken pursuant to the procedures contained in sections 5.4.6 through 5.5 of the following procedure: Institute of Electrical and Electronics Engineers (IEEE) C63.4–2000, entitled ''Interim Standard for Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz,'' published by the Institute of Electrical and Electronics Engineers, Inc. on December 8, 2000 as document number SH94908. 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 of C63.4–2000 may be obtained from: IEEE Standards Department, 455 Hoes Lane, P.O. Box 1331, Piscataway, NJ 08855–1331, telephone 1–800–678–4333. Copies of ANSI C63.4–2000 may be inspected at the following locations:

(i) Federal Communications Commission, 445 12th Street, SW., Office of Engineering and Technology (room 7–B144), Washington, DC 20554,

(ii) Federal Communications Commission Laboratory, 7435 Oakland Mills Road, Columbia, MD 21046, or

(iii) Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

* * * * *

(d) A laboratory that has been accredited with a scope covering the required measurements shall be deemed competent to test and submit test data for equipment subject to verification, DoC and certification. Such a laboratory shall be accredited by an approved accreditation organization based on the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) Standard 17025, ''General Requirements for the Competence of Calibration and Testing Laboratories.'' The organization accrediting the laboratory must be approved by the Commission's Office of Engineering and Technology, as indicated in § 0.241 of this chapter, to perform such accreditation based on ISO/IEC 58, ''Calibration and Testing Laboratory Accreditation Systems—General Requirements for Operation and Recognition.'' The frequency for revalidation of the test site and the information that is required to be filed, or retained by the testing party shall comply with the requirements established by the accrediting organization.

(e) The accreditation of a laboratory located outside of the United States, or its possessions, will be acceptable only under one of the following conditions:

(1) If the accredited laboratory has been designated by a foreign designating authority and recognized by the Commission under the terms of a government-to-government Mutual Recognition Agreement/Arrangement; or

(2) If the laboratory has been recognized by the Commission as being accredited by an organization that has entered into an arrangement between accrediting organizations and the arrangement has been recognized by the Commission.

§ 2.1033 [Amended]

4. Section 2.1033 is amended by redesignating paragraph (c)(17) as paragraph (d).

5. Section 2.1055 is amended by revising paragraph (a)(2) to read as follows:

§ 2.1055 Measurements required: Frequency stability.

(a) * * *

(2) From −20° to +50° centrigrade for equipment to be licensed for use in the Maritime Services under part 80 of this chapter, except for Class A, B, and S Emergency Position Indicating Radiobeacons (EPIRBS), and equipment to be licensed for use above 952 MHz at operational fixed stations in all services, stations in the Local Television Transmission Service and Point-to-Point Microwave under part 21 of this chapter, and equipment licensed for use aboard aircraft in the Aviaiton Services under part 87 of this chapter, and equipment authorized for use in the Family Radio Service under Part 95 of this chapter.

* * * * *

§ 2.1061 [Removed]

6. Remove § 2.1061 and the undesignated center heading immediately preceding it.

§ 2.1063 [Removed]

7. Remove § 2.1063

§ 2.1065 [Removed]

8. Remove § 2.1065

PART 15—RADIO FREQUENCY DEVICES

9. The authority citation for part 15 continues to read as follows:

Authority: 47 U.S.C. 154, 302, 303, 304, 307, 336 and 544A.

10. Section 15.19 is amended by revising paragraphs (b)(1) introductory text and (b)(1)(i) introductory text to read as follows:

§ 15.19 Labeling requirements.

* * * * *

(b) * * *

(1) The label shall be located in a conspicuous location on the device and shall contain the unique identification described in § 2.1074 of this chapter and either of the following logos:

(i) If the product is authorized based on testing of the product or system:

* * * * *

11. Section 15.21 is amended by adding the following sentence to the end of the section to read as follows:

§ 15.21 Information to user.

* * * In cases where the manual is only available electronically through the Internet or other computer network, the information required by this section may be included in the electronic manual.

12. Section 15.31 is amended by revising paragraph (a) to read as follows:

§ 15.31 Measurement standards.

(a) The following measurement procedures are used by the Commission to determine compliance with the technical requirements in this part. Except where noted, copies of these procedures are available from the Commission's current duplicating contractor whose name and address are available from the Commission's Consumer Information Bureau at 1–888–CALL FCC (1–888–225–5322).

(1) FCC/OET MP–2: Measurement of UHF Noise Figures of TV Receivers.

(2) Unlicensed Personal Communication Service (UPCS) devices are to be measured for compliance using American National Standards Institute (ANSI) C63.17–1998, entitled ''American National Standard for Methods of Measurement of the Electromagnetic and Operational Compatibility of Unlicensed Personal Communications Services (UPCS) Devices'', published by the Institute of Electrical and Electronics Engineers, Inc. on March 24, 1998 as document number SH94568. 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.

(3) Other intentional and unintentional radiators are to be measured for compliance using the following procedure excluding sections 4.1.5.2, 5.7, 9 and 14: Institute of Electrical and Electronics Engineers (IEEE) C63.4—2000, entitled ''Interim Standard for Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz,'' published by the Institute of Electrical and Electronics Engineers, Inc. on December 8, 2000 as document number SH94908. 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.

(i) Copies of ANSI C63.17–1998 and C63.4–2000 may be obtained from: IEEE Standards Department, 455 Hoes Lane, P.O. Box 1331, Piscataway, NJ 08855–1331, telephone 1–800–678–4333.

(ii) Copies of ANSI C63.17–1998 and C63.4–2000 may be inspected at the following locations:

(A) Federal Communications Commission, 445 12th Street, SW, Office of Engineering and Technology (room 7–B144), Washington, DC 20554,

(B) Federal Communications Commission Laboratory, 7435 Oakland Mills Road, Columbia, MD 21046, or

(C) Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

13. Section 15.105 is amended by adding a new paragraph (e) to read as follows:

§ 15.105 Information to the user.

* * * * *

(e) In cases where the manual is only available electronically through the Internet or other computer network, the information required by this section may be included in the electronic manual.

§ 15.118 [Amended]

14. Section 15.118(b) is amended by removing the words ''Federal Communications Commission, 1919 M Street, NW., Dockets Branch (Room 239), Washington, DC'' and adding in its place the words, ''Federal Communications Commission, 445 12th Street, SW., Washington, DC.''

§ 15.120 [Amended]

15. Section 15.120(d)(1) is amended by removing the words ''Federal Communications Commission, 2000 M Street, NW., Technical Information Center (Suite 230), Washington, DC'' and adding in its place the words ''Federal Communications Commission, 445 12th Street, SW., Washington, DC''.

16. Section 15.205 is amended by adding paragraph (d)(6) to read as follows.

§ 15.205 Restricted bands of operation.

* * * * *

(d) * * *

(6) Devices operated pursuant to § 15.225 are exempt from complying with this section for the 13.36–13.41 MHz band only.

* * * * *

17. Section 15.215 is amended by adding paragraph (e) to read as follows:

§ 15.215 Additional provisions to the general radiated emission limitations.

* * * * *

(e) Intentional radiators transmitting in the spectrum below 490 kHz with a measured fundamental field strength 40 dB or more below the limits specified in § 15.209(a) for this band, are subject

only to the general conditions of operation in §§ 15.5 and 15.29 and are exempt from the specific technical standards and other requirements contained in this part. The operator of the exempted device shall be required to take any steps necessary to stop transmission from the device upon a finding by the Commission or its representative that the device is causing harmful interference. Transmission shall not resume until the condition causing the harmful interference has been corrected.

18. Section 15.225 is revised to read as follows:

§ 15.225 Operation within the band 13.110–14.010 MHz.

(a) The field strength of any emissions within the band 13.553–13.567 MHz shall not exceed 15,848 microvolts/meter at 30 meters.

(b) Within the bands 13.410–13.553 MHz and 13.567–13.710 MHz, the field strength of any emissions shall not exceed 334 microvolts/meter at 30 meters.

(c) Within the bands 13.110–13.410 MHz and 13.710–14.010 MHz the field strength of any emissions shall not exceed 106 microvolts/meter at 30 meters.

(d) The field strength of any emissions appearing outside of the 13.110–14.010 MHz band shall not exceed 30 microvolts/meter at 30 meters.

(e) The frequency tolerance of the carrier signal shall be maintained within ±0.01% of the operating frequency over a temperature variation of −20 degrees to +50 degrees C at normal supply voltage, and for a variation in the primary supply voltage from 85% to 115% of the rated supply voltage at a temperature of 20 degrees C. For battery operated equipment, the equipment tests shall be performed using a new battery.

(f) In the case of radio frequency powered tags designed to operate with a device authorized under this section, the tag may be approved with the device or be considered as a separate device subject to its own authorization. Powered tags approved with a device under a single application shall be labeled with the same identification number as the device.

19. Section 15.231 is amended by revising the section heading and the first sentence of paragraph (a) to read as follows:

§ 15.231 Operation in the band 40.66–40.70 MHz and above 70 MHz.

(a) The provisions of this section are restricted to operation within the band 40.66–40.70 MHz and above 70 MHz.* * *

* * * * *

20. Section 15.240 is added to read as follows:

§ 15.240 Operation in the band 425–435 MHz.

(a) Operation under the provisions of this section is restricted to devices that use radio frequency energy to locate and identify devices and exchange data. Devices operated pursuant to the provisions of this section shall be digital data devices and not be used for voice communications.

(b) The field strength of any emissions radiated within the specified frequency band shall not exceed 11,000 microvolts per meter measured at a distance of 3 meters. The emission limit in this paragraph is based on measurement instrumentation employing an average detector. The provisions in § 15.35 for limiting peak emissions apply. Additionally, devices authorized under these provisions shall be provided with a means for automatically limiting operation so that the duration of each transmission shall not be greater than 120 seconds and be only permitted to reinitiate an interrogation in the case of a transmission error. Absent such a transmission error, the silent period between transmissions shall not be less than 10 seconds.

(c) The field strength of emissions radiated on any frequency outside of the specified band shall not exceed the general radiated emission limits in § 15.209.

(d) The device shall be self-contained with no external or readily accessible controls that may be adjusted to permit operation in a manner inconsistent with the provisions in this section. Any antenna that may be used with this device shall be permanently attached and shall not be readily modifiable by the user.

(e) In the case of radio frequency powered tags designed to operate with a device authorized under this section, the tag may be approved with the device or be considered as a separate device subject to its own authorization. Powered tags approved with a device under a single application shall be labeled with the same identification number as the device.

21. Section 15.255 is amended by revising paragraph (b)(5) to read as follows.

§ 15.255 Operation within the band 59.0–64.0 GHz.

* * * * *

(b) * * *

(5) The average emission levels shall be calculated, based on the measured peak levels, over the actual time period during which transmission occurs.

* * * * *

PART 18—INDUSTRIAL, SCIENTIFIC, AND MEDICAL EQUIPMENT

22. The authority citation for part 18 continues to read as follows:

Authority: 47 U.S.C. 4, 301, 302, 303, 304, 307.

§ 18.103 [Removed].

23. Remove § 18.103.

§ 18.105 [Removed].

24. Remove § 18.105.

§ 18.119 [Removed].

25. Remove § 18.119.

PART 90—PRIVATE LAND MOBILE RADIO SERVICES

26. The authority citation for part 90 continues to read as follows:

Authority: Sections 4(i), 11, 303(g), 303(r), and 332(c)(7) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 161, 303(g), 303(r), 332(c)(7).

27. Section 90.203 is amended by revising paragraph (k) to read as follows:

§ 90.203 Certification required.

* * * * *

(k) For transmitters operating on frequencies in the 220–222 MHz band, certification will only be granted for equipment with channel bandwidths up to 5 kHz, except that certification will be granted for equipment operating on 220–222 MHz band Channels 1 through 160 (220.0025 through 220.7975/221.0025 through 221.7975), 171 through 180 (220.8525 through 220.8975/221.8525 through 221.8975), and 186 through 200 (220.9275 through 220.9975/221.9275 through 221.9975) with channel bandwidths greater than 5 kHz.

* * * * *

[FR Doc. 01–29344 Filed 11–26–01; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

49 CFR Parts 171, 173, 174, 175, 176, 177, and 178

[Docket No. RSPA–98–4952 (HM–223)]

RIN 2137–AC68

Applicability of the Hazardous Materials Regulations to Loading, Unloading, and Storage; Extension of Comment Period

AGENCY: Research and Special Programs Administration (RSPA), DOT.

ACTION: Proposed rule; extension of comment period.

SUMMARY: On June 14, 2001, RSPA published a notice of proposed rulemaking to clarify the applicability of the Hazardous Materials Regulations to specific functions and activities, including hazardous materials loading, unloading, and storage operations. The comment period for the proposed rule is extended until February 1, 2002, to provide commenters additional time because of delays they may have encountered in developing or submitting comments and to consider and comment on the proposed rule from the perspective of transportation security.

DATES: Submit comments by February 1, 2002. To the extent possible, we will consider comments received after this date in making our decision on a final rule.

ADDRESSES: Submit comments to the Dockets Management System, U.S. Department of Transportation, Room PL 401, 400 Seventh Street, SW., Washington, DC 20590–0001. Comments should identify Docket Number RSPA–98–4952 (HM–223) and be submitted in two copies. If you wish to receive confirmation of receipt of your written comments, include a self-addressed, stamped postcard. You may also e-mail comments by accessing the Dockets Management System Web site at *http://dms.dot.gov/* and following the instructions for submitting a document electronically. If you prefer, you can fax comments to 202–493–2251 for filing in the docket.

The Dockets Management System is located on the Plaza level of the Nassif Building at the Department of Transportation at the above address. You can review public dockets there between the hours of 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. You can also review comments on-line at the DOT Dockets Management System Web site at *http://dms.dot.gov/.*

FOR FURTHER INFORMATION CONTACT: Susan Gorsky (202) 366–8553, Office of Hazardous Materials Standards, Research and Special Programs Administration.

SUPPLEMENTARY INFORMATION:

Background

On June 14, 2001, the Research and Special Programs Administration (RSPA, we) published a notice of proposed rulemaking (NPRM) (66 FR 32420) under Docket RSPA–98–4952 (HM–223) to clarify the applicability of the Hazardous Materials Regulations (HMR; 49 CFR parts 171–180) to specific functions and activities, including hazardous materials loading and unloading operations and storage of hazardous materials during transportation. The HM–223 rulemaking has four overall goals. First, we want to maintain nationally uniform standards applicable to functions performed in advance of transportation to prepare hazardous materials for transportation. Second, we want to maintain nationally uniform standards applicable to transportation functions. Third, we want to distinguish functions that are subject to the HMR from functions that are not subject to the HMR. Finally, we want to clarify that facilities within which HMR-regulated functions are performed may also be subject to federal, state, or local regulations governing occupational safety and health or environmental protection.

To achieve these goals, the NPRM proposes to list in the HMR pre-transportation and transportation functions to which the HMR apply. Pre-transportation functions are functions performed to prepare hazardous materials for movement in commerce by persons who offer a hazardous material for transportation or cause a hazardous material to be transported. Transportation functions are functions performed as part of the actual movement of hazardous materials in commerce, including loading, unloading, and storage of hazardous materials that is incidental to their movement. The NPRM also proposes to clarify that ''transportation in commerce,'' for purposes of applicability of the HMR, begins when a carrier takes possession of a hazardous material and continues until the carrier delivers the package containing the hazardous material to its destination as indicated on shipping papers. In addition, the NPRM proposes to include in the HMR an indication that facilities at which functions regulated by the HMR occur may also be subject to applicable standards and regulations of other federal agencies and state, local, and tribal governments. Finally, the NPRM proposes to include in the HMR the statutory criteria under which non-federal governments may be precluded from regulating in certain areas under the preemption provisions of the federal hazardous materials transportation law (49 U.S.C. 5101 *et seq.*)

As a result of the terrorist atrocities committed against the World Trade Center and the Pentagon on September 11, 2001, and subsequent threats related to biological materials, the Department of Transportation is engaged in a broad review of its transportation safety and security programs, including many of its ongoing rulemaking actions. In light of the potential for continuing terrorist threats and the critical need to assure the security of hazardous materials at fixed facilities and in transportation, a rule that specifies the applicability of the HMR to specific functions and activities and clarifies the relationship of the HMR to programs and regulations administered by EPA and OSHA is more important than ever. We intend to move forward with this rulemaking as expeditiously as possible.

We recognize, however, that the current timeframe for submitting comments on the NPRM may not provide sufficient opportunity for commenters because of delays caused by the terrorist activities and the potential desire of commenters to consider and comment on the proposed rule from the perspective of transportation security. Therefore, we are extending the comment period for the HM–223 rulemaking until February 1, 2002.

You should be aware that we are experiencing some delays in mail deliveries as a result of ongoing efforts to ensure that mail is not contaminated with infectious or harmful materials. We encourage you to take advantage of the opportunities provided by the DOT Dockets Management System to submit comments electronically or by fax.

Issued in Washington, DC, on November 20, 2001.

Robert A. McGuire,

Associate Administrator for Hazardous Materials Safety, Research and Special Programs Administration.

[FR Doc. 01–29392 Filed 11–26–01; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 011015252–1252–01; I.D. 053001E]

RIN 0648–AO23

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Golden Crab Fishery off the Southern Atlantic States; Amendment 3

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS issues this proposed rule to implement Amendment 3 to the Fishery Management Plan for the Golden Crab Fishery of the South Atlantic Region (FMP). This rule would extend through December 31, 2002, the allowed use of cable for a mainline attached to golden crab traps; clarify the size of the required escape panel or door on a golden crab trap; remove the historical catch requirement for renewing a commercial vessel permit for golden crab; allow the issuance of a commercial vessel permit for golden crab for the southern zone for a vessel that held a valid permit for the southern zone in October 2000 but did not meet the 5,000-lb (2,268-kg) requirement for renewal in the following year; allow a vessel with a documented length overall greater than 65 ft (19.8 m) that is permitted to fish in the southern zone to fish also in the northern zone; allow two new commercial vessel permits to be issued for the northern zone; provide that a commercial vessel permit will not be renewed if the Regional Administrator (RA) does not receive an application for renewal by June 30 each year; liberalize the allowed increase in the size of a permitted vessel; create a small-vessel sub-zone in the southern zone in which only permitted vessels 65 feet (19.8 m) or less in length may fish for golden crab but may not do so in the remainder of the southern zone; and add measures related to the proposed sub-zone to the list of management measures that may be modified via the FMP's framework procedure for regulatory adjustments. The intended effect is to protect the golden crab resource while allowing development of the fishery that is dependent on that resource.

DATES: Comments on this proposed rule must be received no later than 5 p.m., eastern time, on January 11, 2002.

ADDRESSES: Written comments on this proposed rule must be mailed to the Regional Administrator, Southeast Region, NMFS, 9721 Executive Center Drive N., St. Petersburg, FL 33702. Comments also may be sent via fax to 727–570–5583. Comments will not be accepted if submitted via e-mail or the Internet.

Copies of Amendment 3, including the environmental assessment, regulatory impact review, and social impact assessment/fishery impact statement may be obtained from Dr. Peter J. Eldridge, Southeast Regional Office, NMFS, 9721 Executive Center Drive N., St. Petersburg, FL 33702, phone: 727–570–5305; fax: 727–570–5583; e-mail: Peter.Eldridge@noaa.gov.

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this rule may be submitted to Robert Sadler, Southeast Regional Office, NMFS, 9721 Executive Center Drive N., St. Petersburg, FL 33702, and to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, DC 20503 (Attention: NOAA Desk Officer).

FOR FURTHER INFORMATION CONTACT: Dr. Peter J. Eldridge, Southeast Regional Office, NMFS; phone: 727–570–5305; fax: 727–570–5583; e-mail: Peter.Eldridge@noaa.gov.

SUPPLEMENTARY INFORMATION: The golden crab fishery off the southern Atlantic states is managed under an FMP that was prepared by the South Atlantic Fishery Management Council (Council) and implemented under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

Use of Wire Cable for Mainlines

The use of cable for mainlines in the South Atlantic golden crab fishery was authorized for an initial trial period when the FMP was implemented in 1996. The trial period was later renewed for an additional period of 20 months. This trial period was instituted at the request of the industry based on possible advantages in handling cable versus rope. One of the original concerns regarding cable used for mainlines was the potential for gear conflicts when it is used in an area where rope mainlines are deployed. The extended trial period, which ended December 31, 2000, was intended to assess that concern. Use of cable has been infrequent; no vessels were using it when the trial period ended, but some vessel owners and/or operators expressed interest in exploring its use. Authorizing the use of cable for mainlines for an additional trial period through December 31, 2002, would facilitate further evaluation of its possible involvement in gear conflicts versus its potential economic benefits for fishermen.

Modification of Escape Panels or Doors

All golden crab traps constructed of material other than webbing are currently required to have an escape panel or door measuring at least 12 by 12 inches (30.5 by 30.5 cm). The purpose of the escape panel or door is to allow golden crabs to escape from traps and reduce crab mortality from lost or ghost traps that continue to trap fish. Golden crab traps are constructed of 2-inch (5.1-cm) mesh. Cutting an opening 6 meshes by 6 meshes would appear to meet the minimum size requirement. However, because of the diameter of the wire mesh, an opening of 6 meshes by 6 meshes is slightly smaller than the size that is required, and an opening 7 meshes by 7 meshes weakens the trap. To accommodate these concerns, the size would be revised to require an escape panel or door of at least 11 7/8 by 11 7/8 inches (30.2 by 30.2 cm). This reduced size would not materially lessen the ability of a golden crab to escape.

Removal of the Minimum Required Harvest Level for Permit Renewal

Currently, for a golden crab vessel permit to be renewed, at least 5,000 lb (2,268 kg) of golden crab from the South Atlantic exclusive economic zone (EEZ) must have been landed by the permitted vessel during at least one of the two 12-month periods immediately prior to the expiration date of the permit. This requirement was intended to reduce the number of permits, particularly in the southern zone. Due in part to this minimum required harvest level, the number of participants in the fishery in the southern zone has been significantly reduced. There are currently zero participants in the northern zone. The Council concluded that because of the low number of participants, the minimum required harvest level for permit renewal is no longer necessary. In fact, if participation in the fishery is reduced, it may result in a negative impact on the economic viability of the fishery. To support the market structure for golden crab that has been developed, a certain level of landings must be maintained.

Additional Permits for the Southern Zone

As discussed above, participation in the fishery is currently at a low level. Some of the vessel owners who initially participated in the fishery in the southern zone have not met the minimum required harvest level for permit renewal in the last two years because of more lucrative alternative fisheries and/or gear conflicts within the golden crab fishery. To benefit the economic viability of the fishery, this rule proposes to issue, upon application, a commercial vessel permit for the southern zone for any vessel submitting an appropriate application if that vessel held a valid permit for the southern zone in October 2000 but did not meet the 5,000-lb (2,268-kg) requirement for renewal for the following permit year beginning November 1, 2000. In order to be considered, an application for a permit under this provision would have to be received by the RA no later than 60 days after the date of publication of the final rule containing this provision.

Additional Fishing in the Northern Zone

Currently, there are no permits issued for vessels in the northern zone. Due to the lack of fisheries effort in the northern zone, information on the population of golden crab in this zone is limited. Additional information would contribute to determining more accurately the maximum sustainable yield (MSY) of golden crab.

Accordingly, this rule would allow a vessel with a documented length overall greater than 65 ft (19.8 m) (large vessel) that is permitted for the southern zone to fish also in the northern zone. This opportunity for these large vessels to fish in the northern zone would expire 3 years after the final rule to implement this measure becomes effective. This opportunity to fish in the northern zone would require a change in a large vessel's permit from the southern zone to the northern zone only if the vessel owner desires to transfer the permit to a vessel whose documented length overall was greater than 20 percent more than the replaced vessel. See ''Less Restrictive Limit on Vessel Size Increases'' below for additional information on transfer of a permit to a vessel of greater length and limited provisions for a change of zone back to the southern zone. The currently available option for the owner of a vessel of any length to change zones to the northern zone would remain in effect, thus allowing a permanent change to the northern zone for a large vessel after the 3-year period expires.

In addition, this rule would allow NMFS to issue up to two new permits for the northern zone. Offers for the two new permits would be made to the individuals on the list of historical participants in the South Atlantic golden crab fishery that was used at the October 1995 meeting of the Council, less those on the list who originally received permits. Placement on the list was based on pounds of golden crab landed, without reference to a specific zone. Offers will be made in writing to individuals highest on the list until two accept and apply for permits. A maximum of 30 days would be allowed for acceptance of such an offer and, if accepted, an application would be required to be received by the RA within 30 days of acceptance. A vessel permit for the northern zone issued under this provision, and any successor permit, could not be changed to another zone. Any successor permit would include a permit issued to that vessel for a subsequent owner and a permit issued via transfer from that vessel to another vessel.

The proposed increased effort in the northern zone would not be expected to result in overfishing in that zone.

Less Restrictive Limit on Vessel Size Increases

Currently, to obtain a permit by transfer of an existing permit, the owner of the receiving vessel must acquire a permit from a vessel with a documented length overall, or permits from vessels with aggregate lengths overall, of at least 90 percent of the documented length overall of the receiving vessel. The Council proposes to ease this restriction. Accordingly, this rule would allow the transfer of a permit or permits for transfer to a replacement vessel whose documented length overall is up to 20 percent more than the documented length overall of the currently permitted vessel(s). For example, permits for vessels whose documented lengths overall totaled 80.0 ft (24.4 m) could be used to obtain a permit for a vessel with documented length overall of up to 96.0 ft (29.3 m) (80.0 + [.20 x 80.0] = 96.0).

The Council believes this measure is desirable for the added safety that generally is associated with the use of larger vessels and for the possible economic benefits of operating from larger vessels. The Council further believes that the increased harvesting capacity that generally occurs when using larger vessels will not jeopardize the continued viability of the fishery.

Because of the harsher weather conditions prevalent in the northern zone and the paucity of vessels permitted in that zone, the proposed limitation on transfers described above would not apply to vessels with permits to fish in the northern zone. To avail oneself of this exemption in the northern zone (i.e., upgrade by more than 20 percent), an owner of a vessel that is permitted for the southern zone would have to request a permit change to the northern zone and would be allowed to change the permit back to the southern zone only by transferring the permit to a vessel with a documented length overall no greater than 20 percent more than the vessel whose permit was originally changed from the southern zone to the northern zone. A request for a change back to the southern zone would have to be received by the RA no later than 3 years after the final rule to implement this measure becomes effective.

Permit Renewals

This rule would provide that NMFS will not renew a permit for golden crab if the RA does not receive an application for renewal by June 30 each year, that is, within 6 months into the fishing year. The Council believes that this 6-month period provides adequate time for a vessel owner to decide whether to continue in the fishery, thus providing the Council advance information necessary to effectively manage the fishery and achieve the stated objectives of the FMP. A specific deadline for renewal would also relieve NMFS of the administrative burden of keeping track of all possible future participants in the fishery.

Small-vessel Sub-zone

This rule would create a sub-zone in the southern zone. The sub-zone would be approximately 22 nautical miles (nm) south of Key West, Florida, and encompass an area of approximately 8 by 30 nm. No vessel with a documented length overall greater than 65 ft (19.8 m) would be allowed to fish for golden crab in this sub-zone, and a vessel with a documented length overall of 65 ft (19.8 m) or less that is permitted for the southern zone would be allowed to fish for golden crab only in this sub-zone. The creation of a small-vessel sub-zone would address reported conflicts between large and small vessels in the southern zone, which have resulted in gear and other economic losses. The Council intends that the sub-zone would exist for a minimum of 3 years, during which time the Council would monitor harvest data from the sub-zone and other information to determine benefits of the sub-zone and alternatives for future action.

Framework Procedure

In accordance with the FMP, certain items related to the management of golden crab may be established or modified via a framework procedure that enables more timely implementation than is possible via an amendment to the FMP. This proposed rule would add the sub-zone in the southern zone to the items for which the framework procedure is applicable. Changes to the sub-zone would include, but not be limited to, the size, timeframe, seasonality, repealing, and eligibility requirements.

Additional Measures in Amendment 3

In addition to the measures described above for the management of golden crab, in Amendment 3 the Council proposed to establish: MSY; maximum fishing mortality threshold (MFMT), the fishing mortality rate which, if exceeded, constitutes overfishing; and minimum stock size threshold (MSST), the stock size below which golden crab are overfished. The Council's proposals are as follows:

MSY—between 4 and 12 million lbs (1,814 and 5,443 metric tons).

MFMT—a fishing mortality rate that is in excess of the fishing mortality rate that produces MSY.

MSST—a ratio of either current biomass to biomass at MSY (B_{MSY}) or one minus the natural mortality rate (1 - M) times B_{MSY}, where 1 - M should never be less than 0.5.

Data for golden crab are very limited and available resources within NMFS do not allow sufficient data collection. Accordingly, the specification of MSY covers a broad range and MFMT and MSST lack numerical specificity. Specificity will be added as data become available. In its ''Report to Congress—Status of Fisheries of the United States,'' January 2001, NMFS concluded that overfishing was not occurring in the golden crab fishery. The FMP does not contain a definition of ''overfished'' at this time.

Partial Approval of Amendment 3—Disapproval of Proposed MSY

On September 12, 2001, NMFS partially approved Amendment 3. NMFS approved all provisions of Amendment 3 except the proposed MSY, 4 to 12 million lb (1.8 to 5.4 million kg). Based on the best available scientific information, including results of the most recent stock status evaluation, NMFS concluded that the proposed MSY was risk prone and could lead to overfishing.

Availability of Amendment 3

Additional background and rationale for the measures discussed above are contained in Amendment 3. The availability of Amendment 3 was announced in the **Federal Register** on June 12, 2001 (66 FR 31608). Written comments on Amendment 3 were invited through August 13, 2001. No public comments were received. All comments received on this proposed rule during the public comment period will be addressed in the preamble to the final rule.

Classification

NMFS has determined that Amendment 3, except for the disapproved MSY, is consistent with the national standards of the Magnuson-Stevens Act and other applicable laws.

This proposed rule has been determined to be not significant for purposes of E.O. 12866.

The Chief Counsel for Regulation of the Department of Commerce has certified to the Chief Counsel of Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities as follows:

The Magnuson-Stevens Act provides the statutory basis for the rule. The proposed rule will not require any new reporting or record keeping on the part of the commercial entities. No duplicative, overlapping or conflicting Federal rules have been identified. The objectives of the proposed rule are: to stabilize yield and maintain population levels sufficient to ensure adequate recruitment; provide a flexible management system; and optimize the social and economic benefits of the golden crab fishery.

Although no participant in the golden crab fishery currently utilizes cable mainlines, they have been successfully used in other fisheries and interest in their use has been expressed by fishery participants. Such interest is due to the fact that some participants already possess this gear for use in other fisheries in which they participate. Fishermen who do not already possess cable gear can choose to obtain it or continue using gear they already possess. Extending the period for allowed use of cable, therefore, will allow operators to utilize potentially more cost- efficient gear, leading to reduced gear-up costs and gear-storage safety gains. The proposed specification of the size of the required escape panel will bring the specification in line with the current dimensions of manufactured mesh. This will reduce enforcement conflict between fishermen and enforcement officers. Elimination of the historical catch requirement will allow historical small-scale participants to remain in the fishery, which will in turn allow for a more stable level of participation as well as product supply to maintain current markets. Allowing the southern-permitted vessels to fish in the northern zone will also assist in achieving this objective. Allowing vessels to increase their size will better fit the safety requirements of their fishery. The creation of a small-vessel sub-zone in the southern zone will reduce vessel conflicts between the large and small vessels, thereby reducing the gear and revenue losses attributed to these conflicts. Between 1997 and 2000, no commercial vessels have operated in the northern zone. Therefore, allowing two new commercial vessel permits to be issued for the northern zone may lead to increased harvests and revenues, and result in better maintenance of a consistent supply of golden crab to the market. Expanding the list of management measures that may be modified via the FMP's framework procedure will result in a more efficient functioning of the management process.

Generally, a fish-harvesting business is considered a small business if it is independently owned and operated and not dominant in its field of operation and if it has annual receipts not in excess of $3.0 million. Business operations in the golden crab fishery consist solely of small business entities. This conclusion is based on the following facts. In 1997, gross revenues from the golden crab fishery in the Southeast region were approximately $1.22 million, of which slightly more than $943,000 came from the South Atlantic. Based on preliminary data for 2000, gross revenues from the golden crab fishery in the Southeast region were approximately $1.04 million, of which slightly more than $858,000 came from the South Atlantic. In 1997, small vessels (65 ft (19.8 m) and below in overall length) accounted for 78 percent of the gross revenues from the Southeast region and 91 percent of the gross revenues from the South Atlantic. In 2000, these percentages were slightly less, at 69 percent and 83 percent, respectively. For small vessels participating in the South Atlantic fishery, average gross revenue from golden crab harvests ranged from a low of $78,267 in 1997 to a high of $163,543 in 1999.

The number of participants that will be affected by the proposed rule is estimated to be between 8 and 12 commercial vessels. In 1997, the year for which participation was the highest, 13 vessels were active in the South Atlantic golden crab fishery. However, based on preliminary data for 2000, there were only 8 active vessels in this fishery. Between 1997 and 2000, less than five large vessels participated in the fishery, while the number of small vessels did not exceed 12. In 2000, 38 percent of the vessels (large and small) generated approximately 95 percent of the gross revenues from the South Atlantic golden crab fishery.

Elimination of the minimum harvest requirement may attract some of the vessels that were eligible for renewal in 2000, but failed to meet the minimum landings requirement in effect at that time. Two vessels could re-enter the fishery as a result of eliminating the minimum harvest requirement. Additionally, two new permits for the northern zone could be issued to vessels that were on the original list of those interested in entering the fishery but

excluded from the original permit distribution. As a result of the existing rules and proposed rule changes, a maximum of 12 commercial vessels will be allowed to participate in the South Atlantic golden crab fishery.

The determination of significant economic impact can be ascertained by examining two criteria, disproportionality and profitability. The disproportionality question is: do the regulations place a substantial number of small entities at a significant competitive disadvantage to large entities? Although some variation exists between vessel lengths and degree of participation in the fishery, all are classified as small entities. Thus, the issue of disproportionality is irrelevant in the present case.

The profitability question is: do the regulations significantly reduce profit for a substantial number of small entities? In 1997, 100 percent of the large vessels' South Atlantic and 32 percent of their total golden crab revenues came from the sub-zone. However, based on the preliminary 2000 data, the vast majority of their gross revenues presently come from the remainder of the southern zone (43 percent) and the Gulf (56 percent). The large vessels would only lose 0.9 percent of their total golden crab revenues as a result of being excluded from the sub-zone. With respect to the South Atlantic component of the fishery, all large vessels have only been permitted to operate in the Southern zone. For small vessels permitted to operate only in the Southern zone, 49 percent of their total golden crab revenues in 1997 came from the southern zone outside the sub-zone. In 2000, this percentage decreased to 28 percent. Even though the latter percentage appears to still be large, it represents a very small dollar figure in absolute terms. This absolute figure cannot be provided for confidentiality reasons. Since the absolute figure is trivial, small vessels will easily be able to compensate for this loss via a minimal increase in their sub-zone activity.

Since profits must necessarily be less than gross revenues, the creation of the sub-zone would not significantly reduce profits for either the large or small vessels. And as the other proposed regulations are expected to either decrease costs, increase revenues, or have no effect on the fishery participants, no small entities are expected to experience any significant and adverse economic impacts as a result of this rule. On this basis, the proposed rule may be adjudged not to have a significant economic impact on a substantial number of small entities.

Accordingly, a regulatory flexibility analysis was not prepared.

Notwithstanding any other provision of law, no person is required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA unless that collection of information displays a currently valid OMB control number.This rule contains but does not change two collection-of-information requirements subject to the Paperwork Reduction Act (PRA); namely, the application for a permit for the South Atlantic golden crab fishery and the submission of fishing vessel logbooks in that fishery. These collections of information have been approved by OMB under control numbers 0648-0205 and 0648-0016, respectively. The public reporting burdens for these collections of information are estimated at 20 minutes for each permit application and 10 minutes for each fishing vessel logbook submission. The estimates of public reporting burdens for these collections of information include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding these burden estimates or any other aspects of the collections of information, including suggestions for reducing the burdens, to NMFS and OMB (see **ADDRESSES**).

List of Subjects in 50 CFR Part 622

Fisheries, Fishing, Puerto Rico, Reporting and recordkeeping requirements, Virgin Islands.

Dated: November 20, 2001.

William T. Hogarth,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 622 is proposed to be amended as follows:

PART 622—FISHERIES OF THE CARIBBEAN, GULF, AND SOUTH ATLANTIC

1. The authority citation for part 622 continues to read as follows:

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

2. In § 622.7, paragraph (z) is revised to read as follows:

§ 622.7 Prohibitions.

* * * * *

(z) Fish for or possess golden crab in or from a fishing zone or sub-zone of the South Atlantic EEZ other than the zone or sub-zone for which the vessel is permitted or authorized, as specified in § 622.17(b).

* * * * *

3. Section 622.17 is revised to read as follows:

§ 622.17 South Atlantic golden crab controlled access.

(a) *General.* In accordance with the procedures specified in the Fishery Management Plan for the Golden Crab Fishery of the South Atlantic Region, initial commercial vessel permits have been issued for the fishery. All permits in the fishery are issued on a fishing-year (calendar-year) basis. No additional permits may be issued except as follows:

(1) *For the southern zone.* (i) Upon application, the RA will reissue a permit for the southern zone for a vessel that held a valid permit for that zone in October 2000 but did not meet the 5,000-lb (2,268-kg) requirement for renewal in the following year.

(ii) An application for a permit under paragraph (a)(1) of this section must be received by the RA no later than 60 days after the date of publication of the final rule containing this paragraph.

(2) *For the northern zone.* (i) The RA will issue up to two new vessel permits for the northern zone. Selection will be made from the list of historical participants in the South Atlantic golden crab fishery. Such list was used at the October 1995 meeting of the South Atlantic Fishery Management Council and was prioritized based on pounds of golden crab landed, without reference to a specific zone. Individuals on the list who originally received permits will be deleted from the list.

(ii) The RA will offer in writing an opportunity to apply for a permit for the northern zone to the individuals highest on the list until two accept and apply in a timely manner. An offer that is not accepted within 30 days after it is received will no longer be valid.

(iii) An application for a permit from an individual who accepts the RA's offer must be received by the RA no later than 30 days after the date of the individual's acceptance. Application forms are available from the RA.

(iv) A vessel permit for the northern zone issued under paragraph (a)(2) of this section, and any successor permit, may not be changed to another zone. A successor permit includes a permit issued to that vessel for a subsequent owner and a permit issued via transfer from that vessel to another vessel.

(b) *Fishing zones*—(1) *Designation of fishing zones.* The South Atlantic EEZ is divided into three fishing zones for golden crab as follows:

(i) Northern zone—the South Atlantic EEZ north of 28° N. lat.

(ii) Middle zone—the South Atlantic EEZ from 28° N. lat. to 25° N. lat.

(iii) Southern zone—the South Atlantic EEZ south of 25° N. lat.

(2) *Authorization to fish in zones.* Each vessel permit indicates one of the zones specified in paragraph (b)(1) of this section. A vessel with a permit to fish for golden crab in the northern zone or the middle zone may fish only in that zone. A vessel with a documented length overall greater than 65 ft (19.8 m) with a permit to fish for golden crab in

the southern zone may fish in that zone, consistent with the provisions of paragraph (b)(3) of this section, and, through a date 3 years from the date this paragraph is effective, may also fish in the northern zone. A vessel may possess golden crab only in a zone in which it is authorized to fish, except that other zones may be transited if the vessel notifies NMFS, Office of Enforcement, Southeast Region, St. Petersburg, FL, by telephone (727–570–5344) in advance and does not fish in a zone in which it is not authorized to fish.

(3) *Small-vessel sub-zone*. Within the southern zone, a small-vessel sub-zone is established bounded on the north by 24°15′ N. lat., on the south by 24°07′ N. lat., on the east by 81°22′ W. long., and on the west by 81°56′ W. long. No vessel with a documented length overall greater than 65 ft (19.8 m) may fish for golden crab in this sub-zone, and a vessel with a documented length overall of 65 ft (19.8 m) or less that is permitted for the southern zone may fish for golden crab only in this sub-zone.

(4) *Procedure for changing zones*. (i) Upon request from an owner of a permitted vessel, the RA will change the zone specified on a permit from the middle or southern zone to the northern zone. No other changes in the zone specified on a permit are allowed, except as specified in paragraph (b)(4)(ii) of this section. An owner of a permitted vessel who desires a change to the northern zone must submit his/her request with the existing permit to the RA.

(ii) Through a date 3 years after the date this paragraph (b)(4) is effective, upon request, the RA will change a vessel permit back to the southern zone for an owner of a vessel, or the subsequent owner of a vessel, whose permit was changed from the southern zone to the northern zone provided that the documented length overall of the vessel to be used in the southern zone is not more than 20 percent greater than the vessel whose permit was originally changed from the southern zone to the northern zone.

(c) *Transferring permits between vessels*—(1) *Procedure for transferring*. An owner of a vessel who desires a golden crab permit may request that NMFS transfer an existing permit or permits to his or her vessel by returning an existing permit or permits to the RA with an application for a permit for the replacement vessel.

(2) *Vessel size limitations on transferring*. (i) To obtain a permit for the middle or southern zone via transfer, the documented length overall of the replacement vessel may not exceed the documented length overall, or aggregate documented lengths overall, of the replaced vessel(s) by more than 20 percent. The owner of a vessel permitted for the middle or southern zone who has requested that NMFS transfer that permit to a smaller vessel (i.e., downsized) may subsequently request NMFS transfer that permit to a vessel of a length calculated from the length of the permitted vessel immediately prior to downsizing.

(ii) There are no vessel size limitations to obtain a permit for the northern zone via transfer.

(d) *Permit renewal*. NMFS will not renew a commercial vessel permit for South Atlantic golden crab if the permit is revoked or if the RA does not receive an application for renewal within 6 months after the permit's expiration, that is, by June 30 each year. See § 622.4(h) for the general procedures and requirements for permit renewals.

4. In § 622.40, the first sentence of paragraph (b)(3)(ii)(B) and paragraph (d)(2)(ii) are revised to read as follows:

§ 622.40 Limitations on traps and pots.

* * * * *

(b) * * *

(3) * * *

(ii) * * *

(B) A golden crab trap constructed of material other than webbing must have an escape panel or door measuring at least 11 7/8 by 11 7/8 inches (30.2 by 30.2 cm), located on at least one side, excluding top and bottom. * * *

* * * * *

(d) * * *

(2) * * *

(ii) Rope is the only material allowed to be used for a buoy line or mainline attached to a golden crab trap, except that wire cable is allowed for a mainline through December 31, 2002.

5. In § 622.48, paragraph (g) is revised to read as follows:

§ 622.48 Adjustment of management measures.

* * * * *

(g) *South Atlantic golden crab*. Biomass levels, age-structured analyses, MSY, ABC, TAC, quotas (including quotas equal to zero), trip limits, minimum sizes, gear regulations and restrictions, permit requirements, seasonal or area closures, sub-zones and their management measures, time frame for recovery of golden crab if overfished, fishing year (adjustment not to exceed 2 months), observer requirements, authority for the RA to close the fishery when a quota is reached or is projected to be reached, definitions of essential fish habitat, and essential fish habitat HAPCs or Coral HAPCs.

* * * * *

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[I.D. 111401B]

RIN 0648–AN55

Fisheries of the Exclusive Economic Zone Off Alaska; Amendments 61/61/13/8 to Implement Major Provisions of the American Fisheries Act

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

ACTION: Notice of availability; request for comments.

SUMMARY: The North Pacific Fishery Management Council (Council) has submitted Amendment 61 to the Fishery Management Plan for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area, Amendment 61 to the Fishery Management Plan for Groundfish of the Gulf of Alaska, Amendment 13 to the Fishery Management Plan for Bering Sea and Aleutian Islands King and Tanner Crab, and Amendment 8 to the Fishery Management Plan for the Scallop Fishery off Alaska (FMPs). These amendments incorporate the provisions of the American Fisheries Act (AFA) into the FMPs and their implementing regulations. These amendments are necessary to implement the requirements of the AFA and are intended to do so in a manner consistent with the environmental and socioeconomic objectives of AFA, the Magnuson-Stevens Fishery Management and Conservation Act (Magnuson-Stevens Act), the FMPs, and other applicable laws. NMFS is requesting comments from the public on Amendments 61/61/13/8, copies of which may be obtained from NMFS (see **ADDRESSES**).

DATES: Comments on Amendments 61/61/13/8 must be submitted by January 28, 2002.

ADDRESSES: Comments on proposed Amendments 61/61/13/8 should be submitted to Sue Salveson, Assistant Regional Administrator for Sustainable Fisheries, Alaska Region, NMFS, P.O. Box 21668, Juneau, AK, 99802, Attn:

Lori Gravel, or delivered to room 401 of the Federal Building, 709 West 9th Street, Juneau, AK. Comments will not be accepted if submitted via e-mail or Internet. Copies of Amendments 61/61/13/8 and the Environmental Impact Statement/Regulatory Impact Review/Initial Regulatory Flexibility Analysis prepared for Amendments 61/61/13/8 are available from the NMFS at the above address.

FOR FURTHER INFORMATION CONTACT: Kent Lind, 907–586–7228 or email at kent.lind@noaa.gov.

SUPPLEMENTARY INFORMATION: The Magnuson-Stevens Act requires that each Regional Fishery Management Council submit any fishery management plan or plan amendment it prepares to NMFS for review and approval, disapproval, or partial approval. The Magnuson-Stevens Act also requires that NMFS, after receiving a fishery management plan or plan amendment, immediately publish a notice in the **Federal Register** that the fishery management plan or plan amendment is available for public review and comment. This action constitutes such notice for Amendments 61/61/13/8. NMFS will consider the public comments received during the comment period in determining whether to approve Amendments 61/61/13/8.

Background on the AFA

On October 21, 1998, the President signed into law the AFA (Div. C, Title II, Pub. L. No. 105-277, 112 Stat. 2681 (1998)). The AFA is divided into two subtitles addressing the requirements for fishery endorsements for all U.S. fishing vessels, and providing for the reorganization and rationalization of the Bering Sea and Aleutian Islands Area (BSAI) pollock fishery, respectively.

Subtitle I–Fisheries Endorsements established a 25 percent foreign ownership and control limit for all U.S. documented fishing vessels over 100 ft (30.9 meters (m)) registered length. Subtitle I also limits new U.S. documented fishing vessels to no more than 165 ft (59.3 m) registered length, no more than 3,000 lbs (1.36 metric tons (mt) shaft horsepower, and no more than 750 gross registered tons (680 mt). The provisions of this subtitle apply to all U.S. documented fishing vessels fishing anywhere in the U.S. EEZ and are being implemented by the Maritime Administration (MARAD) and the U.S. Coast Guard.

Subtitle II–Bering Sea Pollock Fishery mandated sweeping changes to the BSAI pollock fishery and to a lesser extent, affected the management of the other groundfish, crab, and scallop fisheries off Alaska. The purpose of Amendments 61/61/13/8 is to implement the management program required by Subtitle II of the AFA.

Congress identified two primary objectives in passing the AFA. The first objective was to complete the process begun in 1976 to give U.S. interests a priority in the harvest of U.S. fishery resources. This objective was accomplished through the restrictions on foreign ownership and control that are set out in Subtitle I of the AFA. The second objective addressed by Subtitle II of the AFA was to significantly decapitalize the Bering Sea pollock fishery. Under the council system established by the Magnuson-Stevens Act, Congressional action is generally not needed to address fishery conservation and management issues in specific fisheries. However, Congress believed that the overcapacity in the BSAI pollock fishery prior to the AFA was due, in part, to mistakes in, and misinterpretations of, the 1987 Commercial Fishery Industry Vessel Anti-Reflagging Act (Anti-Reflagging Act). In passing the AFA, Congress noted that the Anti-Reflagging Act had allowed a flood of foreign-rebuilt catcher/processors into the BSAI pollock fishery and did not limit foreign control of such vessels in the manner in which Congress had intended. Without an Act of Congress, the Council and NMFS did not have authority to provide funds under the Federal Credit Reform Act to buyout and retire vessels from the BSAI pollock fishery, to strengthen U.S. controlling interest standards for fishing vessels, or to implement the inshore cooperative program contained in the AFA.

Subtitle 2 of the AFA contains numerous provisions that affect the management of the groundfish and crab fisheries off Alaska. Key provisions include:

1. The buyout of nine pollock catcher/processors and the subsequent scrapping of eight of these vessels through a combination of $20 million in Federal appropriations and $75 million in direct loan obligations;

2. A new allocation scheme for BSAI pollock that allocates 10 percent of the BSAI pollock total allowable catch (TAC) to the Community Development Quota (CDQ) program, and after allowance for incidental catch of pollock in other fisheries, allocates the remaining TAC as follows: 50 percent to vessels harvesting pollock for processing by inshore processors, 40 percent to vessels harvesting pollock for processing by catcher/processors, and 10 percent to vessels harvesting pollock for processing by motherships;

3. A fee of six-tenths (0.6) of 1 cent for each pound round weight of pollock harvested by catcher vessels delivering to inshore processors for the purpose of repaying the $75 million direct loan obligation.

4. A prohibition on entry of new vessels and processors into the BSAI pollock fishery. The AFA lists by name vessels and processors and/or provides qualifying criteria for those vessels and processors eligible to participate in the non-CDQ portion of the BSAI pollock fishery;

5. New observer coverage and scale requirements for AFA catcher/processors;

6. New standards and limitations to guide the creation and operation of fishery cooperatives in the BSAI pollock fishery;

7. An individual fishing quota program for inshore catcher vessel cooperatives under which NMFS grants individual allocations of the inshore BSAI pollock TAC to inshore catcher vessel cooperatives that form around a specific inshore processor and agree to deliver at least 90 percent of their pollock catch to that processor;

8. The establishment of harvesting and processing limits known as ''sideboards'' on AFA pollock vessels and processors to protect the interests of fishermen and processors in other fisheries from spillover effects resulting from the rationalization of the BSAI pollock fishery,

9. A 17.5-percent excessive share harvesting cap for BSAI pollock and a requirement that the Council develop excessive share caps for BSAI pollock processing and for the harvesting and processing of other groundfish.

Some of the above provisions of the AFA already have been implemented by NMFS and other agencies. The buyout and scrapping of the nine ineligible factory trawlers were completed by NMFS in 1999 under the schedule mandated by the AFA. This action was accomplished by contract with the vessel owners rather than regulation. The inshore pollock fee program required by the AFA was implemented by NMFS through final regulations published February 3, 2000 (65 FR 5278). MARAD has implemented the new U.S. ownership requirements and size restrictions for U.S. fishing vessels through final regulations published July 19, 2000 (65 FR 44860). MARAD's regulations also set out procedures for review of compliance with excessive share harvesting limits contained in this proposed rule.

Council Development of Amendments 61/61/13/8

Since the passage of the AFA in October 1998, NMFS and the Council have undertaken an extensive public process to develop the management program proposed under Amendments 61/61/13/8. Amendments 61/61/13/8 were developed and revised during the course of 12 Council meetings over the past 2 years and have been the subject of numerous additional public meetings held by the Council and NMFS to address specific aspects of the AFA. While the permanent management program proposed under Amendments 61/61/13/8 was under analysis and development by the Council and NMFS, the statutory deadlines in the AFA were met on an interim basis through several emergency interim rules, and was extended through the end of 2001 by Pub. L. No. 106-554, which mandated that all management measures in effect as of July 2000 would be extended through the end of 2001. The following time line provides a summary of the 2-year public process through which NMFS and the Council developed Amendments 61/61/13/8.

November 1998. After the passage of the AFA in October 1998, the Council held a special meeting in November 1998, in Anchorage, AK to address among other things, the new requirements of the AFA and the effect of the AFA on the fisheries under the jurisdiction of the Council. The Council made various recommendations to NMFS regarding the regulation of cooperatives in the catcher/processor sector and the management of sideboards for AFA catcher/processors for the upcoming 1999 fishery and began the process of identifying issues and alternatives for upcoming AFA-related actions.

December 1998. At its December 1998 meeting in Anchorage, AK the Council approved two emergency rules to implement required provisions of the AFA for the 1999 fishing year. The first emergency interim rule required two observers on all AFA-listed catcher processors and motherships, and established procedures for making inseason sideboard closures (64 FR 3435, January 22, 1999; extended at 64 FR 33425, June 23, 1999). The second emergency interim rule made several technical changes to the CDQ program regulations to accommodate the new requirements of the AFA (64 FR 3887, January 26, 1999; extended at 64 FR 34743, June 29, 1999). After extensive public testimony and input from the Council's Advisory Panel (AP) and Scientific and Statistical Committee (SSC), the Council identified a suite of alternatives for the management program that subsequently became known as Amendments 61/61/13/8.

February 1999. At its February 1999 meeting in Anchorage, AK the Council finalized sideboard and AFA management measure alternatives with the intent that a draft analysis would be reviewed at the April 1999 meeting with a final decision scheduled for June 1999 to allow the Council to meet the July 1999 deadline imposed by the AFA for recommendation of sideboard measures. The Council also began preparation of a separate discussion paper to examine the structure of the inshore cooperative program. This separate analysis was in response to a proposal by a group of independent catcher vessel owners who advocated a change in the program to allow the formation of an independent vessel cooperative that would not be tied to a particular processor. A draft analysis was scheduled for review in June 1999, with further discussion in October 1999.

April 1999. At its April 1999 meeting in Anchorage, AK the Council reviewed its draft analysis for Amendments 61/61/13/8, and received extensive public testimony regarding alternatives and issues that should be considered under Amendments 61/61/13/8. The Council directed staff to make various revisions and additions to the analysis with the intent that the amendment package would be before the Council for final action in June 1999. The Council also reviewed its discussion paper on the structure of the inshore cooperative program and the proposed independent catcher vessel cooperative and requested that a broader analysis be prepared for initial review at the October 1999 meeting. In addition, the Council formed an inshore cooperative implementation committee to advise NMFS on many of the technical issues related to the formation and management of inshore cooperatives.

May 1999. The Council's inshore cooperative implementation committee held a public meeting with NMFS on May 10-13 in Seattle, WA to examine alternative management approaches for inshore catcher vessel cooperatives. The approach to implementing and managing inshore cooperatives developed at this meeting forms the basis of the inshore cooperative management program contained in this proposed rule.

June 1999. At its June 1999 meeting in Kodiak, AK the Council reviewed Amendments 61/61/13/8 and after extensive public testimony, approved a suite of AFA-related recommendations including restrictions on the formation and operation of cooperatives, harvesting sideboards for catcher/processors and catcher vessels, and catch weighing and monitoring requirements. However, the Council was unable to reach a decision on two AFA-related issues: groundfish processing sideboards and excessive processing share caps. To address these issues, the Council established an industry committee to further examine alternatives and work with State of Alaska (State) and Federal managers to resolve implementation issues with the intent that the Council would review the committee's recommendations in October 1999.

August 1999. The Council's processing sideboard industry committee held a public meeting in Seattle, WA to examine alternatives for processing sideboards and excessive processing share caps. The committee was unable to reach complete consensus on a recommended approach for processing sideboard caps. However, the committee did develop some general recommendations for the Council and provided the Council with some requests for additional analysis and information.

October 1999. At its October 1999 meeting in Seattle, WA the Council reviewed its analysis on the structure of the inshore cooperative program, including the proposal to allow formation of independent catcher vessel cooperatives, and received extensive public discussion on this issue. However, the Council voted to postpone action until February 2000 and requested further analysis on this issue. The Council also re-examined its June 1999 catcher vessel sideboard exemption recommendations and requested that NMFS delay implementation of these measures until the Council had the opportunity to analyze and discuss possible revisions to its recommended catcher vessel sideboard exemptions. The Council announced that it would be revising its sideboard exemption recommendations at its December 1999 meeting. Finally, the Council reviewed what had now become a separate analysis of groundfish processing sideboards and excessive processing share caps. After extensive discussion and public comment on this issue, the Council chose to expand and revise its analysis with intent to review the issue again in February 2000 with final action scheduled for June 2000.

December 1999. At its December 1999 meeting in Anchorage, AK the Council approved two emergency interim rules to implement required provisions of the AFA for the 2000 fishing year. These

measures were necessary to meet certain statutory deadlines in the AFA while the comprehensive suite of permanent management measures under Amendments 61/61/13/8 continued to undergo development, revision, and analysis by the Council and NMFS. The first emergency interim rule set out permit requirements for AFA vessels, processors, and cooperatives (65 FR 380, January 5, 2000; extended at 65 FR 39107, June 23, 2000). The second emergency interim rule established sector allocations, cooperative regulations, sideboards, and catch monitoring requirements for the AFA fleets (65 FR 4520, January 28, 2000; extended at 65 FR 39107, June 23, 2000).

February 2000. At its February 2000 meeting in Anchorage, AK the Council reviewed its revised analysis of groundfish processing sideboards and excessive share processing caps and requested analysis of several additional issues with the stated intent that the analysis would be reviewed again in June 2000. The Council postponed action on proposed changes to the structure of the inshore cooperative program and independent catcher vessel proposal until June 2000. Finally, at that meeting, the Council and NMFS decided it would be appropriate to expand the environmental assessment prepared for Amendments 61/61/13/8 into an EIS given the magnitude of the proposed management program to implement the AFA.

April 2000. At its April 2000 meeting in Anchorage, AK the Council received extensive testimony from industry on several elements of Amendments 61/61/13/8. Catcher vessel owners requested that the Council consider revising several of its recommendations related to catcher vessel sideboards, retirement of vessels, and the formula for calculating inshore cooperative allocations. The Council requested preparation of a supplemental analysis of these issues for consideration in June 2000. The Council also received testimony from crab fishermen who opposed the crab processing caps implemented in 2000 through an emergency interim rule. The Council announced its intent to examine alternatives for crab processing caps at its June 2000 meeting with final action on any changes scheduled for September 2000. In addition, the April Council meeting was used as a scoping meeting to solicit input from the public on issues and alternatives that should be addressed in the EIS under preparation for Amendments 61/61/13/8.

June 2000. At its June 2000 meeting in Portland, OR the Council reviewed its analysis of proposed structural changes to the inshore cooperative program including the independent catcher vessel proposal. The Council did not adopt changes promoted by independent catcher vessel owners that would have allowed greater flexibility in choosing which cooperative a vessel could join. Instead, the Council recommended two changes related to retirement of vessels and allocation formulas that would supersede the measures set out in the AFA. These changes were incorporated as revisions to Amendments 61/61/13/8. The Council also examined the issue of groundfish processing sideboards and excessive processing share caps and voted to release its analysis for public review with intent to take final action on these measures at its October 2000 meeting. The Council's original intent was to include groundfish processing sideboards and excessive processing share caps in Amendments 61/61/13/8. However, due to the extensive additional analysis required for these two issues, the Council decided to address these issues on a separate timetable with a separate analysis.

September 2000. At its September 2000 meeting in Anchorage, AK the Council examined proposed changes to crab processing sideboard limits and recommended that the 1995-1997 formula used to calculate crab processing caps under the AFA be revised by adding 1998 processing history and giving it double-weight. In other words, 1995-1998 would be used to determine crab processing history with the 1998 year counting twice. The purpose of this change was to give greater emphasis to recent processing history in consideration of changes to the crab processing industry that have occurred since 1995.

October 2000. At its October 2000 meeting in Sitka, AK the Council considered the issues of BSAI pollock excessive processing share limits and groundfish processing sideboard limits. The Council adopted a 30-percent excessive processing share limit for BSAI pollock that would be applied using the same 10 percent entity rules set out in the AFA to define AFA entities for the purpose of the 17.5 percent excessive harvesting share limit contained in the AFA. This action represents the Council's final revision to Amendments 61/61/13/8 before official submission of the Amendments to the Secretary of Commerce for review and approval. With respect to non-pollock groundfish processing sideboards, the Council took no action. The Council believed that placing non-pollock groundfish processing limits on AFA processors could have negative effects on markets for both AFA and non-AFA catcher vessels. In addition, the Council concluded that its suite of harvesting sideboard restrictions on AFA catcher vessels and catcher/processors also serve to protect non-AFA processors in the BSAI, which are primarily non-AFA catcher/processors. Instead of imposing non-pollock processing limits on AFA processors, the Council indicated its intent to explore revisions to its Improved Retention/Improved Utilization program set out at 50 CFR 679.27. Testimony from non-AFA processors indicated that such changes could be a more effective means of providing a more level playing field for non-AFA catcher/processors.

Public comments are being solicited on Amendments 61/61/13/8 through the end of the comment period specified in this document. A proposed rule that would implement Amendments 61/61/13/8 may be published in the **Federal Register** for public comment following evaluation by NMFS under the Magnuson-Stevens Act procedures. All comments received by the end of the comment period specified in this document, whether specifically directed to Amendments 61/61/13/8 or to the proposed rule, will be considered in the decision to approve, disapprove, or partially approve Amendments 61/61/13/8.

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

Dated: November 20, 2001.

Jon Kurland,

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

[FR Doc. 01–29496 Filed 11–26–01; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[I.D. 053001D]

Groundfish Fisheries of the Bering Sea and Aleutian Islands Area and the Gulf of Alaska

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

ACTION: Notice of intent to revise the Alaska Groundfish Fisheries Draft Programmatic Supplemental Environmental Impact Statement (SEIS).

SUMMARY: NMFS announces its intent to revise the Alaska Groundfish Fisheries

draft Programmatic SEIS. After reviewing more than 21,000 comment letters received on the draft Programmatic SEIS, NMFS has determined that revisions to the draft Programmatic SEIS are appropriate and necessary. NMFS has also determined that these revisions will require the release of a revised draft Programmatic SEIS. Based on these decisions, NMFS announces a new date for the completion of the Programmatic SEIS and issuance of the Record of Decision based thereon.

DATES: *See* **SUPPLEMENTARY INFORMATION** for the dates concerning completion of the Alaska Groundfish Fisheries Programmatic SEIS. The December 2001 North Pacific Fishery Management Council (Council) meeting will be held December 5 through 10, 2001. Additional information concerning the agenda for the Council's December 2001 meeting can be found at *http://www.fakr.noaa.gov/npfmc.*

ADDRESSES: The December 2001 North Pacific Fishery Management Council meeting will be held at the Hilton Hotel, Anchorage, AK.

FOR FURTHER INFORMATION CONTACT: Steven K. Davis, Programmatic SEIS Coordinator, Anchorage, Alaska, (907) 271–3523.

SUPPLEMENTARY INFORMATION: On January 26, 2001, NMFS released a draft of the Alaska Groundfish Fisheries Programmatic SEIS for a 90-day public review and comment period. As a result of NMFS granting requests by the interested public for two extensions of the public comment period, the comment period for the draft Programmatic SEIS ran for a total of 180 days and ended on July 25, 2001. As a result of this extended public comment period and the voluminous public comments received therein, NMFS determined that it would issue a final Programmatic SEIS for the Alaska groundfish fisheries during the summer of 2002 and a Record of Decision shortly thereafter.

NMFS received 21,361 letters commenting on the draft Programmatic SEIS during the comment period. Comments on the draft Programmatic SEIS were received from all 50 States, as well as the District of Columbia and Puerto Rico. Citizens from 28 foreign countries also provided comments. Within these 21,361 letters, NMFS identified 4,044 substantive comments.

Based on its review and preliminary analysis of the comments received on the draft Programmatic SEIS, NMFS has made several decisions concerning the draft Programmatic SEIS. First, NMFS has determined that the draft Programmatic SEIS should be revised to include additional analyses concerning environmental, economic and cumulative impacts. Second, NMFS has determined that the alternatives contained in the draft Programmatic SEIS should be restructured, shifting from single-focus alternatives to more comprehensive, multiple-component alternatives. Third, NMFS has determined that the draft Programmatic SEIS should be edited to evaluate more concisely the proposed action. The revisions to the Programmatic SEIS will build from the information and analyses contained in the January 26, 2001, draft Programmatic SEIS. Given its decisions, NMFS has determined that it will release a revised draft Programmatic SEIS for public review and comment before issuing the final Programmatic SEIS.

General Process and Dates for Completion of the Programmatic SEIS

Given the determinations described above, NMFS has decided that a modification to the current schedule for completion of the Programmatic SEIS is appropriate and necessary. The following dates reflect the amount of time that NMFS has determined will be needed to complete the additional analyses and editing of the draft Programmatic SEIS, and to allow for adequate public review and comment on the revised draft Programmatic SEIS, including the restructured alternatives. NMFS will seek assistance and input from the Council and the public in developing the restructured alternatives. It will consider, among other things, several restructured alternatives in the revised draft Programmatic SEIS, including alternatives that were suggested or proposed in comments received on the January 2001 draft Programmatic SEIS and that are developed in conjunction and cooperation with the Council and/or the public.

December 2001 North Pacific Fishery Management Council Meeting

NMFS will present the Council and the public with a preliminary template that describes the framework within which restructured alternatives will be developed.

January Through August 2002

From January through August 2002, NMFS will prepare the revised draft Programmatic SEIS. NMFS will prepare additional analyses concerning environmental, economic and cumulative impacts, restructure the alternatives and prepare an analysis of the effects of those alternatives on the human environment, and edit the Programmatic SEIS to evaluate more concisely the proposed action. As noted above, NMFS will seek assistance and input from the Council and the public in developing the restructured alternatives.

September Through December 2002

From September through December 2002, NMFS will issue a revised draft Programmatic SEIS for a public review and comment period.

January Through August 2003

From January through August 2003, NMFS will prepare the final Programmatic SEIS. NMFS will review and consider public comments received on the revised draft Programmatic SEIS and will present a summary of those comments to the Council and the public.

September 2003

NMFS will issue a final Programmatic SEIS and allow a 30-day public comment period on the final Programmatic SEIS.

No later than December 31, 2003

NMFS will issue a Record of Decision on the Programmatic SEIS.

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

Dated: November 20, 2001.

Jon Kurland,

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

[FR Doc. 01–29497 Filed 11–26–01; 8:45 am]

BILLING CODE 3510–22–S

Notices

Federal Register

Vol. 66, No. 228

Tuesday, November 27, 2001

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

DEPARTMENT OF AGRICULTURE

Forest Service

Newspaper Used for Publication of Legal Notice of Appealable Decisions for the Intermountain Region; Utah, Idaho, Nevada, and Wyoming

AGENCY: Forest Service, USDA.

ACTION: Notice.

SUMMARY: This notice lists the newspapers that will be used by all ranger districts, forests, and the Regional Office of the Intermountain Region to publish legal notice of all decisions subject to appeal under 36 CFR 215 and 36 CFR 217. The intended effect of this action is to inform interested members of the public which newspapers will be used to publish legal notices of decisions, thereby allowing them to receive constructive notice of a decision, to provide clear evidence of timely notice, and to achieve consistency in administering the appeals process.

DATES: Publication of legal notices in the listed newspapers will begin with decisions subject to appeal that are made on or after December 1, 2000. The list of newspaper will remain in effect until June 1, 2001, when another notice will be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Barbara Schuster, Regional Appeals Manager, Intermountain Region, 324 25th Street, Ogden, UT 84401, and Phone (801) 625–5301.

SUPPLEMENTARY INFORMATION: The administrative appeal procedures 36 CFR 215 and 36 CFR 217, of the Forest Service require publication of legal notice in a newspaper of general circulation of all decisions subject to appeal. This newspaper publication of notices of decisions is in addition to direct notice to those who have requested notice in writing and to those known to be interested and affected by a specific decision.

The legal notice is to identify: the decision by title and subject matter; the date of the decision; the name and title of the official making the decision; and how to obtain copies of the decision. In addition, the notice is to state the date the appeal period begins which is the day following publication of the notice.

The timeframe for appeal shall be based on the date of publication of the notice in the first (principal) newspaper listed for each unit.

The newspapers to be used are as follows:

Regional Forester, Intermountain Region

For decisions made by the Regional Forester affecting National Forests in Idaho:
The Idaho Statesman, Boise Idaho
For decisions made by the Regional Forester affecting National Forests in Nevada:
The Reno Gazette-Journal, Reno, Nevada
For decisions made by the Regional Forester affecting National Forests in Wyoming:
Casper Star-Tribune, Casper, Wyoming
For decisions made by the Regional Forester affecting National Forests in Utah:
Salt Lake Tribune, Salt Lake City, Utah
If the decision made by the Regional Forester affects all National Forests in the Intermountain Region, it will appear in:

Ashley National Forest

Ashley Forest Supervisors decisions:
Vernal Express, Vernal, Utah
Vernal District Ranger decisions:
Vernal Express, Vernal, Utah
Flaming Gorge District Ranger for decisions affecting Wyoming:
Casper Star Tribune, Casper, Wyoming
Flaming Gorge District Ranger for decisions affecting Utah:
Vernal Express, Vernal, Utah
Roosevelt and Duchesne District Ranger decisions:
Utah Basin Standard, Roosevelt, Utah

Boise National Forest

Boise Forest Supervisor decisions:
The Idaho Statesman, Boise, Idaho
Mountain Home District Ranger decisions:
The Idaho Statesman, Boise, Idaho
Idaho City District Ranger decisions:
The Idaho Statesman, Boise, Idaho
Cascade District Ranger decisions:
The Long Valley Advocate, Cascade, Idaho
Lowman District Ranger decisions:
The Idaho World, Garden Valley, Idaho
Emmett District Ranger decisions:
The Messenger-Index, Emmett, Idaho

Bridger-Teton National Forest

Bridger-Teton Forest Supervisor decisions:
Casper Star-Tribune, Casper, Wyoming
Jackson District Ranger decisions:
Casper Star-Tribune, Casper, Wyoming
Buffalo District Ranger decisions:
Casper Star-Tribune, Casper, Wyoming
Big Piney District Ranger decisions:
Casper Star-Tribune, Casper, Wyoming
Pinedale District Ranger decisions:
Casper Star-Tribune, Casper, Wyoming
Greys River District Ranger decisions:
Casper Star-Tribune, Casper, Wyoming
Kemmerer District Ranger decisions:
Casper Star-Tribune, Casper, Wyoming

Caribou-Targhee National Forest

Caribou-Targhee Forest Supervisor decisions for the Caribou portion:
Idaho State Journal, Pocatello, Idaho
Soda Springs District Ranger decisions:
Idaho State Journal, Pocatello, Idaho
Montpelier District Ranger decisions:
Idaho State Journal, Pocatello, Idaho
Westside District Ranger decisions:
Idaho State Journal, Pocatello, Idaho
Caribou-Targhee Forest Supervisor decisions for the Targhee Portion:
The Post Register, Idaho Falls, Idaho
Dubois District Ranger decisions:
The Post Register, Idaho Falls, Idaho
Island Park District Ranger decisions:
The Post Register, Idaho Falls, Idaho
Ashton District Ranger decisions:
The Post Register, Idaho Falls, Idaho
Palisades District Ranger decisions:
The Post Register, Idaho Falls, Idaho
Teton Basin District Ranger decisions:
The Post Register, Idaho Falls, Idaho

Dixie National Forest

Dixie Forest Supervisor decisions:
The Daily Spectrum, St. George, Utah

Pine Valley District Ranger decisions:
The Daily Spectrum, St. George, Utah
Cedar City District Ranger decisions:
The Daily Spectrum, St. George, Utah
Powell District Ranger decisions:
The Daily Spectrum, St. George, Utah
Escalante District Ranger decisions:
The Daily Spectrum, St. George, Utah
Teasdale District Ranger decisions:
The Daily Spectrum, St. George, Utah

Fishlake National Forest

Fishlake Forest Supervisor decisions:
Richfield Reaper, Richfield, Utah
Loa District Ranger decisions:
Richfield Reaper, Richfield, Utah
Richfield District Ranger decisions:
Richfield Reaper, Richfield, Utah
Beaver District Ranger decisions:
Richfield Reaper, Richfield, Utah
Fillmore District Ranger decisions:
Richfield Reaper, Richfield, Utah

Humboldt-Toiyabe National Forests

Humboldt-Toiyabe Forest Supervisor decisions for the Humboldt portion:
Elko Daily Free Press, Elko, Nevada
Humboldt-Toiyabe Forest Supervisor decisions for the Toiyabe portion:
Reno Gazette-Journal, Reno, Nevada
Sierra Ecosystem Coordination Center (SECO):
Carson District Ranger decisions:
Mammoth Times, Mammoth Lakes, California
Bridgeport District Ranger, decisions:
The Review-Herald, Mammoth Lakes, California
Spring Mountains National Recreation Area Ecosystem (SMNRAE):
Spring Mountains National Recreation Area District Ranger decisions:
Las Vegas Review Journal, Las Vegas, Nevada
Central Nevada Ecosystem (CNECO):
Austin District Ranger decisions:
Reno Gazette-Journal, Reno, Nevada
Tonopah District Ranger decisions:
Tonopah Times Bonanza-Goldfield News, Tonopah, Nevada
Ely District Ranger decisions:
Ely Daily Times, Ely, Nevada
Northeast Nevada Ecosystem (NNECO):
Mountain City District Ranger decisions:
Elko Daily Free Press, Elko Nevada
Ruby Mountains District Ranger decisions:
Elko Daily Free Press, Elko Nevada
Jarbridge District Ranger decisions:
Elko Daily Free Press, Elko Nevada
Santa Rosa District Ranger decisions:
Humboldt Sun, Winnemucca, Nevada

Manti-Lasal National Forest

Manti-LaSal Forest Supervisor decisions:
Sun Advocate, Price, Utah
Sanpete District Ranger decisions:
The Pyramid, Mt. Pleasant, Utah
Ferron District Ranger decisions:
Emery County Progress, Castle Dale, Utah
Price District Ranger decisions:
Sun Advocate, Price, Utah
Moab District Ranger decisions:
The Times Independent, Moab, Utah
Monticello District Ranger decisions:
The San Juan Record, Monticello, Utah

Payette National Forest

Payette Forest Supervisor decisions:
Idaho Statesman, Boise, Idaho
Weiser District Ranger decisions:
Signal American, Weiser, Idaho
Council District Ranger decisions:
Council Record, Council, Idaho
New Meadows, McCall, and Krassel District Ranger decisions:
Star News, McCall, Idaho

Salmon-Challis National Forests

Salmon-Challis Forest Supervisor decisions for the Salmon portion:
The Recorder-Herald, Salmon, Idaho
Salmon-Challis Forest Supervisor decisions for the Challis portion:
The Challis Messenger, Challis, Idaho
North Fork District Ranger decisions:
The Recorder-Herald, Salmon, Idaho
Leadore District Ranger decisions:
The Recorder-Herald, Salmon, Idaho
Salmon/Cobalt District Ranger decisions:
The Recorder-Herald, Salmon, Idaho
Middle Fork District Ranger decisions:
The Challis Messenger, Challis, Idaho
Challis District Ranger decisions:
The Challis Messenger, Challis, Idaho
Yankee Fork District Ranger decisions:
The Challis Messenger, Challis, Idaho
Lost River District Ranger decisions:
The Challis Messenger, Challis, Idaho

Sawtooth National Forest

Sawtooth Forest Supervisor decisions:
The Times News, Twin Falls, Idaho
Burley District Ranger decisions:
Ogden Standard Examiner, Ogden, Utah, for those decisions on the Burley District involving the Raft River Unit.
South Idaho Press, Burley, Idaho, for decisions issued on the Idaho portions of the Burley District.
Twin Falls District Ranger decisions:
The Times News, Twin Falls, Idaho
Ketchum District Ranger decisions:
Idaho Mountain Express, Ketchum, Idaho
Sawtooth National Recreation Area:
Challis Messenger, Challis, Idaho
Fairfield District Ranger decisions:
The Times News, Twin Falls, Idaho

Uinta National Forest

Uinta Forest Supervisor decisions:
The Daily Herald, Provo, Utah
Pleasant Grove District Ranger decisions:
The Daily Herald, Provo, Utah
Heber District Ranger decisions:
The Daily Herald, Provo, Utah, and
Spanish Fork District Ranger decisions:
The Daily Herald, Provo, Utah

Wasatch-Cache National Forest

Wasatch-Cache Forest Supervisor decisions:
Salt Lake Tribune, Salt Lake City, Utah
Salt Lake District Ranger decisions:
Salt Lake Tribune, Salt Lake City, Utah
Kamas District Ranger decisions:
Salt Lake Tribune, Salt Lake City, Utah
Evanston District Ranger decisions:
Uintah County Herald, Evanston, Wyoming
Mountain View District Ranger decisions:
Uintah County Herald, Evanston, Wyoming
Ogden District Ranger decisions:
Ogden Standard Examiner, Ogden, Utah
Logan District Ranger decisions:
Logan Herald Journal, Logan, Utah

November 19, 2001.

Jack A. Blackwell,

Regional Forester.

[FR Doc. 01–29438 Filed 11–27–01; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

Notice of Resource Advisory Committee Meeting

AGENCY: Southwest Idaho Resource Advisory Committee, Boise, ID, USDA, Forest Service.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the authorities in the Federal Advisory Committee Act (Public Law 92–463) and under the Secure Rural Schools and Community Self-Determination Act of 2000 (Public Law 106–393) the Boise and Payette National Forests' Southwest Idaho Resource Advisory Committee will meet Wednesday, December 12, 2001 in Boise, Idaho for a business meeting. The meeting is open to the public.

FOR FURTHER INFORMATION CONTACT: Randy Swick, McCall District Ranger and Designated Federal Officer, at (208) 634–0400.

SUPPLEMENTARY INFORMATION: The business meeting on December 12, begins at 10 am, at the Idaho Department of Agriculture Building,

2270 old Penitentiary Road, Boise, Idaho. Agenda topics will include FACA overview, Charter overview, Process for project identification/ recommendation, election of Chairperson, operating guidelines, and establishment of future meeting schedule.

Dated: November 16, 2001.

David F. Alexander,

Forest Supervisor.

[FR Doc. 01–29397 Filed 11–26–01; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

Southwest Oregon Province Interagency Executive Committee (PIEC) Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Southwest Oregon PIEC Advisory Committee will meet on December 5, 2001 in Roseburg, Oregon at the Roseburg Bureau of Land Management Office at 777 NW Garden Valley Blvd. The meeting will begin at 9:00 a.m. and continue until 5 p.m. Agenda items to be covered include: (1) Province Advisory Committee Operating Guidelines; (2) Public Comment; (3) BLM/FS budget overview; and (4) Current issues as perceived by Advisory Committee members.

FOR FURTHER INFORMATION CONTACT: Direct questions regarding this meeting to Roger Evenson, Province Advisory Committee Coordinator, USDA, Forest Service, Umpqua National Forest, 2900 NW Stewart Parkway, Roseburg, Oregon 97470, phone (541) 957–3344.

Dated: November 20, 2001.

Michael D. Hupp,

Acting Designated Federal Official.

[FR Doc. 01–29435 Filed 11–26–01; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

Willamette Provincial Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Willamette Province Advisory Committee (PAC) will meet on Thursday, December 13, 2001. The meeting is scheduled to begin at 9 a.m., and will conclude at approximately 2 p.m. The meeting will be held at the Salem Office of the Bureau of Land Management; 1717 Fabry Road SE; Salem, Oregon; (503) 375–5646. The tentative agenda includes: (1) A status report from the PAC Subcommittees; (2) A review and evaluation of PAC activities in 2001; (3) A discussion of potential issues and agenda items for 2002 PAC activity; (4) Information sharing; (5) Public Forum. The Public Forum is tentatively scheduled to begin at 10:30 a.m. Time allotted for individual presentations will be limited to 3–4 minutes. Written comments are encouraged, particularly if the material cannot be presented within the time limits for the Public Forum. Written comments may be submitted prior to December 13 meeting by sending them to Designated Federal Official Neal Forrester at the address given below.

FOR FURTHER INFORMATION CONTACT: For more information regarding this meeting, contact Designated Federal Official Neal Forrester; Willamette National Forest; 211 East Seventh Avenue; Eugene, Oregon 97401; (541) 465–6924.

Dated: November 20, 2001.

Y. Robert Iwamoto,

Acting Forest Supervisor.

[FR Doc. 01–29439 Filed 11–26–01; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

Withdrawal of the Regional Guide for the Intermountain Region and the Transfer of Select Decisions Therein to Specific Forest Plans

AGENCY: Forest Service, USDA.

ACTION: Notice.

SUMMARY: The Regional Forester for the Intermountain Region of the USDA Forest Service is withdrawing the Regional Guide and transferring selected decisions therein to specific Forest Plans. The Regional Forester is transferring the direction related to maximum size openings for even-aged timber management to those Forests that did not specifically address this requirement in their Forest Plan or that address it by referencing the Regional Guide Direction. Current planning regulations direct that the Regional Forester must withdraw the Regional Guide within 1 year of November 9, 2000. When a Regional Guide is withdrawn, Forest Service policy mandates that the Regional Forester must identify the decisions in the Regional Guide that are to be transferred to a regional supplement to the Forest Service directive system or to one or more forest. This action complies with that direction. A review of the relevant Forest Plans indicates that the Humboldt, Sawtooth, Toiyabe and Uinta National Forests are affected.

DATES: This action is effective November 9, 2001.

FOR FURTHER INFORMATION CONTACT: Bob Davis, (801) 625–5275.

SUPPLEMENTARY INFORMATION: The current regulations governing land and resource management planning (36 CFR part 219) direct Regional Foresters to withdraw their Regional Guide within 1 year of November 9, 2000. In addition, when a Regional Guide is withdrawn, the Regional Forester must identify the decisions in the Regional Guide that are to be transferred to a regional supplement of the Forest Service directive system (36 CFR 200.4) or to one or more plans and give notice in the **Federal Register** of these actions. A review of the management direction contained in the Intermountain Regional Guide indicates that, except for one area, either direction is already incorporated into Forest Plans, is superceded by Forest Service directives or policy, or the direction is obsolete. The one specific area identified for retention and transfer is the direction for maximum size for created openings by even-aged timber harvest (page 3–21 of the Regional Guide). I have determined that this direction should be transferred to those Forests that did not explicitly address it in their Forest Plan or that address it by referencing the Regional Guide—the Humboldt, Sawtooth, Toiyabe and Uinta National Forests. This direction will be in effect until the Forest has completed revision of their Forest Plan. Transferring this direction continues the limitation on the size of harvest openings to 40-acres or less without a 60-day public review and Regional Forester approval that is currently in the Regional Guide and complies with 36 CFR 219.35(e).

Dated: November 5, 2001.

Jack A. Blackwell,

Regional Forester, Intermountain Region.

[FR Doc. 01–29436 Filed 11–26–01; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

Withdrawal of the Regional Guide for the Eastern Region, Forest Service

AGENCY: Forest Service, USDA.

ACTION: Notice.

SUMMARY: Pursuant to 36 CFR 219.35(e) the Regional Forester for the Eastern Region of the Forest Service has withdrawn the Regional Guide for the Eastern Region. There were no decisions from that regional guide transferred to regional supplements of the Forest Service directives system or to any forest plan.

DATES: The withdrawal was effective November 7, 2001.

FOR FURTHER INFORMATION CONTACT: Sam Emmons, Regional Planner, 310 W. Wisconsin Ave., Milwaukee, WI 53203. Phone 414–297–3429 or TDD 414–297–3507.

RESPONSIBLE OFFICIAL: Robert T. Jacobs, Regional Forester, Eastern Region, 310 W. Wisconsin Ave, Milwaukee, Wisconsin 53203.

SUPPLEMENTARY INFORMATION: This action was required to comply with 36 CFR part 219, § 219.35(e) that directs that within one year of November 9, 2000, the Regional Forester must withdraw the regional guide. When a regional guide is withdrawn, the Regional Forester must identify the decisions in the regional guide that are to be transferred to a regional supplement of the Forest Service directive system (36 CFR 200.4) or to one or more plans and give notice in the **Federal Register** of these actions. In the case of the Regional Guide for the Eastern Region, the withdrawal was made November 7, 2001 and documented through a letter to the Chief. There were no decisions that were transferred to the directives system or to forest plans.

Dated: November 7, 2001.

Robert T. Jacobs,

Regional Forester.

[FR Doc. 01–29437 Filed 11–26–01; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF COMMERCE

Economic Development Administration

Notice of Petitions by Producing Firms for Determination of Eligibility To Apply for Trade Adjustment Assistance

AGENCY: Economic Development Administration, Commerce.

ACTION: To give firms an opportunity to comment.

Petitions have been accepted for filing on the dates indicated from the firms listed below.

LIST OF PETITION ACTION BY TRADE ADJUSTMENT ASSISTANCE FOR PERIOD 10/20/01–11/15/01

Firm name	Address	Date petition accepted	Product
Acme Pad Corporation	330 N. Warwick Street, Baltimore, MD 21223.	10/25/01	Shoulder pads used in tailored clothing.
York Mold, Inc,	3865 N. George Street, Manchester, PA 17345.	10/25/01	Cast cold formed battery terminals.
Global Tech Industries, Inc,	418 Highway 441, Cornelia, GA 30531	10/25/01	Specialty candles.
E. E. Dion, Inc,	33 Franklin McKay Road, Attleboro, MA 02703.	11/05/01	Jewelry of plated base and precious metals.
La Abuela Mexican Foods, Inc,	516 South 17th, McAllen, TX 78501	11/05/01	Tortillas.
Belcam, Inc,	27 Montgomery Street, Rouses Point, NY 12979.	11/06/01	Toiletries and fragrances.
B. R. MacD., Inc. d.b.a. McDonald Footwear.	Industrial Park Road, Skowhegan, ME 04975.	11/06/01	Men's and women's hand-sewn casual shoes.
ACO, Inc,	501 SW 9th Street, Oklahoma City, OK 73109.	11/07/01	Plastic injection molding.
Devalmont Vineyards, Inc,	8400 Pan American Freeway N.E., Albuquerque, NM 87113.	11/07/01	White wine.
Fabtech, Inc,	777 N.W. Blue Parkway, Lee's Summit, MO 64086.	11/08/01	Diode wafers.
Haldex Barnes Corporation	2222 15th Street, Rockford, IL 61104	11/08/01	Hydraulic fluid gear pumps.
C. R. Hudgins Plating, Inc,	3600 Candlers Mountain Road, Lynchburg, VA 24502.	11/09/01	Metal plating for electronic components.
Basin Frozen Foods, Inc,	1203 Basin, Warden, WA 98857	11/13/01	Potato products i.e., frozen hash browns and french fries.
Reitz Tool, Inc,	239 South Franklin St. Extension, Cochranton, PA 16314.	11/13/01	Semiconductor molds used in the automotive and telecommunications industries.

The petitions were submitted pursuant to section 251 of the Trade Act of 1974 (19 U.S.C. 2341). Consequently, the United States Department of Commerce has initiated separate investigations to determine whether increased imports into the United States of articles like or directly competitive with those produced by each firm contributed importantly to total or partial separation of the firm's workers, or threat thereof, and to a decrease in sales or production of each petitioning firm.

Any party having a substantial interest in the proceedings may request a public hearing on the matter. A request for a hearing must be received by Trade Adjustment Assistance, Room 7315, Economic Development Administration, U.S. Department of Commerce, Washington, DC 20230, no later than the close of business of the tenth calendar day following the publication of this notice.

(The Catalog of Federal Domestic Assistance official program number and title of the program under which these petitions are submitted is 11.313, Trade Adjustment Assistance.)

Dated: November 16, 2001.

Anthony J. Meyer,

Coordinator, Trade Adjustment and Technical Assistance.

[FR Doc. 01–29434 Filed 11–26–01; 8:45 am]

BILLING CODE 3510–24–P

DEPARTMENT OF COMMERCE

Bureau of Export Administration

Materials Processing Equipment Technical Advisory Committee; Notice of Open Meeting

The Materials Processing Equipment Technical Advisory Committee will be held December 13, 2001, 9:00 a.m., in Room 3884 of the Herbert C. Hoover Building, 14th Street Between Pennsylvania and Constitution Avenues, NW, Washington, DC. The Committee advises the Office of the Assistant Secretary for Export Administration with respect to technical questions that affect the level of export controls applicable to materials processing and related technology.

Agenda

1. Opening remarks by the Chairman.
2. Presentation of papers or comments by the public.
3. Update on Bureau of Export Administration initiatives.
4. Update on the Wassenaar Arrangement with discussion on machine tool issues.
5. Status on post-shipment checks.
6. Status on specially designed entries to the Commerce Control List (CCL).
7. Status on Category 2 Matrix Guide for CCL users. The meeting will be open to the public and a limited number of seats will be available. Reservations are not accepted. To the extent that time permits, members of the public may present oral statements to the Committee. Written statements may be submitted at any time before or after the meeting. However, to facilitate distribution of public presentation materials to Committee members, the Committee suggests that presenters forward the public presentation materials two weeks prior to the meeting date to the following address: Ms. Lee Ann Carpenter, Advisory Committees MS: 3876, Bureau of Export Administration, U.S. Department of Commerce, Washington, DC 20230.

For further information or copies of the minutes, contact Lee Ann Carpenter at 202–482–2583.

Dated: November 20, 2001.

Lee Ann Carpenter,

Committee Liaison Officer.

[FR Doc. 01–29465 Filed 11–26–01; 8:45 am]

BILLING CODE 3510–JT–M

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 1201]

Grant of Authority for Subzone Status, Toyota Motor Manufacturing, Indiana, Inc. (Motor Vehicles), Princeton, IN

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Foreign-Trade Zones Act provides for ''* * * the establishment * * * of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes,'' and authorizes the Foreign-Trade Zones Board (the Board) to grant to qualified corporations the privilege of establishing foreign-trade zones in or adjacent to U.S. Customs ports of entry;

Whereas, the Board's regulations (15 CFR part 400) provide for the establishment of special-purpose subzones when existing zone facilities cannot serve the specific use involved, and when the activity results in a significant public benefit and is in the public interest;

Whereas, the Indiana Port Commission, grantee of Foreign-Trade Zone 177, has made application for authority to establish special-purpose subzone status at the motor vehicle manufacturing plant of Toyota Motor Manufacturing, Indiana, Inc., located in Princeton, Indiana (FTZ Docket 21–2001, filed 5–25–2001);

Whereas, notice inviting public comment was given in the **Federal Register** (66 FR 30408, 6–6–2001); and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and Board's regulations are satisfied, and that approval of the application is in the public interest;

Now, Therefore, the Board hereby grants authority for subzone status at the motor vehicle manufacturing plant of Toyota Motor Manufacturing, Indiana, Inc., located in Princeton, Indiana (Subzone 177B), at the location described in the application, subject to the FTZ Act and the Board's regulations, including Section 400.28.

Signed at Washington, DC, this 16th day of November 2001.

Faryar Shirzad,

Assistant Secretary of Commerce for Import Administration, Alternate Chairman, Foreign-Trade Zones Board.

[FR Doc. 01–29489 Filed 11–26–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 1198]

Approval for Expansion of Subzone 87A, Conoco, Inc. (Oil Refinery), Lake Charles, LA

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Lake Charles Harbor and Terminal District, grantee of FTZ 87, has requested authority on behalf of Conoco, Inc. (Conoco), to add capacity and to expand the scope of authority under zone procedures within Subzone 87A at the Conoco refinery in Lake Charles, Louisiana (FTZ Docket 16–2001, filed 4/9/2001);

Whereas, notice inviting public comment has been given in the **Federal Register** (66 FR 19918, 4/18/01);

Whereas, pursuant to section 400.32(b)(1) of the FTZ Board regulations (15 CFR 400), the Secretary of Commerce's delegate on the FTZ Board has the authority to act for the Board in making decisions regarding manufacturing activity within existing zones when the proposed activity is the same, in terms of products involved, to activity recently approved by the Board and similar in circumstances (15 CFR 400.32(b)(1)(i)); and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and Board's regulations would be satisfied, and that approval of the application would be in the public interest if approval is subject to the conditions listed below;

Now, Therefore, the Board hereby orders:

The application to add capacity and to expand the scope of authority under zone procedures within Subzone 87A on behalf of Conoco, Inc., is approved, subject to the FTZ Act and the Board's regulations, including § 400.28, and subject to the following conditions:

1. Foreign status (19 CFR 146.41, 146.42) products consumed as fuel for the petrochemical complex shall be subject to the applicable duty rate.
2. Privileged foreign status (19 CFR 146.41) shall be elected on all foreign merchandise admitted to the subzone, except that non-privileged foreign (NPF) status (19 CFR 146.42) may be elected on inputs covered under HTSUS Subheadings #2710.00.05–#2710.00.10, #2710.00.25, and #2710.00.4510 which are used in the production of:

—Petrochemical feedstocks (examiner's report, Appendix ''C'');
—Products for export;
—And, products eligible for entry under HTSUS #9808.00.30 and #9808.00.40 (U.S. Government purchases).

Signed at Washington, DC, this 16th day of November 2001.

Faryar Shirzad,

Assistant Secretary for Import Administration, Alternate Chairman, Foreign-Trade Zones Board.

[FR Doc. 01–29486 Filed 11–26–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 1199]

Expansion of Foreign-Trade Zone 54, Clinton County, NY

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a-81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the County of Clinton, New York, grantee of Foreign-Trade Zone 54, submitted an application to the Board for authority to expand FTZ 54 to include a site at the World Warehouse and Distribution, Inc., facility (11.5 acres) in Champlain, New York (Site 5), within the Champlain Customs port of entry (FTZ Docket 12–2001; filed 2/20/01);

Whereas, notice inviting public comment was given in the **Federal Register** (66 FR 12459, 2/27/01) and the application has been processed pursuant to the FTZ Act and the Board's regulations; and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and Board's regulations are satisfied, and that the proposal is in the public interest;

Now, Therefore, the Board hereby orders:

The application to expand FTZ 54 is approved, subject to the Act and the Board's regulations, including Section 400.28, and further subject to the Board's standard 2,000-acre activation limit.

Signed at Washington, DC, this 16th day of November 2001.

Faryar Shirzad,

Assistant Secretary of Commerce for Import Administration, Alternate Chairman, Foreign-Trade Zones Board.

[FR Doc. 01–29487 Filed 11–26–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 1200]

Grant of Authority for Subzone Status, Komatsu America International Co. (Construction Equipment), Chattanooga, TN

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a-81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Foreign-Trade Zones Act provides for '' * * * the establishment * * * of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes,'' and authorizes the Foreign-Trade Zones Board to grant to qualified corporations the privilege of establishing foreign-trade zones in or adjacent to U.S. Customs ports of entry;

Whereas, the Board's regulations (15 CFR part 400) provide for the establishment of special-purpose subzones when existing zone facilities cannot serve the specific use involved, and when the activity results in a significant public benefit and is in the public interest;

Whereas, the Chattanooga Chamber Foundation, grantee of Foreign-Trade Zone 134, has made application to the Board for authority to establish special-purpose subzone status at the manufacturing facilities (construction equipment) of Komatsu America International Co., located in Chattanooga, Tennessee (FTZ Docket 48–2000, filed 7/17/2000; amended 6/6/2001);

Whereas, notice inviting public comment has been given in the **Federal Register** (65 FR 50178, 8/17/2000; amended 66 FR 32600, 6/15/2001); and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and the Board's regulations are satisfied, and that approval of the application would be in the public interest;

Now, Therefore, the Board hereby grants authority for subzone status at the construction equipment manufacturing facilities of Komatsu America International Co., located in Chattanooga, Tennessee (Subzone 134A), at the locations described in the amended application, subject to the FTZ Act and the Board's regulations, including § 400.28.

Signed at Washington, DC, this 16th day of November 2001.

Faryar Shirzad,

Assistant Secretary of Commerce for Import Administration, Alternate Chairman, Foreign-Trade Zones Board.

[FR Doc. 01–29488 Filed 11–26–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–507–601]

Certain In-Shell Roasted Pistachios From Iran: Notice of Initiation of New Shipper Countervailing Duty Review

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

SUMMARY: The Department of Commerce (''the Department'') has received a request for a new shipper review of the countervailing duty order on certain in-shell roasted pistachios from Iran. In accordance with our regulations, we are initiating this new shipper review.

EFFECTIVE DATE: November 27, 2001.

FOR FURTHER INFORMATION CONTACT: Eric B. Greynolds or Darla Brown at (202) 482–2786; AD/CVD Enforcement, Office VI, Group II, Import Administration, International Trade Administration, US Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230.

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. In addition, unless otherwise indicated, all citations to the Department's regulations refer to the regulations codified at 19 CFR part 351 (2001).

SUPPLEMENTARY INFORMATION:

Background

The Department has received a request from Tehran Negah Nima Trading Company, Inc. (''Nima'') to conduct a new shipper review of the countervailing duty order on certain in-shell roasted pistachios, issued October 7, 1986 (51 FR 35679). This request was made pursuant to section 751(a)(2)(B) of the Act and 19 CFR 351.214(b).

On October 31, 2001, Nima also submitted a request for an administrative review of the countervailing duty order on certain in-shell roasted pistachios from Iran, in the event that the Department did not

initiate the new shipper review. As we are initiating this new shipper review, we are not initiating an administrative review at this time.

Initiation of Review

Pursuant to 19 CFR 351.214(b), in its request of September 18, 2001, Nima certified that it did not export the subject merchandise to the United States during the period of investigation (''POI'') and that it is not now and never has been affiliated with any exporter or producer who exported the subject merchandise to the United States during the POI. Nima submitted documentation establishing the date on which its merchandise was first entered for consumption in the United States, the volume of that first shipment and the date of its first sale to an unaffiliated customer in the United States.

In accordance with section 751(a)(2)(B) of the Act and section 351.214(d) of the Department's regulations, we are initiating a new shipper review of the countervailing duty order on certain in-shell roasted pistachios from Iran. In accordance with 19 CFR 351.214(h)(i), we intend to issue the preliminary results of this review not later than 180 days from the date of publication of this notice. The Department's regulations state, in 19 CFR 351.214(g)(2), that the period of review (''POR'') for a CVD new shipper review will be the same period as that specified in 19 CFR 351.213.(e)(2), which states that the Department normally will cover entries of subject merchandise during the most recently completed calendar year. However, the Department noted in the Preamble to its Final Regulations that the regulations continue to ''provide the Department with sufficient flexibility to resolve any problems that may arise by modifying the standard review period.'' *Antidumping Duties; Countervailing Duties; Final Rule,* 62 FR 27320 (May 19, 1997). The Department's regulations permit a party to file a request for a new shipper review during the six month period preceding the anniversary month and the six month period preceding the semiannual anniversary month. If a calendar year standard is utilized, as noted in the Department's regulations, entries may enter during the current year and be lost from the Department's analysis as a result. Because the Department believes that such a situation would arise in this instance, the POR will begin with the last fiscal quarter of the year 2000 and end with the third fiscal quarter of 2001.

	Period to be reviewed
Countervailing duty proceeding	
Iran:	
Certain In-shell Roasted Pistachios, C–507–601:	
Tehran Negah Nima Trading Company	10/01/00–09/30/01

Concurrent with publication of this notice, and in accordance with 19 CFR 351.214(e), we will instruct the Customs Service to allow, at the option of the importer, the posting of a bond or security in lieu of a cash deposit for each entry of the merchandise exported by the company listed above, until the completion of the review.

Interested parties may submit applications for disclosure under administrative protective order in accordance with 19 CFR 351.305.

This initiation notice is in accordance with section 751(a) of the Act (19 U.S.C. 1675(a)) and 19 CFR 351.214.

Dated: November 19, 2001.

Bernard T. Carreau,

Deputy Assistant Secretary for Import Administration, Group II.

[FR Doc. 01–29485 Filed 11–26–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Availability of Seats for the Olympic Coast National Marine Sanctuary Advisory Council

AGENCY: National Marine Sanctuary Program (NMSP), National Ocean Service (NOS), National Oceanic and Atmospheric Administration, Department of Commerce (DOC).

ACTION: Notice and request for applications.

SUMMARY: The Olympic Coast National Marine Sanctuary (OCNMS or Sanctuary) is seeking applicants for the following vacant seats on its Sanctuary Advisory Council (Council): Citizen-At-Large, and Tourism/Recreation. In addition, OCNMS is also seeking applicants to serve as alternates for the Education seat, the Research seat, and the Conservation/Environmental seat. Applicants are chosen based upon their particular expertise and experience in relation to the seat for which they are applying; community and professional affiliations; philosophy regarding the conservation and management of marine resources; and possibly the length of residence in the area affected by the Sanctuary. Applicants who are chosen as members should expect to serve three-year terms, pursuant to the Council's Charter. Applicants for the alternates' positions will serve terms that expire at the end of the current members' terms.

DATES: Applications are due by December 28, 2001.

ADDRESSES: Application kits may be obtained from Andrew Palmer, OCNMS, 138 West First St., Port Angeles, WA 98362. Completed applications should be sent to the same address.

FOR FURTHER INFORMATION CONTACT: Andrew Palmer at (360) 457–6622 x. 30 or *andrew.palmer@noaa.gov.*

SUPPLEMENTARY INFORMATION: The Sanctuary Advisory Council provides NOAA with advice on the management of the Sanctuary. Members provide advice to the Olympic Coast Sanctuary Superintendent on Sanctuary issues. The Council, through its members, also serves as a liaison to the community regarding Sanctuary issues and act as a conduit, relaying the community's interests, concerns, and management needs to the Sanctuary.

The Sanctuary Advisory Council members represent public interest groups, local industry, commercial and recreational user groups, academia, conservation groups, government agencies, and the general public.

Authority: 16 U.S.C. Section 1431 *et seq.*

(Federal Domestic Assistance Catalog Number 11.429 Marine Sanctuary Program)

Dated: November 19, 2001.

Jamison S. Hawkins,

Deputy Assistant Administrator for Ocean Services and Coastal Zone Management.

[FR Doc. 01–29420 Filed 11–26–01; 8:45 am]

BILLING CODE 3510–08–M

DEPARTMENT OF EDUCATION

[CFDA Nos. 84.015A, 84.015B]

Office of Postsecondary Education, Title VI, Higher Education Act of 1965, as Amended, Part A, National Resource Centers Program and Foreign Language and Area Studies Fellowships Program; Notice Announcing Technical Assistance Workshop for Preparing Applications for New Awards for Fiscal Year (FY) 2003

Purpose of Workshop: To assist institutions of higher education in preparing their applications for the competition for new awards for FY 2003 under the National Resource Centers Program and the Foreign Language and Area Studies Fellowships Program authorized by section 602 of the Higher Education Act of 1965, as amended, 20 U.S.C. 1122. The workshop will include sessions on how to develop application narratives and budgets that effectively address the programs' selection criteria, as well as sessions on program evaluation and grant administration. This notice announces the technical assistance workshop only.

Prospective applicants are advised that in August 2002 the Secretary plans to publish a notice inviting applications for FY 2003 new awards, contingent upon Congress appropriating funds for these programs.

DATES: February 3–5, 2002. Workshop sessions will begin at 8 a.m. and end at 5 p.m. Conducting the workshop in February allows prospective applicants sufficient time to develop their applications for submission in fall 2002.

ADDRESSES: The Doubletree Hotel, 300 Army/Navy Drive, Arlington, Virginia. To make a reservation call the Doubletree Hotel, toll free, at 1–800–678–8123.

Assistance to Individuals with Disabilities at the Technical Assistance Workshop: The technical assistance workshop site is accessible to individuals with disabilities. If you will need an auxiliary aid or service to participate in the workshop (*e.g.,* interpreting service, assistive listening device, or materials in an alternate format), notify one of the contact persons listed under **FOR FURTHER INFORMATION CONTACT** at least two weeks before the scheduled workshop date. Although we will attempt to meet a request we receive after this date, we may not be able to make available the requested auxiliary aid or service because of insufficient time to arrange it.

FOR FURTHER INFORMATION CONTACT: The National Resource Centers Program and Foreign Language and Area Studies Fellowships Program Team: Cheryl Gibbs, Ed McDermott, Amy Wilson, or Karla Ver Bryck Block, U.S. Department of Education, International Education and Graduate Programs Service, 1990 K Street, NW., 6th Floor, Washington, DC 20006–8521. Telephone: (202) 502–7700 or via Internet: *http://www.OPE__nrc-flas@ed.gov*

If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

Individuals with disabilities may obtain this document in an alternative format (*e.g.,* Braille, large print, audiotape, or computer diskette) on request to one of the program contact persons listed under **FOR FURTHER INFORMATION CONTACT.**

Electronic Access to This Document

You may view this document, as well as all other Department of Education documents published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/legislation/FedRegister*

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.access.gpo.gov/nara/index.html*

Program Authority: 20 U.S.C. 1122.

Dated: November 21, 2001.

Maureen A. McLaughlin,

Deputy Assistant Secretary for Policy, Planning and Innovation, Office of Postsecondary Education.

[FR Doc. 01–29453 Filed 11–26–01; 8:45 am]

BILLING CODE 4001–01–P

DEPARTMENT OF ENERGY

Draft Environmental Impact Statement for the Proposed Kentucky Pioneer Integrated Gasification Combined Cycle Demonstration Project at Trapp, KY

AGENCY: Department of Energy.

ACTION: Notice of availability.

SUMMARY: The Department of Energy (DOE) announces the availability for public review and comment of the Kentucky Pioneer Integrated Combined Cycle (IGCC) Demonstration Project Draft Environmental Impact Statement (Draft EIS) (DOE/EIS–0318). DOE also announces two public hearings on the Draft EIS. DOE prepared the Draft EIS pursuant to the National Environmental Policy Act (NEPA) of 1969, as amended (42 U.S.C. 4321 *et seq.*), Council on Environmental Quality NEPA regulations (40 CFR Parts 1500–1508), and the DOE NEPA regulations (10 CFR Part 1021). The Draft EIS evaluates the environmental impacts of the Kentucky Pioneer Integrated Gasification Combined Cycle Project, a proposed Clean Coal Technology Program demonstration project in Clark County, Kentucky that was proposed by Global Energy, Inc. DOE's proposed action is to provide cost-shared funding of approximately $78 million (about 18 percent of the total cost of $432 million) for the proposed project. The project would involve constructing and operating a 540 megawatt-electric IGCC plant at the J.K. Smith Site owned by Eastern Kentucky Power Cooperative. The plant would be powered by synthesis gas generated from coal and refuse-derived fuel and a molten-carbonate fuel cell operating on the synthesis gas. This proposed project is expected to demonstrate the commercial viability of the fixed bed British Gas Lurgi process in the United States, and the operation of a high temperature molten carbonate fuel cell using synthesis gas. IGCC plants can operate at significantly higher efficiencies than conventional coal-fired power plants.

DATES: DOE invites the public to comment on the Kentucky Pioneer IGCC Demonstration Project Draft EIS. Comments should be submitted by January 4, 2002 to ensure consideration (see **ADDRESSES** section for more details). DOE will consider comments submitted after January 4, 2002, to the extent practicable. Public hearings on the Kentucky Pioneer IGCC Demonstration Project Draft EIS will be held at the Lexington Public Library, 140 East Main Street, Lexington, Kentucky, December 10, 2001, from 7 PM to 9 PM, and at Trapp Elementary School, Clark County, Kentucky, December 11, 2001, from 7 PM to 9 PM. In addition, informal sessions will be held prior to both hearings beginning at 4 p.m. for the public to learn more about the proposed action. Displays and other information about the proposed agency action and location will be available, and DOE personnel will be present to answer questions. The hearings will provide an opportunity for information

exchange and discussion among DOE and the public, as well as opportunities for the public to present oral or written comments.

ADDRESSES: Comments may be submitted by U.S. mail, fax, telephone, or electronic mail to: Mr. Roy Spears, NEPA Document Manager, U.S. Department of Energy, National Energy Technology Laboratory, P.O. Box 880, Morgantown, WV 26507–0880, Telephone: 304–285–5460, Fax 304–285–4403, leave message at 1–800–276–9851, rspear@netl.doe.gov.

Requests for copies of the Kentucky Pioneer IGCC Demonstration Project Draft EIS or other information regarding this environmental analysis should be addressed to Mr. Spears at any of the addresses above.

FOR FURTHER INFORMATION CONTACT: For further information on the proposed project or the environmental impact statement, please contact Mr. Spears as directed above. For general information on the Department's NEPA process, please contact Ms. Carol M. Borgstrom, Director, Office of NEPA Policy and Compliance, EH–42, U.S. Department of Energy, 1000 Independence Avenue, SW, Washington, DC 20585. Ms. Borgstrom may be contacted by calling 202–586–4600 or by leaving a message at 1–800–472–2756.

SUPPLEMENTARY INFORMATION:

Background

On April 14, 2000, the Department published a Notice of Intent (65 FR 20142) to prepare an environmental impact statement for the proposed Kentucky Pioneer Energy Integrated Gasification Combined Cycle Demonstration Project, in Clark County, Kentucky. The Notice of Intent informed the public of the proposed scope of the EIS, solicited public input, and announced a public scoping meeting that was held on May 4, 2000, in Trapp, Kentucky. The public scoping period closed on May 31, 2000. Comments received during the public scoping process were considered in preparing the Draft EIS.

Since then, the participant in the Cooperative Agreement, Global Energy, Inc. (Global), changed the proposed solid fuel source from fuel briquettes made from high-sulfur coal and municipal solid waste to co-feeding coal and refuse-derived fuel pellets.

Alternatives Considered

The Draft EIS evaluates a proposed action and two no-action alternatives. DOE's proposed action is to provide Kentucky Pioneer Energy, Inc., a subsidiary of Global, with cost-shared funding of approximately $78 million for the construction and operation of a 540 megawatt-electric (MWe) IGCC plant utilizing synthesis gas generated from coal and refused-derived fuel. The plant would also demonstrate a molten-carbonate fuel cell operating on coal-derived synthesis gas. The proposed location for the project is a 300-acre parcel within the existing 3,120-acre J.K. Smith Site, owned by East Kentucky Power Cooperative. The site is approximately two miles west of Trapp, Kentucky.

The two no-Action alternative scenarios are: (1) Global would not construct power generation facilities; and (2) Global would construct a combined-cycle gas turbine plant fueled by natural gas, without DOE funding. The Draft EIS compares the environmental impacts expected to occur from construction and operation of the proposed IGCC plant and fuel cell under the proposed action with the impacts that would be likely from each of the two no-action alternative scenarios.

The Draft EIS focuses on impacts from construction and operation of the proposed project on the following resource areas: human health, air quality, surface water, groundwater, ecological resources, socioeconomic resources, environmental justice, noise, and traffic and transportation. In addition, impacts on land use, floodplains, wetlands, waste management, and cultural resources are considered.

Availability of the Draft EIS

DOE has distributed copies of the Draft EIS to appropriate Members of Congress, State and local government officials in Kentucky, Federal agencies, and other groups and interested parties. Copies of the document may be obtained by contacting DOE as provided in the section of this notice entitled **ADDRESSES.** Copies of the Draft EIS are also available for inspection at the locations identified below:

(1) U.S. Department of Energy, Freedom of Information Reading Room, 1E–190, Forrestal Building, 1000 Independence Avenue, SW, Washington, DC 20585.

(2) U.S. Department of Energy, National Energy Technology Laboratory, 3610 Collins Ferry Road, Morgantown, WV 26507–0880.

(3) U.S. Department of Energy, National Energy Technology Laboratory Federal Energy Technology Center, 626 Cochrans Mill Road, Pittsburgh, PA 15236–0940.

(4) Trapp Elementary School, 11400 Irvine Road, Winchester, Kentucky 40391.

(5) Clark County Public Library, 370 South Burns Avenue, Winchester, Kentucky 40391.

(6) Lexington Public Library, 140 East Main Street, Lexington, Kentucky 40507.

Comments on the Draft EIS may be submitted to Mr. Roy Spears (see **ADDRESSES** above) or provided at public hearings (see **DATES** above). After the public comment period ends on January 4, 2002, DOE will consider all comments received, revise the Draft EIS as appropriate, and issue a Final EIS. DOE will consider the Final EIS, along with other information, such as economic and technical factors, in deciding whether or not to provide funding for the Kentucky Pioneer IGCC Demonstration Project.

Issued in Washington, DC, this 20th day of November, 2001.

Richard D. Furiga,

Acting Principal Deputy Assistant Secretary for Fossil Energy.

[FR Doc. 01–29576 Filed 11–23–01; 12:51 pm]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Office of Civilian Radioactive Waste Management; Site Recommendation Consideration Process; Correction to Mailing Address for Internal Mail Code

AGENCY: Office of Civilian Radioactive Waste Management, Department of Energy.

ACTION: Notice correcting mail address.

SUMMARY: On November 14, 2001, the Department of Energy (the Department) announced a supplemental comment period for the public to comment on supplemental analyses addressing changes from the proposed to the final regulations for the three Federal Agencies with regulatory authority over Yucca Mountain site in Nevada (66 FR 57049). On November 21, the Department announced the dates and locations for hearings to gather public comments during the supplemental comment period (66 FR 58460). In each of the notices, the internal mail code address was incorrectly printed. The correct address is: Carol Hanlon, U.S. Department of Energy, Yucca Mountain Site Characterization Office (M/S #025), P.O. Box 364629, North Las Vegas, Nevada, 89036–8629. Comments addressed to Ms. Hanlon with the incorrect mail code will still be delivered to her.

Additional information on the Civilian Radioactive Waste Management program may be obtained at the Yucca Mountain web site at *www.ymp.gov* or by calling 1–800–967–3477.

Issued in Washington, DC on November 21, 2001.

Ronald A. Milner,

Chief Operating Officer.

[FR Doc. 01–29440 Filed 11–26–01; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER01–3056–001]

Cedar Brakes III, L.L.C.; Notice of Filing

November 20, 2001.

Take notice that on November 16, 2001, Cedar Brakes III, L.L.C. (CBIII), filed with the Federal Energy Regulatory Commission (Commission) a revised tariff with a provision prohibiting power sales to, or purchases from, an affiliated public utility with a franchised service territory absent the filing for separate authorization under section 205 of the Federal Power Act. Further, CBIII requested a shortened notice period and expedited consideration of its application in this proceeding.

Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions and protests should be filed on or before November 30, 2001. Protests will be considered by the Commission to determine the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the Commission's web site at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). Comments, protests and interventions may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-filing'' link.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–29409 Filed 11–26–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP01–350–002]

Colorado Interstate Gas Company; Notice of Compliance Filing

November 20, 2001.

Take notice that on November 15, 2001, Colorado Interstate Gas Company (CIG) tendered for filing certain statements and schedules initially filed in CIG's general rate proceeding in the referenced docket. CIG states that as required by section 154.311(a); the submitted statements and schedules have been updated with actual data through September 30, 2001.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with section 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–29417 Filed 11–26–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL02–23–000]

Consolidated Edison Company of New York, Inc. Complainant, v. Public Service Electric and Gas Company PJM Interconnection, L.L.C. New York Independent System Operator, Respondents; Notice of Complaint

November 20, 2001.

Take notice that on November 19, 2001, Consolidated Edison Company of New York, Inc. (Con Edison) filed a Complaint against Public Service Electric and Gas Company (Public Service) and named PJM Interconnection, L.L.C. (PJMISO) and the New York Independent System Operator (NYISO) as necessary parties to the complaint proceeding. Con Edison filed its complaint pursuant to Section 206 of the Federal Power Act and to Rule 206 of the Commission's Rules of Practice and Procedure. Con Edison's complaint requests that the Commission investigate and remedy curtailments by Public Service of transmission service rendered pursuant to bilateral contracts between Con Edison and Public Service.

Con Edison states that it has served a copy of the complaint by mail upon Public Service, PJMISO, the NYISO, the New York State Public Service Commission, and the New Jersey Board of Public Utilities.

Any person desiring to be heard or to protest this filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests must be filed on or before December 10, 2001. 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. Answers to the complaint shall also be due on or before December 10, 2001. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the

instructions on the Commission's web site under the ''e-Filing'' link.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–29406 Filed 11–26–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER01–3055–001]

Eagle Point Cogeneration Partnership; Notice of Filing

November 20, 2001.

Take notice that on November 16, 2001, Eagle Point Cogeneration Partnership (Eagle Point), filed with the Federal Energy Regulatory Commission (Commission) a revised tariff with provisions that: (1) prohibits power sales to, or purchases from, an affiliated public utility with a franchised service territory absent the filing for separate authorization under section 205 of the Federal Power Act; and (2) establishes the pricing parameters for the reassignment of excess transmission capacity. Further, Eagle Point requested a shortened notice period and expedited consideration of its application in this proceeding.

Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions and protests should be filed on or before November 30, 2001. Protests will be considered by the Commission to determine the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the Commission's web site at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). Comments, protests and interventions may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-filing'' link.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–29408 Filed 11–26–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. ER01–3000–001, EC01–146–001 and RT01–101–001]

International Transmission Company; DTE Energy Company; Notice of Filing

November 20, 2001.

Take notice that on November 15, 2001, International Transmission Company filed a Supplemental Agreement to amend the ''Appendix I Agreement by and Between International Transmission Company and the Midwest Independent Transmission System Operator, Inc. dated August 31, 2001.''

Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions and protests should be filed on or before November 30, 2001. Protests will be considered by the Commission to determine the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–29407 Filed 11–26–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER02–64–000]

Mirant Delta, LLC and Mirant Potrero, LLC; Notice of Filing

November 20, 2001.

Take notice that on November 7, 2001, Mirant Delta, LLC and Mirant Potrero, LLC provided to the Federal Energy Regulatory Commission (Commission) an informational filing in compliance with Schedule F of their respective Must-Run Service Agreements with the California Independent System Operator Corporation.

Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions and protests should be filed on or before November 30, 2001. Protests will be considered by the Commission to determine the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the Commission's web site at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). Comments, protests and interventions may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-filing'' link.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–29410 Filed 11–26–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2000–036–New York]

Power Authority of the State of New York; Notice

November 20, 2001.

The following Commission staff were assigned to help facilitate resolution of

environmental and related issues associated with development of the St. Lawrence-FDR Power Project license application that was filed on October 31, 2001. These staff will continue to be available to assist the parties, if requested, to resolve issues during the pendency of the license application. However, these ''separated staff'' will take no part in Commission review of the application, or deliberations concerning the merits of the application.

Office of General Counsel

Merrill Hathaway

Office of Energy Projects

Jennifer Hill

Mark Pawlowski

Patti Leppert

Steve Naugle

Different Commission ''advisory staff'' will be assigned to process the license application, including providing advice to the Commission with respect to it. Separated staff and advisory staff are prohibited from communicating with one another concerning this license application. However, in the interest of efficiency and consistency, Environmental Resource Management, Inc. (ERM), per agreement with and under the direction of the New York Department of Environmental Conservation (Department) and the Commission, will continue to assist the Department and the Commission in producing the final project environmental impact statement.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–29416 Filed 11–26–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL01–118–000]

Investigation of Terms and Conditions of Public Utility Market-Based Rate Authorizations; Notice of Initiation of Proceeding and Refund Effective Date

November 21, 2001.

Take notice that on November 20, 2001, the Commission issued an order in the above-indicated dockets initiating a proceeding in Docket No. EL01–118–000 under section 206 of the Federal Power Act.

The refund effective date in Docket No. EL01–118–000 will be 60 days after publication of this notice in the **Federal Register**.

David P. Boergers,

Secretary.

[FR Doc. 01–29449 Filed 11–26–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL01–118–000]

Before Commissioners: Pat Wood, III, Chairman; William L. Massey, Linda Breathitt, and Nora Mead Brownell; Investigation of Terms and Conditions of Public Utility Market-Based Rate Authorizations; Order Establishing Refund Effective Date and Proposing To Revise Market-Based Rate Tariffs and Authorizations

Issued November 20, 2001.

I. Introduction

In this order, the Commission institutes a proceeding pursuant to section 206 of the Federal Power Act (FPA)[1] to investigate the justness and reasonableness of the terms and conditions of market-based rate tariffs and authorizations[2] of public utilities that sell electric energy and ancillary services at wholesale in interstate commerce. As discussed below, the Commission proposes to revise all existing market-based rate tariffs and authorizations to condition all public utility sellers' market-based rate authority to ensure that such rates remain just and reasonable and do not become unjust or unreasonable as a result of anticompetitive behavior or abuse of market power. The Commission intends to condition all new market-based rate tariffs and authorizations in a similar manner. The proposed condition, including the refund effective date, will protect customers from excessive rates and charges resulting from anticompetitive behavior or abuse of market power, as discussed more fully below.

Independently, in light of numerous concerns raised by market participants in cases involving market-based rates, the Commission intends to review its approach to evaluating market-based rate applications. The Commission will in the near future hold a series of outreach meetings with industry experts. The Commission expects that such meetings will inform a generic rulemaking proceeding on potential new analytical methods for assessing markets and market power. In addition, the Commission has initiated a proceeding on market design and market structure to reform open access transmission tariffs and standardize market design rules as appropriate.

II. Discussion

In an order issued on November 1, 2000, we found that the ''electric market structure and market rules for wholesale sales of electric energy in California were seriously flawed and that these structures and rules, in conjunction with an imbalance of supply and demand in California, have caused, and continue to have the potential to cause, unjust and unreasonable rates for short-term energy * * * under certain conditions.''[3] In a series of subsequent orders, the Commission reiterated those earlier findings and, among other things, established conditions, including refund liability, on sellers' market-based rate authority to prevent anticompetitive bidding behavior.[4] In its June 19 Order, the Commission stated that abuse of market power cannot and will not be tolerated, that sellers will be subject to losing their market-based rates for engaging in anti-competitive conduct, and that ''as a condition of continued authorization of market-based rates, public utility sellers in the WSCC [Western Systems Coordinating Council] must agree to refunds, with interest pursuant to 18 CFR 35.19a, of any overcharges resulting from anticompetitive bidding or behavior.''[5]

Based on our recent experience involving wholesale electric markets in California and the rest of the WSCC, and consistent with our intention to review the Commission's approach to evaluating market-based rate applications and also to explore generic transmission and market design protocols, we believe it is necessary and appropriate to impose a tariff condition on all public utility sellers with market-based rate authority. This tariff condition, described more fully below, will ensure that rates collected pursuant

[1] 16 U.S.C. § 824e (1994).

[2] Our use in this order of the term ''market-based rate tariffs and authorizations'' is intended to include all tariffs and rate schedules under which a public utility is authorized to make sales of electric energy and ancillary services at market-based rates.

[3] San Diego Gas & Electric Company, *et al.,* 93 FERC ¶61,121 at 61,349–50 (2000), *reh'g pending* (November 1 Order).

[4] San Diego Gas & Electric Company, *et al.,* 93 FERC ¶61,294 (2000), *reh'g pending* (December 15 Order); San Diego Gas & Electric Company, *et al.,* 95 FERC ¶61,115 at 61,360 (2001) (April 26 Order), *order on reh'g,* 95 FERC ¶61,418 (2001), *reh'g pending* (June 19 Order); San Diego Gas & Electric Company, *et al.,* 96 FERC ¶ 61,120 (2001), *reh'g pending* (July 25 Order).

[5] June 19 Order, 95 FERC at 62,548, 62,565.

to market-based rate tariffs and authorizations are just and reasonable and that customers have full refund protection against anticompetitive behavior or abuse of market power.[6]

In today's electric industry, the Commission is faced with power and energy sales markets that are increasingly interstate in nature and increasingly dependent upon one another, and with power and energy sales markets that are in varying stages of transition to competition at the wholesale and, in numerous states, the retail level. We have a responsibility under the FPA to monitor wholesale markets to ensure that jurisdictional rates in the markets remain within a zone of reasonableness. Our responsibility is to ensure that sellers not charge unjust and unreasonable wholesale rates, and that the market structures and market rules governing public utility sellers nationwide, and affecting the wholesale rates of such public utility sellers, do not result in, or have the potential to result in, wholesale rates that are unjust, unreasonable, unduly discriminatory, or preferential. We have become increasingly concerned about the potential that public utilities with market-based rate authorization might, under certain circumstances, exercise market power or engage in anticompetitive behavior that could result in unjust or unreasonableness rates.

Although we do not find here that particular sellers have, for example, exercised market power, we propose to take steps now to minimize the potential for any such market power abuse or anticompetitive behavior and thus protect against possible unjust and unreasonable rates. Pursuant to FPA section 206, we are establishing a refund effective date 60 days from the date on which notice of initiation of this investigation is published in the **Federal Register** and seek comments on our proposal to revise all market-based rate tariffs and authorizations in effect to condition public utility sellers' market-based rate authority to prevent anticompetitive behavior or the exercise of market power. In particular, all such market-based rate tariffs and authorizations would be revised to include the following provision: ''As a condition of obtaining and retaining market-based rate authority, the seller is prohibited from engaging in anticompetitive behavior or the exercise of market power. The seller's market-based rate authority is subject to refunds or other remedies as may be appropriate to address any anticompetitive behavior or exercise of market power.'' We will also require that this provision be included in all new market-based rates tariffs and authorizations. Violation of such provision would constitute a violation of a tariff or rate schedule on file under FPA section 205, and the Commission would have the authority to address promptly potential instances of anticompetitive behavior or exercises of market power through the imposition of refunds or such other remedies as may be appropriate.

Anticompetitive behavior or exercises of market power include behavior that raises the market price through physical or economic withholding of supplies. Such behavior may involve an individual supplier withholding supplies, or a group of suppliers jointly colluding to do so. Physical withholding occurs when a supplier fails to offer its output to the market during periods when the market price exceeds the supplier's full incremental costs. For example, physical withholding would occur when a generator declares a forced outage when its unit is not, in fact, experiencing mechanical problems, and when the market price is above the unit's full incremental costs. Economic withholding occurs when a supplier offers output to the market at a price that is above both its full incremental costs and the market price (and thus, the output is not sold). For example, we would expect that, during periods of high demand and high market prices, all generation capacity whose full incremental costs do not exceed the market price would be either producing energy or supplying operating reserves. Failing to do so would be an example of economic withholding. Withholding supplies can also occur when a seller is able to erect barriers to entry that limit or prevent others from offering supplies to the market or that raise the costs of other suppliers. Examples would include denying, delaying or requiring unreasonable terms, conditions, or rates for natural gas service to a potential electric competitor in bulk power markets.

Should public utility market participants engage in prohibited behavior, their rates will be subject to increased scrutiny by the Commission, and to potential refunds or such other remedies as may be appropriate. This could result in further conditions or restrictions on their market-based rate authority, including, for example, prospective revocation of the market-based rate authority of the seller or any of its affiliates, or conditions precluding the seller from selling at market-based rates to its affiliate.

We believe that our proposal herein is necessary to ensure that rates which are market-based remain just and reasonable, and to ensure that the Commission can adequately remedy any anticompetitive behavior or the exercise of market power that might subsequently be brought to the Commission's attention, and protect customers through refunds or other remedies where appropriate.

We conclude that a trial-type hearing is not necessary to resolve the matter that is the subject of the proceeding that we are instituting here.[7] Rather, we believe that a ''paper'' hearing will allow us to determine whether the condition we propose to add to all market-based rate tariffs and authorizations is appropriate given the state of today's wholesale electric markets. Further, given our statutory responsibility to ensure that rates under existing market-based rate tariffs and authorizations remain just and reasonable, we believe that expeditious resolution of this proceeding is critical. Accordingly, the Commission will provide interested entities an opportunity to file comments and reply comments regarding our proposal to

[6] The Commission proposes to apply the condition to all public utility sellers currently authorized to sell at market-based rates and to make the condition effective 60 days following publication in the **Federal Register** of the notice of the Commission's initiation of this proceeding. A list of such sellers and the docket numbers in which they previously received market-based rate authorization is attached as Appendix A. In the event that a public utility with market-based rate authority as of the date of issuance of this order is not listed in Appendix A, such omission is inadvertent and does not mean that a non-listed utility is exempt from the tariff condition proposed herein. The Commission does not, however, propose a specific date by which each such seller must make a compliance filing, but instead proposes to direct each seller to include the required revision to its tariff the next time that it files an amendment to the tariff or seeks continued authorization to sell at market-based rates. The date of submission of the compliance filing will not, however, delay the effective date of the condition.

The Commission intends to condition all future market-based rate tariffs and authorizations in a similar manner.

[7] The use of a ''paper'' hearing rather than a trial-type evidentiary hearing has been addressed in numerous cases. *See, e.g.,* Public Service Company of Indiana, 49 FERC ¶61,346 (1989), *order on reh'g,* 50 FERC ¶61,186, *opinion issued,* Opinion 349, 51 FERC ¶61,367, *order on reh'g,* Opinion 349–A, 52 FERC ¶61,260, *clarified,* 53 FERC ¶61,131 (1990), *dismissed,* Northern Indiana Public Service Company v. FERC, 954 F.2d 736 (D.C. Cir. 1992). As the Commission noted in Opinion No. 349, 51 FERC at 62,218–19 & n.67, while the FPA and the case law require that the Commission provide the parties with a meaningful opportunity for a hearing, the Commission is required to reach decisions on the basis of an oral, trial-type evidentiary record only if the material facts in dispute cannot be resolved on the basis of the written record, *i.e.,* where the written submissions do not provide an adequate basis for resolving disputes about material facts.

revise all market-based rate tariffs and authorizations in effect to condition public utility sellers' market-based rate authority to prevent anticompetitive behavior or the exercise of market power. Initial comments will be due 15 days from the date of this order, and reply comments will be due 15 days from the date of filing of initial comments.

In cases where the Commission institutes a section 206 proceeding on its own motion, as here, section 206(b) requires that the Commission establish a refund effective date that is no earlier than 60 days after publication of notice of the Commission's intent to institute a proceeding in the **Federal Register**, and no later than five months subsequent to the expiration of the 60-day period. We will establish a refund effective date of 60 days from the date on which notice of our initiation of this investigation is published in the **Federal Register**. The Commission is also required by section 206 to indicate when it expects to issue its final order. The Commission expects to issue a final order in this proceeding by the end of March 2002.

The Commission Orders

(A) Pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by section 402(a) of the Department of Energy Organization Act and by the Federal Power Act, particularly section 206 thereof, and pursuant to the Commission's Rules of Practice and Procedure and the regulations under the Federal Power Act (18 CFR chapter I), the Commission proposes to revise all public utility sellers' market-based rate tariffs and authorizations, and to conduct the proceedings directed in Ordering Paragraph (B) below, as discussed in the body of this order.

(B) Interested persons may submit to the Commission arguments and evidence as outlined in the body of this order 15 days from the date of this order. Replies may be made 15 days thereafter.

(C) The Secretary shall promptly publish in the **Federal Register** a notice of the Commission's initiation of the proceeding under section 206 of the FPA in Docket No. EL01–118–000.

(D) The refund effective date established pursuant to section 206(b) of the FPA will be 60 days following publication in the **Federal Register** of the notice discussed in Ordering Paragraph (C) above.

(E) The Secretary shall promptly publish this order in the **Federal Register**.

By the Commission.

David P. Boergers,

Secretary.

[FR Doc. 01–29450 Filed 11–26–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. MG02–1–000]

Southern LNG Inc.; Notice of Filing

November 20, 2001.

On October 24, 2001, Southern LNG submitted its revised standards of conduct.

Southern LNG Inc. states that it served copies of the filing on all customers and interested state commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest in this proceeding with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC, 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure. (18 CFR 385.211 or 385.214) All such motions to intervene or protest should be filed on or before December 5, 2001. 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 this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–29411 Filed 11–26–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP02–48–000]

Transcontinental Gas Pipe Line Corporation; Notice of Tariff Filing

November 20, 2001.

Take notice that on November 15, 2001, Transcontinental Gas Pipe Line Corporation (Transco) tendered for filing as part of its FERC Gas Tariff, Third Revised Volume No. 1, certain revised tariff sheets, which sheets are enumerated in Appendix A attached to the filing. The proposed effective date of such tariff sheets is November 1, 2001.

Transco states that the purpose of the instant filing is to track rate changes attributable to: (1) Transportation service purchased from Dominion Transmission, Inc. (Dominion) under its Rate Schedule GSS, the costs of which are included in the rates and charges payable under Transco's Rate Schedules GSS and LSS, and (2) transportation service purchased from Texas Gas Transmission Corporations (Texas Gas) under its Rate Schedule FT, the costs of which are included in the rates and charges payable under Transco's Rate Schedule FT–NT. This filing is being made pursuant to tracking provisions under Section 3 of Transco's Rate Schedule GSS, Section 4 of Transco's Rate Schedule LSS and Section 4 of Transco's Rate Schedule FT–NT.

Transco states that included in Appendices B and C attached to the filing are the explanations of the rate changes and details regarding the computation of the revised GSS, LSS and FT–NT rates.

Transco states that copies of the filing are being mailed to affected customers and interested State Commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the web at *http://*

www.ferc.gov using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance). Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–29418 Filed 11–26–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application Accepted for Filing, Soliciting Motions to Intervene and Protests, Ready for Environmental Analysis, and Soliciting Comments, and Terms and Conditions, Recommendations, and Prescriptions

November 20, 2001.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* small hydroelectric exemption.

b. *Project No.:* 12094–000.

c. *Date filed:* July 24, 2001.

d. *Applicant:* Hydro Technology Systems, Inc.

e. *Name of Project:* 1910 Meyers Falls Hydroelectric Plant.

f. *Location:* On the Colville River, near the City of Kettle Falls, in Stevens County, Washington. The proposed exemption would not occupy any federal lands.

g. *Filed Pursuant to:* Public Utility Regulatory Policies Act of 1978, 16 U.S.C. §§ 2705, 2708.

h. *Applicant Contact:* Michael E. Johnson, Hydro Technology Systems, Inc., P.O. Box 683 Kettle Falls, WA 99141; (509) 738–6544.

i. *FERC Contact:* John B. Smith, (202) 219–2460, *john.smith@ferc.fed.us.*

j. *Deadline for filing motions to intervene and protests, comments, and terms and conditions, recommendations, and prescriptions:* 60 days from the issuance date of this notice.

All documents (original and eight copies) should be filed with: David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426. Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

Motions to intervene and protests, comments, terms and conditions, recommendations, and prescriptions may be filed electronically via the Internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site (*http://www.ferc.gov*) under the ''e-Filing'' link.

k. This application has been accepted for filing, and is now ready for environmental analysis.

We will consider the prefiling consultation process that has occurred as satisfying National Environmental Policy Act scoping and intend on issuing one environmental assessment (EA) rather than issuing a draft and final EA. Tentatively, we plan on issuing an EA by March 2002.

l. The proposed project would consist of: (1) The existing concrete intake structure, restored and equipped with a new trash screen and headgate, located on the south bank of the Colville River between 2 waterfalls; (2) a new 230-foot-long, 42-inch-diameter welded-steel penstock; (3) the existing 60-foot-long by 30-foot-wide concrete powerhouse restored and equipped with a new, horizontal Francis turbine coupled to a generator with an output rating of 300 kilowatts at a design turbine flow of 50 cubic feet per second; (4) a 1,500-foot-long, 11-kilovolt, underground transmission line; and (5) other appurtenances.

m. A copy of the application is on file with the Commission and is available for public inspection. This filing may also be viewed on the web at *http://www.ferc.gov* using the ''RIMS'' link—select ''Docket #'' and follow the instructions (call 202–208–2222 for assistance). A copy is also available for inspection and reproduction at the address in item h above.

n. Any qualified applicant desiring to file a competing application must submit to the Commission, on or before the specified deadline date for the particular application, a competing development application, or a notice of intent to file such an application. Submission of a timely notice of intent allows an interested person to file the competing development application no later than 120 days after the specified deadline date for the particular application. Applications for preliminary permits will not be accepted in response to this notice.

A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

Anyone may submit comments, a protest or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 385.211, and 385.214. In determining the appropriate action to take, the Commission will consider all protests filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified deadline date for the particular application.

The Commission directs, pursuant to section 4.34 (b) of the Regulations (see Order No. 533 issued May 8, 1991, 56 FR 23108, May 20 1991) that all comments, recommendations, terms and conditions, and prescriptions concerning the application be filed with the Commission within 60 days from the issuance date of this notice. All reply comments must be filed with the Commission within 105 days from the date of this notice.

Anyone may obtain an extension of time for these deadlines from the Commission only upon a showing of good cause or extraordinary circumstances in accordance with 18 CFR 385.2008.

All filings must (1) Bear in all capital letters the title ''PROTEST'', ''MOTION TO INTERVENE'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION,'' ''COMPETING APPLICATION,'' ''COMMENTS,'' ''REPLY COMMENTS,'' ''RECOMMENDATIONS,'' ''TERMS AND CONDITIONS,'' or ''PRESCRIPTIONS;'' (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All

comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–29412 Filed 11–26–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application Accepted for Filing and Soliciting Motions To Intervene, Protests, and Comments

November 20, 2001.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 12102–000.

c. *Date filed:* July 31, 2001.

d. *Applicant:* Mark R. Frederick.

e. *Name of Project:* Outfall of the Chicago Park Powerhouse Project.

f. *Location:* On Bear River and Chicago Park Flume, in Placer and Nevada Counties, California. Would be on land owned by Pacific Gas and Electric Company.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. §§ 791(a)—825(r).

h. *Applicant Contact:* Mr. Mark R. Frederick, 17825 Crother Hills Road, Meadow Vista, CA 95722, (530) 887–1984.

i. *FERC Contact:* Robert Bell, (202) 219–2806.

j. *Deadline for filing motions to intervene, protests and comments:* 60 days from the issuance date of this notice.

All documents (original and eight copies) should be filed with: David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426. Comments, protests and interventions may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-filing'' link.

Please include the project number (P–12102–000) on any comments or motions filed.

The Commission's Rules of Practice and Procedure require all interveners filing documents with the Commission to serve a copy of that document on each person in the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Project:* The proposed project would consist of: (1) A proposed intake, (2) a proposed powerhouse containing one generating having an installed capacity of 1,800 kW, (3) a proposed 80-foot-long, 12kV transmission line, and (4) appurtenant facilities.

The project would have an annual generation of 15.5 GWh that would be sold to a local utility.

l. Copies of this filing are on file with the Commission and are available for public inspection. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance).

m. Preliminary Permit—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (see 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

n. Preliminary Permit—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

o. Notice of Intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

p. Proposed Scope of Studies under Permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

q. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 385.211, 385.214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

r. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''PROTEST'', ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent,

competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

s. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–29413 Filed 11–26–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application Accepted for Filing and Soliciting Motions To Intervene, Protests, and Comments

November 20, 2001.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 12103–000.

c. *Date filed:* July 31, 2001.

d. *Applicant:* Mark R. Frederick.

e. *Name of Project:* Chicago Park Flume Project.

f. *Location:* On Bear River, Dutch Flat Afterbay and Dutch Flat Flume, in Placer and Nevada Counties, California. Would be located on land owned by Pacific Gas and Electric Company.

g. *Filed Pursuant to:* Federal Power Act, 16 USC 791(a)–825(r).

h. *Applicant Contact:* Mr. Mark R. Frederick, 17825 Crother Hills Road, Meadow Vista, CA 95722, (530) 887–1984.

i. *FERC Contact:* Robert Bell, (202) 219–2806.

j. *Deadline for filing motions to intervene, protests and comments:* 60 days from the issuance date of this notice.

All documents (original and eight copies) should be filed with: David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426. Comments, protests and interventions may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-filing'' link.

Please include the project number P–12103–000 on any comments or motions filed.

The Commission's rules of practice and procedure require all interveners filing documents with the Commission to serve a copy of that document on each person in the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Project:* The proposed project would consist of: (1) A proposed intake, (2) a proposed powerhouse containing one generating unit having an installed capacity of 900 kW, (3) an 80-foot-long, 12kV transmission line, and (4) appurtenant facilities.

The project would have an annual generation of 7.7 GWh that would be sold to a local utility.

l. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance).

m. Preliminary Permit—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (see 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

n. Preliminary Permit—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

o. Notice of Intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

p. Proposed Scope of Studies under Permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

q. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of rules of practice and procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

r. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''PROTEST'', ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each

representative of the Applicant specified in the particular application.

s. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–29414 Filed 11–26–01; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application Accepted for Filing and Soliciting Motions to Intervene, Protests, and Comments

November 20, 2001.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 12130–000.

c. *Date filed:* October 1, 2001.

d. *Applicant:* Blackfeet Tribe of the Blackfeet Indian Reservation.

e. *Name of Project:* Swift Dam Project.

f. *Location:* On an existing dam owned by Pondera County Canal and Reservoir Company, on Birch Creek, in Pondera County, Montana. The project would be located within the Blackfeet Indian Reservation.

g. *Filed Pursuant to:* Federal Power Act, 16 USC §§ 791(a)–825(r).

h. *Applicant Contact:* Ms. Jeanne S. Whiteing, Blackfeet Tribe of the Blackfeet Indian Reservation, Whiteing & Smith, 1136 Pearl Street, Suite 203, Boulder, CO 80302 (303) 444–2549.

i. *FERC Contact:* Robert Bell, (202) 219–2806.

j. *Deadline for filing motions to intervene, protests and comments:* 60 days from the issuance date of this notice.

All documents (original and eight copies) should be filed with: David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Copies of this filing are on file with the Commission and are available for public inspection. Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the ''e-Filing'' link.

Please include the project number (P–12130–000) on any comments or motions filed.

The Commission's Rules of Practice and Procedure require all interveners filing documents with the Commission to serve a copy of that document on each person in the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Competing Application:* Project No. 12037–000, Date Filed: June 4, 2001, Date Notice Closed: September 4, 2001.

l. *Description of Project:* The proposed project would consist of: (1) An existing 560-foot-long, 205-foot-high concrete dam, (2) an existing reservoir having a surface area of 540 acres with a storage capacity of 30,000 acre-feet and normal water surface elevation of 4,884 feet msl, (3) a proposed intake structure, (4) two proposed 20-foot-long, 48-inch-diameter steel penstocks; (5) a proposed powerhouse containing two generating units with a total installed capacity of 2.2 MW, (6) a proposed 11-mile-long 15 kV transmission line, and (7) appurtenant facilities.

The project would have an annual generation of 9.6 GWh that would be sold to a local utility.

m. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the web at *http://www.ferc.gov* using the ''RIMS'' link, select ''Docket#'' and follow the instructions (call 202–208–2222 for assistance).

n. Preliminary Permit—Public notice of the filing of the initial preliminary permit application, which has already been given, established the due date for filing competing preliminary permit applications or notices of intent. Any competing preliminary permit or development application or notice of intent to file a competing preliminary permit or development application must be filed in response to and in compliance with the public notice of the initial preliminary permit application. No competing applications or notices of intent to file competing applications may be filed in response to this notice. A competing license application must conform with 18 CFR 4.30 (b) and 4.36.

o. Proposed Scope of Studies under Permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

p. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 385.211, 385.214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

q. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''PROTEST'', ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Project Review, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

r. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–29415 Filed 11–26–01; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7108–1]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; Requirements for Generators, Transporters, and Hazardous Waste Management Facilities Under the RCRA Hazardous Waste Manifest System, EPA ICR No. 801.14

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that EPA is planning to submit the following proposed and/or continuing Information Collection Request (ICR) to the Office of Management and Budget (OMB): Requirements for Generators, Transporters, and Hazardous Waste Management Facilities Under the RCRA Hazardous Waste Manifest System, EPA ICR No. 801.14, OMB Control Number 2050–0039, current expiration date 3/31/2002. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection described below.

DATES: Comments must be submitted on or before January 28, 2002.

ADDRESSES: Commenters must send an original and two copies of their comments referencing docket number F–2001–RW3P–FFFFF to RCRA Docket Information Center, Office of Solid Waste (5305G), U.S. Environmental Protection Agency, Ariel Rios Building, 1200 Pennsylvania Avenue NW., Washington, DC 20460. Hand deliveries of comments should be made to the Arlington, VA, address listed below. Comments may also be submitted electronically by sending electronic mail through the Internet to: *rcra-docket@epamail.epa.gov.* Comments in electronic format should also be identified by the docket number F–2001–RW3P–FFFFF. All electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Public comments and supporting materials are available for viewing in the RCRA Information Center (RIC), located at Crystal Gateway 1, 1235 Jefferson Davis Highway, first floor, Arlington, VA. The RIC is open from 9 a.m. to 4 p.m., Monday through Friday, excluding federal holidays. To review docket materials, the public must make an appointment by calling 703–603–9230. The public may copy a maximum of 100 pages from any regulatory docket at no charge. Additional copies cost $.15/page. Copies of the original ICR may be requested from the docket address and phone number listed above or may be found on the Internet at: *http://www.epa.gov/epaoswer/hazwaste/gener/manifest/icr-man.htm.*

The official record for this action will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into paper form and place them in the official record, which will also include all comments submitted directly in writing. The official record is the paper record maintained in the RCRA Information Center (the RIC address is listed above in this section).

FOR FURTHER INFORMATION CONTACT: For general information, contact the RCRA Hotline at 1–800–424–9346 or TDD 1–800–553–7672 (hearing impaired). In the Washington metropolitan area, call 703–412–9610 or TDD 703–412–3323. For technical information, contact Bryan Groce at 703–308–8750, *groce.bryan@epa.gov.*

SUPPLEMENTARY INFORMATION:

Title: Requirements for Generators, Transporters, and Hazardous Waste Management Facilities Under the RCRA Hazardous Waste Manifest System, OMB Control No. 2050–0039; EPA ICR No. 801.14) expiring 3/30/2002. This is an extension of a currently approved collection.

Abstract: The Resource Conservation and Recovery Act (RCRA), as amended, establishes a national program to assure that hazardous waste management practices are conducted in a manner that is protective of human health and the environment. EPA's authority to require compliance with the manifest system stems primarily from RCRA section 3002(a)(5). This section mandates a hazardous waste manifest ''system'' to assure that all hazardous waste generated is designated for and arrives at the appropriate treatment, storage, and disposal facility. An essential part of this manifest system is the Uniform Hazardous Waste Manifest (Form 8700–22A). The manifest is a tracking document that accompanies the waste from its generation site to its final disposition. The manifest lists the wastes that are being shipped and the final destination of the waste. The manifest system is a self-enforcing mechanism that requires generators, transporters, and owner/operators of treatment, storage, and disposal facilities to participate in hazardous waste tracking. In addition the manifest provides information to transporters and waste management facility workers on the hazardous nature of the waste, identifies wastes so that they can be managed appropriately in the event of an accident, spill, or leak, and ensures that shipments of hazardous waste are managed properly and delivered to their designated facilities.

This system does not ordinarily involve intervention on the part of EPA unless hazardous wastes do not reach their point of disposition within a specified time frame. In most cases, RCRA-authorized States operate the manifest system, and requirements may vary among authorized States.

EPA believes manifest requirements and the resulting information collection mitigate potential hazards to human health and the environment by ensuring that hazardous waste is sent to and received by appropriate treatment, storage, and disposal facilities, by initiating appropriate response actions if a shipment does not reach its intended destination, and by providing necessary emergency response information in the event of an accident, spill, or leak during transportation.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR Chapter 15. The Agency notes that the burden hour and cost estimates given below are based on estimates approved by OMB during the 1999 ICR renewal process. The Agency did not have the most recent Biennial Reporting System (BRS) information available at the time of completion of this ICR. The Agency will update these burden estimates using the most recent BRS information and publish the revised burden estimates in a second **Federal Register** notice. Affected entities will have an opportunity to comment on the revised burden estimates during a comment period for the second FR notice. EPA would like to solicit comments to:

(i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) Enhance the quality, utility, and clarity of the information to be collected; and

(iv) Minimize the burden of the collection of information on those who are to respond, including through the

use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* allowing electronic submission of responses.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 1.26 hours per response.

Respondents/Affected Entities: Generators, transporters, and treatment, storage, and disposal facilities (TSDFs).

Estimated Number of Respondents: 105,558.

Frequency of Response: Per shipment of hazardous waste.

Estimated Total Annual Hour Burden: 2,920,383 hours.

Estimated Total Annualized Capital, Operating/Maintenance Cost Burden: $1,871,246. 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.

Dated: November 20, 2001.

Elizabeth A. Cotsworth,

Director, Office of Solid Waste.

[FR Doc. 01–29472 Filed 11–26–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7109–2]

Notice of Availability for Draft Guidance on Source Determinations for Combined Heat and Power Facilities Under the Clean Air Act New Source Review and Title V Programs

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability; reopening of comment period.

SUMMARY: The EPA is hereby reopening for 15 days the public review and comment period regarding a preliminary draft of its pending guidance on Source Determinations for Combined Heat and Power (CHP) Facilities under the Clean Air Act New Source Review and Title V Programs (66 FR 52403, October 15, 2001). The combined generation of heat and power, also known as cogeneration, has been an energy supply option for nearly 100 years and is used in many sectors of the economy. In light of ever increasing demand for energy, electric power industry restructuring and cross-program pollution prevention initiatives, EPA is committed to improving the efficiency at which we convert fuels into useful energy. Properly designed and implemented CHP is a key element to achieving the nation's energy goals, because CHPs are capable of independently providing power to the grid or customers other than the host facility and therefore can help alleviate power shortfalls. Recognizing this, the Report of the National Energy Policy Development Group recommends ''that the President direct the EPA Administrator to promote CHP through flexibility in environmental permitting.''

A draft of EPA's guidance is available for public review and comment. The EPA does not intend to respond to individual comments, but rather to consider the comments from the public in the preparation of the final guidance. It is important that the draft guidance being made available today for public review and comment does not represent official EPA policy or a formal position on the subject matter discussed and therefore is not to be relied on in interpreting EPA policy.

DATES: The comment period on the draft guidance will close on December 12, 2001.

ADDRESSES: Written comments should be sent to Pamela J. Smith, Information Transfer and Program Integration Division (MD–12), Office of Air Quality Planning and Standards, U.S. EPA, Research Triangle Park, North Carolina 27711, telephone 919–541–0641, telefax 919–541–5509 or E-mail *smith.pam@epa.gov.*

FOR FURTHER INFORMATION CONTACT: Kathy Kaufman, Office of Air Quality Planning and Standards, U.S. EPA, MD–12, Research Triangle Park, NC 27711, telephone 919–541–0102 or E-mail *kaufman.kathy@epa.gov.*

SUPPLEMENTARY INFORMATION: A copy of the draft guidance document may be obtained by calling or E-mailing Pamela J. Smith. The draft guidance may also be downloaded from the NSR Web Site *http://www.epa.gov/ttn/nsr* under the topic ''What's New on NSR.''

Dated: November 16, 2001.

Jeffrey Clark,

Acting Director, Office of Air Quality Planning and Standards.

[FR Doc. 01–29546 Filed 11–26–01; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATONS COMMISSION

[CC Docket No. 01–194; FCC 01–338]

Joint Application by SBC Communications Inc., Southwestern Bell Telephone Company, and Southwestern Bell Communications Services, Inc. d/b/a Southwestern Bell Long Distance To Provide In-Region, InterLATA Service in the States of Arkansas and Missouri

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In this document, the Federal Communications Commission (Commission) grants the section 271 application of Southwestern Bell Telephone Company (SWBT) for authority to enter the interLATA telecommunications market in the States of Arkansas and Missouri. The Commission grants SWBT's application based on our conclusion that Southwestern Bell satisfies all of the statutory requirements established by Congress in section 271 of the Communications Act.

DATES: Effective November 26, 2001.

FOR FURTHER INFORMATION CONTACT: Scott Bergmann, Legal Counsel, Common Carrier Bureau, at (202) 418–1580, or via the Internet at *sbergman@fcc.gov.* The full text of the Order is available for inspection and copying during normal business hours in the FCC Reference Information Center, CY–A257, 445 12th Street, SW., Washington, DC 20554. Further information may also be obtained by calling the Common Carrier Bureau's TTY number: (202) 418–0484.

SUPPLEMENTARY INFORMATION: This document is a brief description of the Commission's Memorandum Opinion and Order adopted November 16, 2001, and released November 16, 2001. The full text also may be obtained through the World Wide Web, at <<http://www.fcc.gov/Bureaus/Common_Carrier/in-region_applications/sbcksok/welcome.html>>, or may be purchased from the Commission's copy contractor, Qualex International Transcription Service Inc. (ITS), CY B–402, 445 12th Street, SW., Washington, DC.

Synopsis of the Memorandum Opinion and Order

1. *History of the Application.* On August 20, 2001, SWBT filed a joint application, pursuant to section 271 of the Telecommunications Act of 1996 with the Commission to provide in-region, interLATA service in the States of Arkansas and Missouri.

2. *The State Commissions' Evaluations.* The Arkansas Public Service Commission and Missouri Public Service Commission both advised the Commission that, following more than two years of extensive review, SWBT met the checklist requirements of section 271(c) and had taken the statutorily required steps to open its local markets to competition. Specifically, both commissions stated that SWBT met its obligation under ''Track A'' (or section 271(c)(1)(A)) by entering into interconnection agreements with competing carriers that are serving residential and business customers either exclusively or predominantly over their own facilities. Both state commissions found that SWBT had fully complied with section 271, and each voted to support the application.

3. *The Department of Justice's Evaluation.* The Department of Justice submitted its evaluation of SWBT's application on September 24, 2001. In its evaluation, the Department of Justice raised concerns about pricing of interconnection and unbundled network elements (UNEs) in Missouri. Second, the Department of Justice raised concerns about SWBT's ability to provide non-discriminatory access to its maintenance and repair functions and finally suggests that performance problems may occur in after section 271 approval in Arkansas because of the limited enforcement authority of the Arkansas Commission. The Department of Justice recognized that the Commission may gather additional information on these issues during the pendency of the application, and ''may therefore be able to assure itself that the remaining questions have been answered and may be in a position to approve SBC's [SWBT's] joint application.''

4. *Compliance with Section 271(c)(1)(A).* In order for the Commission to approve a BOC's application to provide in-region InterLATA services a BOC must first demonstrate that it satisfies the requirements of either section 271(c)(1)(A) (Track A) or section 271(c)(1)(B) (Track B). To qualify for Track A, a BOC must have interconnection agreements with one or more competing providers of ''telephone exchange service * * * to residential and business subscribers.'' We conclude that SWBT demonstrates that it satisfies Track A in Arkansas based on the interconnection agreements it has implemented with ALLTEL. Although commenters dispute the exact number of residential and business subscribers in Arkansas, the Commission concludes that a sufficient number of customers are being served by ALLTEL through the use of their own facilities. No commenter has challenged SWBT's claim regarding the number of customers served by ALLTEL. With respect to Missouri, the Commission concludes that SWBT demonstrates that it satisfies the requirements of Track A based upon interconnection agreements it has implemented with AT&T and WorldCom. No commenter has challenged SWBT's assertion that it qualifies for Track A in Missouri.

5. *Checklist Item 2—Access to Unbundled Network Elements.* We conclude that SWBT satisfies the requirements of checklist item 2 in both Arkansas and Missouri. For purposes of the checklist, SWBT's obligation to provide ''access to unbundled network elements,'' or the individual components of the telephone network, includes access to its OSS—the term used to describe the systems, databases and personnel necessary to support the network elements or services. Nondiscriminatory access to OSS ensures that new entrants have the ability to order service for their customers and communicate effectively with SWBT regarding basic activities such as placing orders, and providing maintenance and repair service for customers. We find that, for each of the primary OSS functions (pre-ordering, ordering, provisioning, maintenance and repair, and billing, as well as change management and technical assistance), SWBT provides access that enables competing carriers to perform the function in substantially the same time and manner as SWBT or, if there is not an appropriate retail analogue in SWBT's systems, in a manner that permits an efficient competitor a meaningful opportunity to compete. In reaching this conclusion, we find that SWBT provides non-discriminatory access to its OSS in Arkansas and Missouri.

6. With respect to pre-ordering, or the activities that a competing carrier undertakes to gather and verify the information necessary to place an order, the Commission finds that SWBT provides carriers in Arkansas and Missouri nondiscriminatory access to all pre-ordering functions and enables carriers to integrate pre-order and pre-ordering functions through DataGate and VeriGate. Navigator, nevertheless suggests that it experiences a variety of problems when attempting to reserve a telephone number using VeriGate. We find that Navigator's claims do not overcome the detailed affidavit and performance data evidence submitted by SWBT that indicates that VeriGate and other SWBT systems operate properly.

7. In addition, with respect to maintenance and repair, the Commission finds that SWBT demonstrates that it provides nondiscriminatory access to the maintenance and repair OSS functions. While commenters raise questions about the functioning of the SWBT's maintenance and repair databases, we find that those potential deficiencies have not had a significant effect on competitive entry in Arkansas and Missouri and as such do not warrant a finding of noncompliance with checklist item 2.

8. With respect to billing, SWBT demonstrates that it provides complete and accurate reports on the service usage of competing carriers' customers in the same manner that SWBT provides such information to itself. SWBT also demonstrates that it provides the documentation and support necessary to provide competitive carriers nondiscriminatory access to its OSS by showing that it has an adequate change management process in its five-state region, which includes Arkansas and Missouri. The Commission finds that SWBT provides carriers with nondiscriminatory access to functionality of it billing systems.

9. Pursuant to this checklist item, SWBT must also provide nondiscriminatory access to network elements in a manner that allows other carriers to combine such elements. Based on the evidence in the record, and upon SWBT's legal obligations under interconnection agreements offered in Arkansas and Missouri, SWBT demonstrates that it provides to competitors combinations of already-combined network elements as well as nondiscriminatory access to unbundled network elements in a manner that allows competing carriers to combine those elements themselves.

10. Finally, the Commission finds that SWBT satisfies the pricing requirements of checklist item 2 in both Arkansas and Missouri. In fulfilling its obligation under this checklist item, SWBT demonstrates that it provides nondiscriminatory access to UNEs at any technically feasible point at rates, terms and conditions that are just, reasonable, and nondiscriminatory. We

find that SWBT's recurring charges for UNEs made available in both Arkansas and Missouri are just and reasonable and nondiscriminatory in compliance with checklist item 2. The Commission finds that SWBT's voluntarily-reduced rates in Missouri fall within a reasonable range of what TELRIC based ratemaking would produce, based upon comparisons between SWBT's rates in Missouri and SWBT's previously approved rates in Texas. We also find that SWBT passes this checklist item in Arkansas by adopting in whole the Kansas rates, which we previously reviewed and accepted in SWBT's Kansas 271 proceeding, and by showing that Arkansas costs are the same or higher than costs in Kansas. The Missouri and Arkansas Commissions concluded separately that SWBT satisfies this checklist item. The Department of Justice originally expressed concerns about SWBT's recurring rates in SWBT's first Missouri 271 application and urged the Commission to independently determine whether the prices were appropriately cost-based, but the Department of Justice did not specifically recommend denial based upon pricing. In its evaluation of SWBT's second Missouri application filed jointly with Arkansas, the Department of Justice stated that its original concerns would be moot if the Commission determines that the current rates are set within a reasonable total element long run incremental cost (TELRIC) range.

11. *Checklist Item 4 " Unbundled Local Loops.* SWBT satisfies the requirements of checklist item 4 in both Arkansas and Missouri. Local loops are the wires that connect the telephone company end office to the customer's home or business. To satisfy the nondiscrimination requirement under checklist item 4, SWBT must demonstrate that it can efficiently furnish unbundled local loops to other carriers within a reasonable time frame, with a minimum level of service disruption, and of a quality similar to that which it provides for its own retail customers. Nondiscriminatory access to unbundled local loops ensures that new entrants can provide quality telephone service promptly to new customers without constructing new loops to each customer's home or business.

12. SWBT provides evidence and performance data establishing that it can efficiently furnish unbundled loops, for the provision of both traditional voice services and various advanced services, to other carriers in a nondiscriminatory manner. More specifically, SWBT demonstrates that it provides unbundled local loops in accordance with the requirements of section 271 and our rules. The Commission's conclusion is based upon our review of SWBT's performance for all loop types, which include, as in past section 271 orders, voice grade loops, hot cuts, xDSL-capable loops, digital loops, high capacity loops and our review of SWBT's process for line sharing and line splitting. SWBT establishes that it provides coordinated cutovers of voice grade loops, i.e., hot cuts, in a manner that permits competing carriers a meaningful opportunity to compete.

13. SWBT also establishes that it provides competing carriers with voice grade unbundled loops through new stand-alone loops in substantially the same time and manner as SWBT does for its own retail services. Moreover, SWBT demonstrates that it provides maintenance and repair functions for competing carriers in substantially the same time and manner as it provides for SWBT retail customers for both hot cut loops and new stand-alone loops. SWBT also demonstrates that it provides xDSL-capable loops to competing carriers in a nondiscriminatory manner, providing timely order processing and installation that provides an efficient competitor a meaningful opportunity to compete. Furthermore, SWBT demonstrates that it provides maintenance and repair functions for competing carriers in substantially the same time and manner that it provides such services for SWBT retail customers.

14. *Checklist Item 1* "Interconnection. Based on the evidence in the record, we conclude that SWBT satisfies the requirements of checklist item 1 in both Arkansas and Missouri. Pursuant to this checklist item, SWBT must allow other carriers to interconnect their networks to its network for the mutual exchange of traffic, using any available method of interconnection at any available point in SWBT's network. The Commission has concluded that SWBT demonstrates that it is in compliance with the requirement of this checklist item. SWBT provides interconnection at any technically feasible point, including the option to interconnect at only one technically feasible point within a LATA, within its network. Furthermore, interconnection between networks must be equal in quality whether the interconnection is between SWBT and an affiliate, or between SWBT and another carrier. SWBT demonstrates that it provides interconnection that meets this standard. We reject arguments raised in the initial Missouri proceeding that SWBT does not meet this checklist item due to interconnection installation performance. We find that these allegations are not substantiated in the current performance measures, which indicate that SWBT is providing installation of interconnection trunks to CLECs with far fewer missed due dates than it provides to itself.

15. SWBT also offers interconnection in Arkansas and Missouri to other telecommunications carriers at just, reasonable, and nondiscriminatory rates, in compliance with checklist item 1. SWBT's collocation rates meet the standards for interim rates set forth in our order approving SWBT's Texas section 271 application and Bell Atlantic's New York section 271 application. *See Application of SWBT Texas for Authorization Under Section 271 of the Communications Act*, 65 FR 42361 (2000); *Application of Bell Atlantic New York for Authorization Under Section 271 of the Communications Act*, 64 FR 73555 (1999).

16. *Checklist Item 6 " Unbundled Local Switching.* Based on the evidence in the record, we find that SWBT satisfies the requirements of checklist item 6 in both Arkansas and Missouri. The Commission finds that SWBT satisfies the requirements of checklist item 6, and note that the Arkansas and Missouri Commissions found that SWBT satisfies this checklist item. SWBT demonstrates that it provides competing carriers all of the features, functions, and capabilities of the switch. We reject Sage's arguments that the Commission should deny SWBT's 271 application for Missouri because SWBT refuses to allow access to the line class codes and/or other features of the SWBT switch that are used to provide extended calling area scopes, such as SWBT's Local Calling Plus service. Based on the record before us, it appears that there is a factual dispute between Sage and SWBT that would be better resolved in another proceeding.

17. *Checklist Item 14—Resale.* SWBT demonstrates that it makes telecommunications services available for resale in accordance with sections 251(c)(4) and 252(d)(3), and thus satisfies the requirements of checklist item 14 in both Missouri and Arkansas. SWBT also makes its retail telecommunications services available for resale without unreasonable or discriminatory conditions or limitations.

18. *Checklist Items 3, 5, 7, 8, 9, 10, 11, 12 and 13.* An applicant under section 271 must also demonstrate that it complies with checklist item 3 (poles, ducts, conduits and rights of way), item 5 (unbundled local transport), item 7 (911/E911 access and directory assistance/operator services), item 8

(White Page Directory Listing), item 9 (numbering administration), item 10 (databases and associated signaling), item 11 (number portability), item 12 (local dialing parity), and item 13 (reciprocal compensation). Based upon the evidence in the record, we conclude that SWBT demonstrates that it is in compliance with checklist items 3, 5, 7,8, 9, 10, 11, 12 and 13 in both Arkansas and Missouri. The Arkansas and Missouri Commissions also conclude that SWBT complies with the requirements of each of these checklist items.

19. *Section 272 Compliance.* SWBT demonstrates that it will comply with the requirements of section 272. Pursuant to section 271(d)(3), SWBT must demonstrate that it will comply with the structural, transitional, and nondiscriminatory requirements of section 272, as well as certain requirements governing its marketing arrangements. SWBT shows that it will provide interLATA telecommunications through structurally separate affiliates, and that it will operate in a nondiscriminatory manner with respect to these affiliates and unaffiliated third parties. In addition, SWBT demonstrates that it will comply with public disclosure requirements of section 272, which requires SWBT to post on the Internet certain information about transactions with its affiliates. Finally, SWBT demonstrates compliance with the joint marketing requirements of section 272.

20. *Public Interest Standard.* We conclude that approval of this application is consistent with the public interest, convenience, and necessity. While no single factor is dispositive in our public interest analysis, our overriding goal is to ensure that nothing undermines our conclusion, based on our analysis of checklist compliance, that markets are open to competition. We note that a strong public interest showing cannot overcome failure to demonstrate compliance with one or more checklist items.

21. Among other factors, we may review the local and long distance markets to ensure that there are not unusual circumstances that would make entry contrary to the public interest under the particular circumstances of this Application. We find that, consistent with our extensive review of the competitive checklist, barriers to competitive entry in the local market have been removed and the local exchange market today is open to competition. We also find that the record confirms our view that a BOC's entry into the long distance market will benefit consumers and competition if the relevant local exchange market is open to competition consistent with the competitive checklist.

22. We also find that the performance monitoring and enforcement mechanisms developed in Arkansas and Missouri, in combination with other factors, provide meaningful assurance that SWBT will continue to satisfy the requirements of section 271 after entering the long distance market. Where, as here, a BOC relies on performance monitoring and enforcement mechanisms to provide such assurance, we review the mechanisms involved to ensure that they are likely to perform as promised. We conclude that these mechanisms have a reasonable design and are likely to provide incentives sufficient to foster post-entry checklist compliance.

23. *Section 271(d)(6) Enforcement Authority.* Congress sought to create incentives for BOCs to cooperate with competitors by withholding long distance authorization until they satisfy various conditions related to local competition. We note that these incentives may diminish with respect to a given state once a BOC receives authorization to provide interLATA service in that state. The statute nonetheless mandates that a BOC comply fully with section 271's requirements both before and after it receives approval from the Commission and competes in the interLATA market. Working in concert with state commissions, we intend to monitor closely post-entry compliance and to enforce vigorously the provisions of section 271 using the various enforcement tools Congress provided us in the Communications Act. Swift and effective post-approval enforcement of section 271's requirements is essential to Congress' goal of achieving last competition in local markets.

Federal Communications Commission.

William F. Caton,

Deputy Secretary.

[FR Doc. 01–29501 Filed 11–26–01; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The 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. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

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 December 20, 2001.

A. Federal Reserve Bank of Atlanta (Cynthia C. Goodwin, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30309–4470:

1. West Metro Financial Services, Inc., Dallas, Georgia; to become a bank holding company by acquiring 100 percent of the voting shares of First National Bank of West Metro (in organization), Dallas, Georgia.

Board of Governors of the Federal Reserve System, November 20, 2001.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 01–29419 Filed 11–26–01; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Government in the Sunshine Meeting Notice

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System.

TIME AND DATE: 11 a.m., Monday, December 3, 2001.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Future capital framework.

3. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Michelle A. Smith, Assistant to the Board; 202–452–3204.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at http://www.federalreserve.gov for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: November 23, 2001.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 01–29560 Filed 11–23–01; 11:37 am]

BILLING CODE 6210–01–P

GENERAL SERVICES ADMINISTRATION

[GSA Bulletin FPMR D–258]

Public Buildings Space

This notice contains GSA Bulletin FPMR D–258 which announces the redesignation of a Federal Building. The text of the bulletin follows:

TO: Heads of Federal Agencies

SUBJECT: Redesignation of a Federal Building

1. *Purpose.* This bulletin announces the redesignation of a Federal Building.

2. *Expiration date.* This bulletin expires April 20, 2002. However, the building redesignation announced by this bulletin will remain in effect until canceled or superseded.

3. *Redesignation.* The former and new names of the building being redesignated is as follows:

Former name	New name
The Main Justice Department Building 950 Pennsylvania Avenue, NW Washington, DC 20530	Robert F. Kennedy Department of Justice Building. 950 Pennsylvania Avenue, NW. Washington, DC 20530.

Dated: November 20, 2001.

Stephen A. Perry,

Administrator of General Services.

[FR Doc. 01–29451 Filed 11–26–01; 8:45 am]

BILLING CODE 6820–34–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–02–11]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639–7090.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project

Weekly Morbidity and Mortality Reports and Annual Morbidity Series—OMB #0920–0007—Extension—Epidemiology Program Office (EPO), Centers for Disease Control and Prevention (CDC). In 1878, Congress authorized the U.S. Marine Hospital Service (later renamed the U.S. Public Health Service (PHS)) to collect morbidity reports on cholera, smallpox, plague, and yellow fever from U.S. consuls overseas; this information was to be used for instituting quarantine measures to prevent the introduction and spread of these diseases into the United States. In 1879, a specific Congressional appropriation was made for the collection and publication of reports of these notifiable diseases. The authority for weekly reporting and publication was expanded by Congress in 1893 to include data from state and municipal authorities throughout the United States. To increase the uniformity of the data, Congress enacted a law in 1902 directing the Surgeon General of the Public Health Service (PHS) to provide forms for the collection and compilation of data and for the publication of reports at the national level.

Reports on notifiable diseases were received from very few states and cities prior to 1900, but gradually more states submitted monthly and annual summaries. In 1912, state and territorial health authorities— in conjunction with PHS— recommended immediate telegraphic reports of five diseases and monthly reporting by letter of 10 additional diseases, but it was not until after 1925 that all states reported regularly. In 1942, the collection, compilation, and publication of morbidity statistics, under the direction of the Division of Sanitary Reports and Statistics, PHS, was transferred to the Division of Public Health Methods, PHS.

A PHS study in 1948 led to a revision of the morbidity reporting procedures, and in 1949 morbidity reporting activities were transferred to the National Office of Vital Statistics. Another committee in PHS presented a revised plan to the Association of State and Territorial Health Officers (ASTHO) at its meeting in Washington, DC, October 1950. ASTHO authorized a Conference of State and Territorial Epidemiologists (CSTE) for the purpose of determining the diseases that should be reported by the states to PHS. Beginning in 1951, national meetings of CSTE were held every two years until 1974, then annually thereafter.

In 1961, responsibility for the collection of data on nationally notifiable diseases and deaths in 122 U.S. cities was transferred from the National Office of Vital Statistics to CDC. For 37 years the Morbidity and Mortality Weekly Report (MMWR) has consistently served as CDC's premier communication channel for disease outbreaks and trends in health and health behavior. In collaboration with the Council of State and Territorial Epidemiologists (CSTE), CDC has demonstrated the efficiency and effectiveness of computer transmission of data. The data collected electronically for publication in the MMWR provides information which CDC and State epidemiologists use to detail and more effectively interrupt outbreaks. Reporting also provides the timely information needed to measure and demonstrate the impact of changed immunization laws or a new therapeutic measure. Users of data include, but are not limited to, congressional offices, state and local health agencies, health care providers, and other health related groups.

The dissemination of public health information is accomplished through the MMWR series of publications. The publications consist of the MMWR, the CDC Surveillance Summaries, the Recommendations and Reports, and the Annual Summary of Notifiable Diseases.

The estimated cost to respondents is $51,194.00 assuming an hourly wage of $11.00.

Type of respondents	Number of respondents	Frequency of response	Average time of response	Annual hour burden
State and Local Health Departments	179	52	30/60	4,654

Dated: November 20, 2001.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 01–29433 Filed 11–26–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–07–02]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–7090. Send written comments to CDC, Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project: The State and Local Area Integrated Telephone Survey (SLAITS) (OMB No. 0920–0416)—Revision—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC). This is a request to continue for three years the integrated and coordinated survey system designed to collect needed health and welfare related data at the state and local levels. Using the random-digit-dial sampling frame from the ongoing National Immunization Survey (NIS) and Computer Assisted Telephone Interviewing (CATI), the State and Local Area Integrated Telephone Survey (SLAITS) has quickly collected and produced data to monitor health status, child and family well-being, health care utilization, access to care, program participation, chronic conditions, and changes in health care coverage at the state and local levels. These efforts are conducted in cooperation with Federal, state, and local officials. SLAITS offers a centrally administered data collection mechanism with standardized questionnaires and quality control measures which allow comparability of estimates between states, over time, and with national data. SLAITS is designed to allow oversampling of population subdomains and to meet federal, state and local needs for subnational estimates which are compatible with national data.

For some SLAITS modules, questionnaire content was drawn from existing surveys including the National Health Interview Survey (NHIS), the National Health and Nutrition Examination Survey (NHANES), the Current Population Survey (CPS), the Survey of Income and Program Participation (SIPP), the National Household Education Survey, and the National Survey of America's Families. Other questionnaire modules were developed specifically for SLAITS during the pilot study phase and during the past three years. The existing modules include General Health, Child Well-Being and Welfare, Children with Special Health Care Needs, Asthma Prevalence and Treatment, Knowledge of Medicaid and the State Children's Health Insurance Program (SCHIP), Survey of Early Childhood Health, and HIV/STD Related Risk Behavior.

Over the past three years, SLAITS has provided policy analysts, program planners, and researchers with high quality data for decision making and program assessment. The module on Medicaid and SCHIP will be featured prominently in a report to Congress on insuring children. The module on children with special health care needs (CSHCN) will be used by federal and state Maternal and Child Health Bureau Directors in evaluating programs and service needs. The American Academy of Pediatrics is using the module on early childhood health to advise pediatricians on patient care standards and informing parents about the health and well-being of young children.

Funding for SLAITS is obtained through a variety of mechanisms including Foundation grants, State collaborations, and federal appropriation and evaluation monies. The level of implementation depends on the amount of funding received and can be expanded as funding permits. Questionnaire modules will be compiled to address the data needs of interest to the federal, state or local funding agency or organization. Possible topics include but are not limited to disability, children's health, violence against women, health behaviors, unintentional injuries, program participation, health care coverage, or any of the topics previously studied. The annualized burden for this data collection is 150,606 hours.

Module	Year	Number of responses	Responses per respondent	Average burden (in hours)
Asthma—Screener	2002	36,000	1	8/60
Asthma—Survey	.....	4,920	1	20/60
Pretest—General Children's Health— Screener	2002	4,398	1	5/60
Pretest—General Children's Health— Survey	.....	1,000	1	20/60
General Children's Health—Screener	2003	448,596	1	5/60
General Children's Health—Survey	.....	102,000	1	20/60
Pretest Module #3 Screener	2003	4,398	1	5/60
Pretest Module #3 Survey	.....	1,000	1	20/60
Module #3 Screener	2004	448,596	1	5/60
Module #3 Survey	.....	102,000	1	20/60
Pretest 2005 Module—Screener	2004	4,398	1	5/60
Pretest 2005 Module—Survey	.....	1,000	1	20/60

Dated: November 20, 2001.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning, and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 01–29432 Filed 11–26–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 02008]

Integrated, Multi-Level Interventions To Improve Adolescent Health Through the Prevention of Sexually Transmitted Diseases, Including HIV, and Teen Pregnancy; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2002 funds for a cooperative agreement research program for Integrated, Multi-level Interventions to Improve Adolescent Health through the Prevention of Sexually Transmitted Diseases, including HIV, and Teen Pregnancy. This program addresses the ''Healthy People 2010'' priority area(s) of Sexually Transmitted Diseases, HIV, and Family Planning. For the conference copy of ''Healthy People 2010'', visit the Internet site: *http://www.health.gov/healthypeople.*

The goal of this cooperative agreement research program is to develop, implement and evaluate interventions to prevent STD, including HIV, and pregnancy among adolescents. These interventions should be multi-level and should be integrated, interactive, and synergistic. CDC expects that continuation funds will be available for project periods of up to eight years.

The goal of this research program is to take a developmental approach to delivering multi-level interventions, that change over time to be age appropriate. Applications should include three groups of adolescents: (1) Younger adolescents (*i.e,* about 11 to 13 years of age) who will be followed through late adolescence (*i.e.,* about 16 to 18 years of age); (2) middle adolescents (*i.e,* about 14–16 years) who will be followed through late adolescence (*i.e.,* 2–3 years); and (3) younger (*i.e,* about 11 to 13 years of age) adolescents who will be recruited 2 to 3 years after groups 1 and 2 and followed for a shorter duration (*e.g.,* 2–3 years). These three groups will allow examination of both longitudinal and cross-sectional effects as well as cohort effects of integrated multi-level interventions. Interventions should target adolescents at high risk for STD, including HIV, and teen pregnancy. Catchment areas should have rates of chlamydia and teen pregnancy that exceed ''Healthy People 2010'' targets. Interventions should be community-wide, with sufficient numbers of communities to appropriately address study questions, and contamination across communities should be minimal.

Study Objectives

Note: Please see Appendix A for a complete background and level-specific objectives for this research program. Appendix A is available as part of this program announcement contained in the application kit (available by calling 1–888–GRANTS4) and on the CDC home page Internet address—*http://www.cdc.gov.* Click on ''Funding'' then ''Grants and Cooperative Agreements.''

The overall objectives of this research program are:

1. To design developmentally appropriate, interactive and synergistic interventions to prevent STD, including HIV, and teen pregnancy.

2. To develop and implement interventions at a minimum of three social context levels, including (1) parents, and (2) providers or medical institutions, and (3) at least one other level of the applicants' choice. Interventions should address level-specific objectives as presented in Appendix A and may include existing interventions, new interventions or some combination of both.

3. To develop, implement and evaluate the main and interactive effects of these multi-level interventions using strong experimental or quasi-experimental research designs.

4. To examine the effects of integrated, multi-level interventions on: (1) Behavioral outcomes: rates of unprotected intercourse, delay of coital debut among non-sexually active adolescents, and return to abstinence after coital debut; (2) Process outcomes: annual clinical preventative health services utilization among adolescents and annual chlamydia screening; (3) Morbidity outcomes: Rates of STD, HIV, and teen pregnancy among adolescents in the target community. (Assessment of outcomes should be age-appropriate.)

B. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit organizations, State and local governments or their bona fide agents, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau, and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations.

Note: Public Law 104–65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible

to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

C. Availability of Funds

Approximately $1,000,000 is available in FY 2002 to fund up to three awards. It is expected that the average award will range from $300,000 to $500,000, including indirect costs. It is expected that the awards will begin on or about September 30, 2002, and will be made for a 12-month budget period within a project period for up to eight years. Funding estimates may change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

Use of Funds

Funds are awarded for a specifically defined purpose and may not be used for any other purpose or program. Funds may be used to support personnel and to purchase equipment, supplies and services directly related to project activities. Funds may not be used to supplant state or local health department funds. Funds may not be used to provide direct medical care or prevention case management.

Funding Preferences

Funds may be awarded in such a way as to achieve geographic distribution.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1. (Recipient Activities), and CDC will be responsible for the activities listed under 2. (CDC Activities).

1. Recipient Activities

a. Design and conduct research to address the study objectives (s) as listed above and in Appendix A.

b. Design and conduct necessary formative research and pilot testing of interventions in Years 1 and 2. Implementation and evaluation of interventions will begin in Year 3.

c. Collaborate with other recipients in developing and collecting a common set of core variables to permit systematic comparisons.

d. Collaborate with other recipients and CDC during the development, implementation and evaluation of the project.

e. Collaborate with other recipients and CDC to disseminate interim reports of research activities to regional, state and local partners.

f. Submit and receive approval of study protocol by the recipient's local Institutional Human Investigation Review Board (IRB) and the CDC IRB.

g. Establish procedures to maintain the rights and confidentiality of all study participants, including securing any assurances necessary to conduct research involving human subjects.

h. Conduct local data management activities.

i. Analyze and disseminate results.

2. CDC Activities

A cooperative agreement reflects an assistance relationship between the Federal Government and the recipient in which substantial programmatic involvement is anticipated about the scientific or technical management of an activity during its performance. CDC will:

a. Provide up-to-date scientific information, technical assistance, and guidance in the design and conduct of the research as needed.

b. Provide technical advice as needed to awardees in developing and collecting a common set of core variables to enable comparisons. Collaborative activities may include technical advice on awardee-development of common data collection instruments.

c. Assist in the development of a research protocol for Institutional Review Board (IRB) review by all cooperating institutions participating in the research project as needed. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

d. Assist in ensuring human subjects assurances are in place as needed.

e. Assist in analysis and dissemination of results as needed.

f. Monitor and evaluate the scientific and operational accomplishments of the project as needed. This will be accomplished through periodic site visits, telephone calls, and review of technical reports and interim data analyses.

g. Convene a first meeting within three months of funding and annual meetings of all grantees for the exchange of information.

E. Content

Applications must be developed in accordance with the information contained in this program announcement, the PHS 398 Grant Application, and the instructions provided in this section. Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in describing your program plan. The program narrative for sections 1–5 below should be no more than 25 single-spaced pages, printed on one side, with one-inch margins, and unreduced font. All pages, including appendices, should be numbered sequentially. The narrative must contain the following sections in the order presented below:

1. Abstract

Provide a brief abstract of the project. The abstract must reflect the project's focus and the length of the project period (maximum is 8 years) for which assistance is being requested (see ''Availability of Funds'' for additional information).

2. Specific Aims/Objectives

List the broad, long-term objectives and the specific research questions this application is intended to address. State the hypotheses to be tested. One page is recommended.

3. Background and Significance

Briefly sketch the background leading to the present application, including the theoretical or conceptual framework, critically evaluate existing knowledge, and specifically identify the gaps which the project is intended to fill. State concisely the importance and health relevance of the research described in this application by relating the specific aims to the broad, long-term objectives. Two to three pages are recommended.

4. Preliminary Studies

Use this section to provide an account of the research team members' preliminary studies pertinent to the application that will help to establish the experience and competence of the research team members to pursue the proposed project. Include information about the research team members' experience with the target population, levels of intervention, and history of collaboration with relevant community partners. The complete references to appropriate publications and manuscripts submitted or accepted for publication may be listed and are not part of the page limitations. Five collated sets of no more than 10 such items of background material may be submitted in an appendix. Six to eight pages are recommended for the narrative portion of the Preliminary Studies section.

5. Research Design and Methods

(a) Describe the research design and the procedures to be used to accomplish the specific aims of the project.

Applications must include three groups of adolescents: (1) Younger adolescents (*i.e.,* about 11 to 13 years of age) who will be followed through late adolescence; (2) middle adolescents (*i.e.,* about 14–16 years) who will be followed through late adolescence; and (3) younger adolescents who will be followed for a shorter duration (*e.g.,* 2 to 3 years). Applications must include community-wide interventions, communities must be randomized and must include sufficient numbers of communities. (b) Describe intervention development process, content and delivery for each level, including specific intervention protocols or plans for the development of intervention protocols. Applications must take an interactive, synergistic as well as developmental approach to multi-level intervention design. Applications must address three or more intervention levels, including provider/medical institution, parent, and at least one additional level of the applicants choice. Describe how the interventions within the package will be linked and interactive so that they reinforce each other. Although applicants are not required to measure the synergistic nature of the intervention package, such demonstration would be valuable. Include a description of how members of the target population will be involved in the planning and development of intervention activities. (c) Describe the recruitment plan and how participants will be sampled and retained. (d) Describe the measures to be used. Applications must include the use of self-report, behavioral and biological measures. Outcomes should include: (1) Behavioral outcomes (*e.g.,* rates of unprotected intercourse, delay of coital debut among non-sexually active adolescents, and return to abstinence after coital debut); (2) Process outcomes (*e.g.,* annual clinical preventative health services utilization among adolescents and annual chlamydia screening); and (3) Morbidity outcomes (*e.g.,* rates of STD, HIV, and teen pregnancy among adolescents in the target community). Assessment of outcomes should be age-appropriate. (e) Describe how the data will be collected. Sampling schemes should be the same across all three groups of adolescents. Choose and justify the sample size (s) considering the various levels of the intervention and the different outcomes of interest. (f) Describe the data analysis plan, including a justification for the statistical techniques chosen to analyze the multi-level intervention data. (f) Describe quality assurance plans. (g) Provide a tentative sequence or timetable for the project. (h) Describe the nature and extent of collaboration with CDC and/or others during various phases of the project.

6. Inclusion of Women and Racial and Ethnic Populations

Describe the proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation. Describe the proposed justification when representation is limited or absent. Include a statement as to whether the design of the study is adequate to measure differences when warranted. Include a statement as to whether the plans for recruitment and outreach for the study participants include the process of establishing partnerships with communities and recognition of mutual benefits.

7. Human Subject Involvement

Describe procedures that will provide for the protection of human subjects, including procedures to obtain appropriate parental consent where necessary. Address how these procedures adequately address the requirements of 45 CFR part 46 for the protection of human subjects.

F. Submission and Deadline

Letter of Intent (LOI)

A LOI is requested and appreciated but is not required for this program. The narrative should be no more than three, double spaced pages, printed on one side, with one inch margins, and unreduced font. Your letter of intent will be used for planning purposes, and should include the following information: Program Announcement Number [02008], name and address of institution; name, address, and telephone number of contact person; and specific objectives to be addressed by the proposed project.

On or before March 1, 2002, submit the LOI to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

Application

Submit the original and five copies of PHS–398 (OMB Number 0925–0001). Forms are available in the application kit and at the following Internet address: *www.cdc.gov/od/pgo/forminfo.htm*

Adhere to the instructions on the Errata Sheet for form PHS 398. The Errata Sheet is attached at the end of this program announcement posted in the internet Web site: *www.cdc.gov/od/pgo/funding/grantmain.htm.*

On or before June 1, 2002, submit the application to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

Deadline: Applications shall be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date; or

(b) Sent on or before the deadline date and received in time for submission to the independent review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

Late: Applications which do not meet the criteria in (a) or

(b) above will be returned to the applicant.

G. Evaluation Criteria

Each application will be evaluated individually against the following criteria by a special emphasis panel appointed by CDC. Applications will be reviewed by CDC for completeness and responsiveness to the purpose of this program announcement (as described in Section A), and as outlined under Eligible Applicants and Program Requirements (Items A to B). Incomplete applications and applications that are not responsive will be returned to the applicant without further consideration. It is important that the applicant's abstract reflects the project's focus, because the abstract will be used to help determine the responsiveness of the application.

All applications will be independently reviewed for scientific merit to evaluate the methods and scientific quality of the application. Factors to be considered will include:

1. Specific Aims. (5 percent) The specific aims of the research project, *i.e.,* the intended accomplishment of the specific research project, and the hypotheses to be tested. Whether the specific aims of the project appropriately address the overall objectives and level-specific objectives for a minimum of three contextual levels as described in Appendix A.

2. Background. (5 percent) The background of the project, *i.e.,* the basis for the present proposal, the critical evaluation of existing knowledge, and identification of specific knowledge gaps which the proposal is intended to fill.

3. Significance. (15 percent) The significance and innovation from scientific and programmatic standpoints of the proposed research, including the adequacy of the theoretical and

conceptual framework for the research and the rigor and appropriateness with which the outcomes are evaluated.

4. Research Design. (35 percent) (a) The adequacy of the proposed research design to address the overall objectives and the appropriate level-specific objectives. (b) Plans for formative work, the development of intervention content and delivery plans for each level, including specific intervention protocols or plans for the development of intervention protocols, and how members of the target population are involved in that process. (c) The inclusion of a strong experimental or quasi-experimental design, including whether the applicant plans to include three groups of adolescents as described in the program announcement. (d) The recruitment and retention plan. (e) The self-report, behavioral and biological outcome measures to be assessed. Outcomes should include: (1) Behavioral outcomes (rates of unprotected intercourse, delay of coital debut among non-sexually active adolescents, and return to abstinence after coital debut); (2) process outcomes (annual clinical preventative health services utilization among adolescents and annual chlamydia screening); and (3) morbidity outcomes (rates of STD, HIV, and teen pregnancy among adolescents in the target community). Assessment of outcomes should be age-appropriate. (f) The plan for data collection and data management, including quality assurance procedures. (g) A statistical analysis plan appropriate to multi-level intervention evaluation. (h) The tentative sequence or timetable for the project. (i) The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes: (1) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation; (2) the proposed justification when representation is limited or absent; (3) a statement as to whether the design of the study is adequate to measure differences when warranted; (4) a statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with communities and recognition of mutual benefits.

5. Intervention levels. (15 percent) Applications must address three or more intervention levels, including provider/medical institution, parent, and at least one additional level of the applicants choice. The adequacy with which the applicant describes the rationale for the intervention levels (*i.e,* provider, parent, school, peer and community) chosen, the feasibility of the proposed interventions, how well they will be linked and integrated, how that integration will be measured, and which levels will receive most emphasis at particular age periods. Applications must include community-wide interventions, communities must be randomized and must include sufficient numbers of communities.

6. Research team. (15 percent) The qualifications and appropriateness of the proposed personnel to accomplish the proposed activities. Applicants should include multi-disciplinary teams, including (but not limited to) epidemiologists, behavioral scientists, health services researchers, and statisticians. The combined members of the research team must demonstrate a history of familiarity with, access to, and success working with the target populations (*e.g.,* adolescents, health care providers, parents, community members, etc.) and each level of intervention. This familiarity, access and success will be demonstrated through biographical sketches, previous studies, letters of support. Applicants are also expected to collaborate with their local or state health department because this linkage is critical to the successful conduct of this research. The degree of commitment and cooperation of proposed collaborators, including the health department, and organizations (as evidenced by letters detailing the nature and extent of the involvement) should be presented.

7. Research Capacity. (10 percent) The adequacy of existing and proposed facilities and resources.

8. Human Subjects. (Not Scored) What are the strategies for the recruitment and retention of human subjects? How will the applicant obtain appropriate parental consent when necessary. Are the procedures proposed adequate for the protection of human subjects and are they fully documented? Does the application adequately address the requirements of Title 45 CFR part 46 for the protection of human subjects?

9. Budget. (Not Scored) The reasonableness of the proposed budget to the proposed research and demonstration program.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of

1. Annual progress reports;

2. Financial status report, no more than 90 days after the end of the budget period; and

3. Final financial and performance reports, no more than 90 days after the end of the project period. Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I in the application kit.

AR–1 Human Subjects Requirements
AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR–5 HIV Program Review Panel Requirements
AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2010
AR–12 Lobbying Restrictions
AR–14 Accounting System Requirements
AR–21 Small, Minority, And Women-owned Business
AR–22 Research Integrity

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 318 of the Public Health Service Act, (42 U.S.C. 247c (b(c)): 318a (42 U.S.C. 241 *et seq* and 42 CFR part 51b), as amended. The Catalog of Federal Domestic Assistance number is 93.977.

J. Where To Obtain Additional Information

This and other CDC announcements can be found on the CDC home page Internet address—*http://www.cdc.gov* Click on ''Funding'' then ''Grants and Cooperative Agreements.''

To receive additional written information and to request an application kit, call 1–888–GRANTS4 (1–888 472–6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Kang Lee, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Room 3000, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone number: (770) 488–2733, Email address: *kil8@cdc.gov.*

For program technical assistance, contact: Janet St. Lawrence, Ph.D., Chief, Behavioral Interventions and Research Branch, Division of STD

Prevention, Centers for Disease Control and Prevention (CDC), Mail Stop E44, 1600 Clifton Road NE, Atlanta, GA 30333, Telephone number: (404) 639–8298, Email address: *nzs4@cdc.gov.*

Dated: November 20, 2001.

Rebecca B. O'Kelly,

Acting Chief, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–29431 Filed 11–26–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Agency Information Collection; Comment Request

AGENCY: Indian Health Service, HHS.

ACTION: Request for public comment: 30-day notice; Proposed information collection: Indian Health Service Contract Health Service Report.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed information collection projects, the Indian Health Service (IHS) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection project was previously published in the **Federal Register** (66 FR 17565) on April 2, 2001 and allowed 60 days for public comment. No public comment was received in response to the notice. The purpose of this notice is to allow 30 days for public comment to be submitted directly to OMB.

Proposed Collection

Title: 09–17–0002, ''IHS Contract Health Service Report.'' *Type of Information Collection Request:* Reinstatement, without change, of a previously approved information collection. *Form Number(s):* IHS 843–1A, ''Purchase-Delivery Order for Health Services.'' *Need and Use of Information Collection:* The Contract Health Service health care providers complete form IHS–843–1A to certify that they have performed the health services authorized by the IHS. The information is used to manage, administer, and plan for the provision of health services to eligible American Indian patients, process payments to providers, obtain program data, provide program statistics, and, serves as a legal document for health care services rendered. *Frequency:* As needed, per health service order. *Affected Public:* Businesses or other for-profit, Individuals, not-for-profit institutions and State, local or Tribal Government. *Type of Respondents:* Health care providers. *Total Annual Burden Hours:* The table below provides burden hour information:

Data collection instrument	Estimated number of respondents	Responses per respondent	Annual number of responses	Average burden hour per response*	Total annual burden hours
IHS–843–1A	7,399	42	310,758	0.05 (3 min)	15,538
IDS**	16,356	1	16,356	0.05 (3 min)	818

* For ease of understanding, burden hours are also provided in actual minutes.
** Inpatient Discharge Summary (IDS).

There are no Capital Costs, Operating Costs and/or Maintenance Costs to report for this collection of information.

Request for Comments

Your written comments and/or suggestions are invited on one or more of the following points: (a) Whether the information collection activity is necessary to carry out an agency function; (b) whether the IHS processes the information collected in a useful and timely fashion; (c) the accuracy of the public burden estimate (the estimated amount of time needed for individual respondents to provide the requested information); (d) whether methodology and assumptions used to determine the estimate are logical; (e) ways to enhance the quality, utility, and clarity of the information being collected; and (f) ways to minimize the public burden through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB

Send your written comments and suggestions regarding the proposed information collection contained in this notice, especially regarding the estimated public burden and associated response time, to: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for Indian Health Service.

To request more information on the proposed collection or to obtain a copy of the data collection plan(s) or instruction(s), contact Mr. Lance Hodahkwen, Sr., M.P.H., IHS Reports Clearance Officer, 12300 Twinbrook Parkway, Suite 450, Rockville, MD 20852–1601, at (301) 443–5938 (non-toll free), or send facsimile to (301) 443–2613 or E-mail requests, comments, and return address to: *lhodahkwen@hqe.ihs.gov.*

Comment Due Date

Your comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: October 29, 2001.

Michael H. Trujillo,

Assistant Surgeon General, Director, Indian Health Service.

[FR Doc. 01–29441 Filed 11–26–01; 8:45 am]

BILLING CODE 4160–16–M

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Bureau of Indian Affairs

Office of the Special Trustee for American Indians

Office of Indian Trust Transition

Tribal Consultation on Indian Trust Asset Management

AGENCIES: Office of the Secretary, Bureau of Indian Affairs, Office of the Special Trustee for American Indians, Office of Indian Trust Transition, Interior.

ACTION: Notice of tribal consultation meetings.

SUMMARY: The Office of the Secretary along with the Bureau of Indian Affairs,

the Office of the Special Trustee for American Indians, and Office of Indian Trust Transition will conduct consultation meetings on Indian trust asset management. The purpose is to discuss a proposed reorganization of the Department's trust responsibility functions to improve the management of Indian trust assets. Any Indian tribe, band, nation or individual Indian is encouraged to attend the meeting and to submit written comments.

DATES: The first consultation meeting will be held in Albuquerque, N.M. on December 13, 2001 at 9:00 AM (local time). Dates, times and locations of additional consultation meetings will be announced shortly. All written comments must be received on or before January 15, 2002.

ADDRESSES: The Albuquerque meeting will be held on December 13, 2001 at the All Indian Pueblo Council, 123 4th St, S.W., Albuquerque, New Mexico. Send written comments to the Office of the Secretary, Attn: Office of Executive Secretariat, 1849 C St. NW., MS7229–MIB, Washington, DC 20240. Send written comments by electronic mail to *www.doi.gov/oait.*

FOR FURTHER INFORMATION CONTACT: Wayne Smith, 1849 C St. NW., MS–4140 MIB, Washington, DC 20240, (202) 208–7163, Fax (202) 208–5320.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to involve affected and interested parties in the process of organizing the Department's trust asset management responsibility functions. The Department has determined that there is a need for dramatic change in the management of Indian trust assets. This need has been made apparent in several ways. An independent consultant has analyzed important components of the Department's trust reform activities and made several recommendations, including the recommendation that the Department consolidate trust functions under a single entity. Concerns have also been raised in the *Cobell* v. *Norton* case, which is currently pending in the Federal District Court for the District of Columbia. Internal review has also supported reorganization. A new office in the Department, the Office of Indian Trust Transition, has been created to plan and support reorganization. While preliminary actions have been taken by the Department, the plan is still in the early stages of development. The meeting is the first in a series of public meetings. Future meetings may be held in Portland, OR; Rapid City, SD; Minneapolis, MN; Oklahoma City, OK; Washington, DC, and potentially other sites. The dates and locations of these meetings will be announced in a future notice.

Written comments, including names, street addresses, and other contact information of persons submitting comments will be available for public review at the address stated in the **ADDRESSES** section. Interested persons may examine the written comments during regular business hours (7:45 a.m. to 4:15 p.m. EST), Monday through Friday, except Federal holidays. Individuals who submit comments may request confidentiality. If you wish us to withhold your name, street address, and other contact information (such as fax or phone number) from public review or from disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your comment. We will honor your request to the extent allowable by law. We will make available for public inspection in their entirely all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses.

This meeting supports administrative policy on tribal consultation by encouraging maximum direct participation of representatives of tribal governments, tribal organizations, and other interested persons in important processes.

Dated: November 23, 2001.

J. Steven Griles,

Deputy Secretary.

[FR Doc. 01–29583 Filed 11–26–01; 8:45 am]

BILLING CODE 4310–02–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WY–920–09–1320–EL, WYW154839]

Coal Lease Exploration License, WY; Correction

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice; correction.

SUMMARY: The Bureau of Land Management published a document in the **Federal Register** on November 7, 2001, concerning a notice of invitation for coal exploration license. The document contained an incorrect land description.

FOR FURTHER INFORMATION CONTACT: Julie Weaver, 307–775–6260.

Correction

In the **Federal Register** on November 7, 2001, in FR Doc. 01–27914, on page 56336, in the third column, under SUMMARY, in the fifteenth line, ''T. 41 N.,'' should read ''T.44N.''. The correct land description should read:

''T. 44N., R. 71 W., 6th P.M., Wyoming
Sec. 26: Lots 3–6 and 11–14.
Containing 323.69 acres, more or less.''

Dated: November 20, 2001.

Phillip C. Perlewitz,

Chief, Branch of Solid Minerals.

[FR Doc. 01–29430 Filed 11–26–01; 8:45 am]

BILLING CODE 4310–22–M

DEPARTMENT OF JUSTICE

Office of Community Oriented Policing Services

Agency Information Collection Activities; Proposed Collection; Comments Requested

ACTION: 60-Day Notice of Information Collection Under Review: Reinstatement, with change, of a previously approved collection for which approval has expired; Universal Hiring Program (UHP) and COPS In Schools (CIS) Grant Applications.

The Department of Justice, Office of Community Oriented Policing Services, has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with emergency review procedures of the Paperwork Reduction Act of 1995. OMB approval has been requested by December 3, 2001. The proposed information collection is published to obtain comments from the public and affected agencies. If granted, the emergency approval is only valid for 180 days. Comments should be directed to OMB, Office of Information Regulation Affairs, Attention: Department of Justice Desk Officer (202) 395–6466, Washington, DC 20503.

During the first 60 days of this same review period, a regular review of this information collection is also being undertaken. All comments and suggestions, or questions regarding additional information, to include obtaining a copy of the proposed information collection instrument with instructions, should be directed to Gretchen DePasquale, 202–305–7780, Office of Community Oriented Policing Services, U.S. Department of Justice, 1100 Vermont NW., Washington, DC 20530.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Reinstatement, with change, of a previously approved collection instrument.

(2) *Title of the Form/Collection:* Universal Hiring Program and COPS In Schools Grant Applications.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection: Form Number:* None, Office of Community Oriented Policing Services, Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* State, Local or Tribal Government; *Other:* None; *Abstract:* The application will be used by state, local and tribal law enforcement agencies to apply for Federal funding which will be used to increase the number of sworn law enforcement positions in their agencies. These grants are meant to enhance law enforcement infrastructures and community policing efforts in both local communities (Universal Hiring Program) and local schools (COPS In Schools).

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* There are an estimated 2,000 respondents for UHP, and 1,500 for the CIS program. The amount of estimated time required for the average respondent to respond is: 9 hours per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are 18,000 burden hours annually for UHP and 13,500 for CIS, for a total of 31,500 hours.

If additional information is required contact: Mrs. Brenda Dyer, Department Deputy Clearance Officer, Information Management and Security Staff, Justice Management Division, United States Department of Justice, 601 D Street NW., Patrick Henry Building, Suite 1600, Washington, DC 20530.

Dated: November 20, 2001.

Brenda E. Dyer,

Department Deputy Clearance Officer, United States Department of Justice.

[FR Doc. 01–29421 Filed 11–26–01; 8:45 am]

BILLING CODE 4410–AT–M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

Agency Information Collection Activities: Comment Request

ACTION: Notice of information collection under review; Immigration user fee.

The Department of Justice, Immigration and Naturalization Service has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until January 28, 2002.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of currently approved collection.

(2) *Title of the Form/Collection:* Immigration User Fee.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* No Agency Form Number (File No. OMB–1). Office of Finance, Immigration and Naturalization Service.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals and Households. The information requested from commercial air carriers, commercial vessel operators, and tour operators is necessary for effective budgeting, financial management, monitoring, and auditing of User Fee collections.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 325 responses at 15 minutes (.25) per response for reporting, in addition to 25 respondents at 10 hours per response for recordkeeping.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 331 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan, 202–514–3291, Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, U.S. Department of Justice, Room 4034, 425 I Street, NW., Washington, DC 20536. Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Patrick Henry Building 601 D Street, NW., Suite 1600, Washington, DC 20530.

Dated: November 20, 2001.

Richard A. Sloan,

Department Clearance Officer, United States Department of Justice, Immigration and Naturalization Service.

[FR Doc. 01–29460 Filed 11–26–01; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: Notice of information collection under review: Notice to student or exchange visitor.

The Department of Justice, Immigration and Naturalization Service (INS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on June 16, 2001 at 66 FR 30486, allowing for a 60-day public comment period. No public comment was received on this information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until December 27, 2001. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Department of Justice Desk Officer, 725—17th Street, NW., Room 10235, Washington, DC 20530.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of the information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Revision of a currently approved information collection.

(2) *Title of the Form/Collection:* Notice to Student or Exchange Visitor.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form I–515, Immigration Services Division, Immigration and Naturalization Service.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or Households. This form will be used by the INS to notify students or exchange visitors admitted to the United States as nonimmigrant that they have been admitted without required forms and that they have 30 days to present the required forms and themselves to the appropriate office for correct processing.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 3,000 responses at 5 minutes (.083 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 249 annual burden hours.

If you have additional comments suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan 202–514–3291, Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, U.S. Department of Justice, Room 4034, 425 I Street, NW., Washington, DC 20536. Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Patrick Henry Building, 601 D Street, NW, Ste. 1600, Washington, DC 20530.

Dated: November 19, 2001.

Richard A. Sloan,

Department Clearance Officer, United States Department of Justice, Immigration and Naturalization Service.

[FR Doc. 01–29459 Filed 11–26–01; 8:45 am]

BILLING CODE 4410–01–M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: Notice of information collection under review: Biographic information.

The Department of Justice, Immigration and Naturalization Service (INS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on July 26, 2001 at 66 FR 39053, allowing for a 60-day public comment period. No public comment was received on this information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until December 27, 2001. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulator Affairs, Attention: Department of Justice Desk Officer, 725 17th Street, NW., Room 10235, Washington, DC 20530.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information collection:* Extension of a currently approved information collection.

(2) *Title of the Form/Collection:* Biographic Information.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* FormG–325, Adjudications Division, Immigration and Naturalization Service.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or Households. This form is used to check other agency records on applications or petitions submitted for benefits under the Immigration and Nationality Act. Additionally, this form is required for applicants for adjustments to permanent resident status and specific applicants for naturalization.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 1,144,994 responses at 15 minutes (.025 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 286,249 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan 202–514–3291, Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, U.S. Department of Justice, 425 I Street, NW., Room 4034, Washington, DC 20536. Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Patrick Henry Building, 601 D Street, NW., Ste. 1600, Washington, DC 20530.

Dated: November 19, 2001.

Richard A. Sloan,

Department Clearance Officer, United States Department of Justice, Immigration and Naturalization Service.

[FR Doc. 01–29461 Filed 11–26–01; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: Notice of information collection under review: Petition for Amerasian, widow(er), or Special immigrant.

The Department of justice, Immigration and Naturalization Service (INS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on July 26, 2001 at 66 FR 39054, allowing for a 60-day public comment period. No public comment was received on this information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until December 27, 2001. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Department of Justice Desk Officer, 725—17th Street, NW., Room 10235, Washington, DC 20530.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approved information collection.

(2) *Title of the Form/Collection:* Petition for Amerasian, Widow(er), or Special Immigrant.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* form I–360, Adjudications Division, Immigration and Naturalization Service.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or Households. This form is used to determine eligibility or to classify an alien as an Amerasian, widow or widower, battered or abused spouse or child and special immigrant, including religious worker, juvenile court dependent and armed forces member.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 8,397 responses at 2 hours per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 16,794 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan 202–514–3291, Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, U.S. Department of Justice, Room 4034, 425 I Street, NW., Washington, DC 20536. Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Patrick Henry Building, 601 D Street, NW., Ste. 1600, Washington, DC 20530.

Dated: November 19, 2001.

Richard A. Sloan,

Department Clearance Officer, United States Department of Justice, Immigration and Naturalization Service.

[FR Doc. 01–29462 Filed 11–26–01; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

Agency Information Collection Activities: Comment Request

ACTION: Notice of information collection under review: Petition for nonimmigrant filing fee exemption.

The Department of Justice, Immigration and Naturalization Service (INS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on September 28, 2001 at 66 FR 49697, allowing for a 60-day public comment period. No comments were received.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until December 27, 2001. This process is concluded in accordance with 5 CFR 1320.10. Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Department of Justice Desk Officer, 725—17th Street, NW., Room 10235, Washington, DC 20530.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of currently approved collection.

(2) *Title of the Form/Collection:* H–1B Date Collection and Filing Fee Exemption.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form I–129W, Adjudications Division, Immigration and Naturalization Service.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit. This addendum to Form I–129 will be used by the INS to determine if an I–1B petitioner is exempt from the additional filing fee of $500, as provided by the American Competitiveness and Workforce Improvement Act of 1998.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 128,092 respondents 30 minutes (.50 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 64,046 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan 202–514–3291, Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, U.S. Department of Justice, Room 4304, 425 I Street, NW., Washington, DC 20536. Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, 601 D Street, NW., Patrick Henry Building, Suite 1600, Washington, DC 20530.

Dated: November 19, 2001.

Richard A. Sloan,

Department Clearance Officer, United States Department of Justice, Immigration and Naturalization Service.

[FR Doc. 01–29463 Filed 11–26–01; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: Notice of information collection under review: Certificate of eligibility for nonimmigrant student (F–1) status—For academic and language students.

The Department of Justice, Immigration and Naturalization Service (INS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on July 27, 2001 at 66 FR 39204, allowing for a 60-day public comment period. No public comment was received on this information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until December 27, 2001. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office or Information and Regulatory Affairs, Attention: Department of Justice Desk Officer, 725—17th Street, NW., Room 10235, Washington, DC 20530.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology,

e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approval information collection.

(2) *Title of the Form/Collection:* Certificate of Eligibility for Nonimmigrant Student (F–1) status—For Academic and Language Students.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form I–20AB/ID, Adjudications Division, Immigration and Naturalization Service.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or Households. This form is used to collect information from nonimmigrant students applying for an extension for the length of time of their legal status in the United States as a nonimmigrant student while transferring from one school to another and permission to accept or continue employment.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 165,000 responses at 4 minutes (.066 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 10,890 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan 202–514–3291, Director, Policy Directive and Instructions Branch, Immigration and Naturalization Service, U.S. Department of Justice, 425 I Street, NW., Room 4034, Washington, DC 20536. Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Patrick Henry Building, 601 D Street, NW., Ste. 1600, Washington, DC 20530.

Dated: November 19, 2001.

Richard A. Sloan,

Department Clearance Officer, United States Department of Justice, Immigration and Naturalization Service.

[FR Doc. 01–29464 Filed 11–26–01; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Pension and Welfare Benefits Administration, Department of Labor.

ACTION: Notice of approval.

SUMMARY: The Pension and Welfare Benefits Administration (PWBA) is announcing that collections of information included in regulations pertaining to: PTCE 81–8, investment of plan assets in certain types of short-term investments; PTCE T88–1, adoption by the FERS Thrift Savings Fund of certain prohibited transaction class exemptions granted pursuant to section 408(a) of the Employee Retirement Income Security Act of 1974 (ERISA); and, PTCE 94–71, certain transactions or activities authorized by a settlement agreement resulting from an investigation of an employee benefit plan conducted by the Department of Labor, have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA 95). This notice announces the OMB approval numbers and expiration dates.

FOR FURTHER INFORMATION CONTACT: Address requests for copies of the information collection requests (ICRs) to Gerald B. Lindrew, U.S. Department of Labor, Pension and Welfare Benefits Administration, 200 Constitution Avenue, NW., Room N–5647, Washington, DC 20210. Telephone: (202) 219–4782. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 27, 2001 (66 FR 34269), PWBA announced its intent to request renewal of its current OMB approval for the information collection provisions in a regulation pertaining to investment of plan assets in certain types of short-term investments. In accordance with the PRA 95, OMB has renewed its approval for the ICR under OMB control number 1210–0061. The approval expires November 30, 2004.

In the **Federal Register** of June 27, 2001 (66 FR 34271), the Agency announced its intent to request renewal of its current OMB approval for the information collection provisions of Transaction Exemption T88–1, related to the adoption by the FERS Thrift Savings Fund of certain class exemptions granted pursuant to section 408(a) of ERISA. In accordance with PRA 95, OMB has renewed its approval for the ICR under OMB control number 1210–0074. The approval expires November 30, 2004.

In the **Federal Register** of June 27, 2001 (66 FR 34270), the Agency announced its intent to request renewal of its current OMB approval for the information collection provisions of PTCE 94–71, exempting certain transactions authorized by a settlement agreement resulting from an investigation of an employee benefit plan under ERISA. In accordance with PRA 95, OMB has renewed its approval for the ICR under OMB control number 1210–0091. The approval expires November 30, 2004.

Under 5 CFR 1320.5 (b), 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 control number.

Dated: November 20, 2001.

Gerald B. Lindrew,

Deputy Director, Office of Policy and Research, Pension and Welfare Benefits Administration.

[FR Doc. 01–29422 Filed 11–26–01; 8:45 am]

BILLING CODE 4510–29–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (01–151)]

NASA Advisory Council (NAC); Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Pub. L. 92–463, as amended, the National Aeronautics and Space Administration announces an open meeting of the NASA Advisory Council (NAC).

DATES: Thursday, December 6, 2001, 8 a.m. to 3:30 p.m; and Friday, December 7, 2001, 8 a.m. to 1:30 p.m.

ADDRESSES: NASA Headquarters, 300 E Street, SW., Room MIC–7, Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Mr. Philip Cleary, Code IC, National Aeronautics and Space Administration, Washington, DC 20546–0001, 202/358–4461.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the seating capacity of the room. The meeting will be closed to the public on Thursday, December 6, 2001, from 3:30 p.m. to 5:30 p.m. in accordance with 5 U.S.C. 552b(c)9(B), to hear a briefing on Space Shuttle privatization. The agenda for the meeting is as follows:

—Complete the deliberations of the report of the International Space Station Management and Cost Evaluation (IMCE) Task Force
—An evaluation of NASA's Strategic Resource Review
—An evaluation of NASA's performance against the FY 2001 Revised Final Performance Plan

Due to increased security measures at NASA Headquarters, please contact Ms. Kathy Dakon at 202/358–0732 if you plan to attend the meeting. Visitors will be requested to sign a visitor's register and will require escort within the NASA Headquarters building. It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants.

Sylvia K. Kraemer,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 01–29395 Filed 11–26–01; 8:45 am]

BILLING CODE 7510–01–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Advisory Committee on the Records of Congress; Meeting

AGENCY: National Archives and Records Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the National Archives and Records Administration (NARA) announces a meeting of the Advisory Committee on the Records of Congress. The committee advises NARA on the full range of programs, policies, and plans for the Center for Legislative Archives in the Office of Records Services.

DATES: December 10, 2001, from 10:30 a.m. to 11:30 a.m.

ADDRESSES: Members Room, Library of Congress, Thomas Jefferson Building, Room LJ–162.

FOR FURTHER INFORMATION CONTACT: Michael L. Gillette, Director, Center for Legislative Archives, (202) 501–5350.

SUPPLEMENTARY INFORMATION:

Agenda

SAA Forum on the Third Advisory Committee Report—Summary
Center for Legislative Archives—Update
Other current issues and new business
The meeting is open to the public.

Dated: November 19, 2001.

Mary Ann Hadyka,

Committee Management Officer.

[FR Doc. 01–29398 Filed 11–26–01; 8:45 am]

BILLING CODE 7515–01–U

THE NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Meetings of Humanities Panel

AGENCY: The National Endowment for the Humanities.

ACTION: Additional notice of meetings.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92–463, as amended), notice is hereby given that the following meetings of the Humanities Panel will be held at the Old Post Office, 1100 Pennsylvania Avenue, NW., Washington, DC 20506.

FOR FURTHER INFORMATION CONTACT: Laura S. Nelson, Advisory Committee Management Officer, National Endowment for the Humanities, Washington, DC 20506; telephone (202) 606–8322. Hearing-impaired individuals are advised that information on this matter may be obtained by contacting the Endowment's TDD terminal on (202) 606–8282.

SUPPLEMENTARY INFORMATION: The proposed meetings are for the purpose of panel review, discussion, evaluation and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the agency by the grant applicants. Because the proposed meetings will consider information that is likely to disclose trade secrets and commercial or financial information obtained from a person and privileged or confidential and/or information of a personal nature the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, pursuant to authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee meetings, dated July 19, 1993, I have determined that these meetings will be closed to the public pursuant to subsections (c) (4), and (6) of section 552b of Title 5, United States Code.

1. *Date:* December 10, 2001.
Time: 8:30 a.m. to 5 p.m.
Room: 426.
Program: This meeting will review applications for Humanities Projects in Museums and Historical Organizations, submitted to the Division of Public Programs at the November 1, 2001 deadline.

2. *Date:* December 14, 2001.
Time: 8:30 a.m. to 5 p.m.
Room: 426.
Program: This meeting will review applications for Humanities Projects in Museums and Historical Organizations, submitted to the Division of Public Programs at the November 1, 2001 deadline.

3. *Date:* December 14, 2001.
Time: 8:30 a.m. to 5 p.m.
Room: 730.
Program: This meeting will review applications for Humanities Projects in Museums and Historical Organizations, submitted to the Division of Public Programs at the November 1, 2001 deadline.

4. *Date:* December 18, 2001.
Time: 8:30 a.m. to 5 p.m.
Room: 415.
Program: This meeting will review applications for Humanities Projects in Museums and Historical Organizations, submitted to the Division of Public Programs at the November 1, 2001 deadline.

Laura S. Nelson,

Advisory Committee Management Officer.

[FR Doc. 01–29493 Filed 11–26–01; 8:45 am]

BILLING CODE 7536–01–M

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–250 and 50–251]

Florida Power and Light Company; Turkey Point Plant, Units 3 and 4; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of an exemption from the requirements of Title 10, Code of Federal Regulations (10 CFR), section 50.44, and 10 CFR part 50, appendix A, General Design Criteria 41, 42, and 43, for Facility Operating License Nos. DPR–31, and DPR–41, issued to Florida Power and Light Company (the licensee), for operation of the Turkey Point Plant, Units 3 and 4, located in Miami-Dade County, Florida. Therefore, as required by 10 CFR 51.21, the NRC is issuing this environmental assessment and finding of no significant impact.

Environmental Assessment

Identification of the Proposed Action

The proposed exemption would exempt the Turkey Point Plant, Units 3 and 4, from the requirements of 10 CFR 50.44; 10 CFR part 50, appendix A, General Design Criteria 41, 42, and 43; and 10 CFR part 50, appendix E, section IV; related to combustible gas control systems. The purpose of the exemption request is to remove the requirements for the hydrogen control systems from the Turkey Point Plant design basis. The staff has reviewed the information

provided and concluded that the requested exemption for the hydrogen recombiners and the post-accident containment vent system is justified because special circumstances necessary to meet the criteria of 10 CFR 50.12(a)(2)(ii) do exist to justify the exemption from certain parts of 10 CFR 50.44 and General Design Criteria 41, 42, and 43. The staff will act on the exemption request for the containment hydrogen monitors and their associated Technical Specification revision by separate correspondence. The proposed exemption is in accordance with the licensee's application dated October 23, 2000.

The Need for the Proposed Action

The requested exemption to remove the requirements pertaining to recombiners and the post-accident containment vent system would improve the safety focus at Turkey Point during an accident and would represent a more effective and efficient method of maintaining adequate protection of public health and safety by simplifying the Emergency Response Plan Procedures. In a postulated loss-of-coolant accident, the Turkey Point emergency operating procedures (EOPs) direct the control room operators to monitor and control the hydrogen concentration inside the containment after they have carried-out the steps to maintain and control the higher priority critical safety functions. These hydrogen control activities could distract operators from more important tasks in the early phases of accident mitigation and could have a negative impact on the higher priority critical operator actions. An exemption from the hydrogen recombiner and the post-accident containment vent system requirements will eliminate the need for these systems in the EOPs and, hence, simplify the EOPs. The staff still expects the licensee's severe accident management guidelines to address combustible gas control. Therefore, this simplification would provide a safety benefit, and this action reduces unnecessary regulatory burden on the licensee, which is one of the NRC's outcome goals of effective regulation.

Environmental Impacts of the Proposed Action

The NRC has completed its evaluation of the proposed action and concludes, as set forth below, that there are no significant environmental impacts associated with the removal of the recombiners and the post-accident containment vent system from the Turkey Point Plant design basis.

The proposed action will not significantly increase the probability or consequences of accidents, no changes are being made in the types or amounts of any effluents that may be released offsite, 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 have a potential to affect 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.

Environmental Impacts on the Alternatives to the Proposed Action

There are two alternatives to the proposed action. The first one is the 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 denial of the action are similar. The second alternative is to grant the exemption as requested by the licensee in its submittal of October 23, 2000. The NRC does not endorse the second alternative at this time. Nevertheless, the environmental impacts of the second alternative and the environmental impacts of the proposed action are similar.

Alternative Use of Resources

This action does not involve the use of any different resources than those previously considered in the Final Environmental Statement for the Turkey Point Plant, Units 3 and 4, dated July 1972.

Agencies and Persons Consulted

On September 18, 2001, the staff consulted with the Florida State official, Mr. William A. Passetti of the Bureau of Radiation Control, 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 NRC concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the NRC 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 October 23, 2000. Documents may be examined, and/or copied for a fee, at the NRC's Public Document Room (PDR), located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the ADAMS Public Library component on the NRC Web site, *http://www.nrc.gov* (the Public Electronic Reading Room). If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC PDR Reference staff at 1–800–397–4209, or 301–415–4737, or by e-mail at *pdr@nrc.gov.*

Dated at Rockville, Maryland, this 20th day of November, 2001.

For the Nuclear Regulatory Commission.

Kahtan N. Jabbour,

Senior Project Manager, Section 2, Project Directorate II, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.

[FR Doc. 01–29448 Filed 11–26–01; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–131]

Department of Veterans Affairs; Nebraska—Western Iowa Health Care System; Alan J. Blotcky Reactor Facility; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of an amendment for Facility Operating License No. R–57, issued to the Department of Veterans Affairs, Nebraska—Western Iowa Health Care System (the licensee or VA) for operation of the Alan J. Blotcky Reactor Facility (AJBRF) located in Omaha, Douglas County, Nebraska.

Environmental Assessment

Identification of the Proposed Action

The proposed action would renew the license for the AJBRF for 20 years from the date of issuance of the license amendment. The proposed action is in accordance with the licensee's application for amendment dated May 10, 1993, as supplemented on March 1, 1995, December 17, 1997, March 12, April 5, July 29, November 24 and December 2, 1999, January 4, September 25, October 2 and October 24, 2000, and August 8 and October 16, 2001. In

accordance with 10 CFR 2.109, the license remains in effect until the NRC takes final action on the renewal application.

Need for the Proposed Action

The proposed action is needed to allow continued operation of the AJBRF in order to continue educational training and academic research beyond the current term of the license.

Environmental Impact of the Proposed Action

The AJBRF is located in the basement of the Department of Veterans Affairs, Nebraska—Western Iowa Health Care System, Omaha Division (formerly known as the VA Medical Center Omaha) in Omaha, Nebraska. The main hospital building is 11 stories high and is constructed of brick and reinforced concrete construction, including the ceilings and floors. The hospital building is built on a knoll in a commercial area within the city limits. To the north is a large county hospital, to the south a commercial district, to the west a residential area, and to the east a golf course. The medical center grounds are sufficiently large so that the nearest offsite dwelling is more than 520 ft. (158 m) away.

The reactor is located near the bottom of a cylindrical pool 20 ft (6.1 m) below the floor of the reactor room. The only access to the reactor pool is from the top. The reactor control console is located near the reactor pool in the reactor room.

On June 24, 1959, the U.S. Atomic Energy Commission (AEC) issued VA a Construction Permit (CPRR–36) authorizing construction of a General Atomics TRIGA-type research reactor. On June 26, 1959, Facility Operating License No. R–57 was issued authorizing VA to operate the TRIGA reactor at steady-state power levels up to 10 kW(t). The reactor first reached criticality on June 30, 1959. Amendment No. 2 to the license issued in September 1963 increased the steady-state thermal power level of the reactor to 18 kW(t) and Amendment No. 9 issued in April 1991 increased the power level to 20 kW(t). The license has been renewed twice prior to this renewal with the last renewal issued in August 1983. The licensee submitted an updated safety analysis report and technical specifications as part of the application for license renewal. Over the last ten years the facility has operated an average of 344 full power hours per year. Facility modifications have been minor. The licensee has not indicated any plans to significantly change the design of the facility.

The radioactive releases from the AJBRF have been well within regulatory limits of 10 CFR part 20. Argon-41, a product from neutron irradiation of air during operation, is the principle airborne radioactive effluent from the AJBRF during routine operations. During the last 10 years, the licensee has calculated that the amount of argon-41 discharged from the facility to the environment has ranged from 1 mCi (37 MBq) to 300 mCi (11,100 MBq) per year. The maximum dose to members of the public has been less than 1 mrem (0.01 mSv) per year. The staff calculates that even given continuous operation of the reactor, the maximum dose to members of the public would still be less than 1 mrem (0.01 mSv) per year.

Over the last ten years the licensee has released no liquid or solid waste from the AJBRF. Any future releases would be performed within the requirements of the regulations.

Currently, there are no plans to change any operating or radiological release practices or characteristics of the reactor during the license renewal period. The NRC concludes that conditions are not expected to change and that the radiological effects of operation during the renewal period will continue to be minimal. The radiological exposures for facility operations have been within regulatory limits and should continue to remain so.

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 to occupational or public radiation exposure. Therefore, there are no significant radiological environmental impacts associated with the proposed action.

With regard to potential non-radiological impacts, the proposed action does not involve any historic sites. It does not affect non-radiological facility effluents and has no other environmental impact. Therefore, there are no significant non-radiological environmental impacts associated with the proposed action.

In addition, the environmental impact associated with operation of research reactors has been generically evaluated by the staff and is discussed in the attached generic evaluation. This evaluation concludes that no significant environmental impact is associated with the operation of research reactors licensed to operate at power levels up to and including 2 megawatts thermal. The NRC staff has determined that this generic evaluation is applicable to operation of the AJBRF and that there are no special or unique features that would preclude reliance on the generic evaluation.

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). If the NRC denied license renewal, AJBRF operations would stop and decommissioning would be required with no significant benefit to the environment. The environmental impacts of the proposed action and alternative are similar.

Alternative Use of Resources:

This action does not involve the use of any resources not previously considered in the safety analysis and evaluation for the operating license renewal in 1983.

Agencies and Persons Contacted

In accordance with its stated policy, on June 19, 2001, the staff consulted with the Nebraska State official, Ms. Julia Schmitt of the Nebraska Department of Health and Human Services Regulation and Licensure, regarding the environmental impact of the proposed action. The State official had no comment.

Finding of No Significant Impact

On the basis of the environmental assessment, the NRC concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the NRC 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 May 10, 1993, as supplemented on March 1, 1995, December 17, 1997, March 12, April 5, July 29, November 24 and December 2, 1999, January 4, September 25, October 2 and October 24, 2000, and August 8 and October 16, 2001. Documents may be examined, and/or copied for a fee, at the NRC's Public Document Room, located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland. The NRC maintains an Agencywide Documents Access and Management System (ADAMS), which provides text and image files of NRC's public documents. Documents from November 24, 1999, may be accessed through the NRC's Public Electronic Reading Room on the internet at *http://www.nrc.gov/NRC/ADAMS/index.html.* If you do not

have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1–800–397–4209, 301–415–4737 or by email to *pdr@nrc.gov.*

Dated at Rockville, Maryland, this 20th day of November, 2001.

For the Nuclear Regulatory Commission.

Eugene V. Imbro,

Acting Chief, Operational Experience, and Non-Power Reactors Branch, Division of Regulatory Improvement Programs, Office of Nuclear Reactor Regulation.

Environmental Considerations Regarding the Licensing of Research Reactors and Critical Facilities

Introduction

This discussion deals with research reactors and critical facilities which are designed to operate at low power levels, 2 MWt and lower, and are used primarily for basic research in neutron physics, neutron radiography, isotope production, experiments associated with nuclear engineering, training and as a part of a nuclear physics curriculum. Operation of such facilities will generally not exceed a 5-day week, 8-hour day, or about 2000 hours per year. Such reactors are located adjacent to technical service support facilities with convenient access for students and faculty.

Sited most frequently on the campuses of large universities, the reactors are usually housed in already existing structures, appropriately modified, or placed in new buildings that are designed and constructed to blend in with existing facilities. However, the environmental considerations discussed herein are not limited to those facilities which are part of universities.

Facility

There are no exterior conduits, pipelines, electrical or mechanical structures or transmission lines attached to or adjacent to the facility other than for utility services, which are similar to those required in other similar facilities, specifically laboratories. Heat dissipation, if required, is generally accomplished by a heat exchanger whose secondary side includes a cooling tower located on the roof of or nearby the reactor building. The size of these cooling towers typically are on the order of 10 ft by 10 ft by 10 ft (3 m by 3 m by 3 m) and are comparable to cooling towers associated with the air-conditioning systems of large office buildings. Heat dissipation may also be accomplished by transfer through a heat exchanger to water flowing directly to a sewer or a chilled water system. Make-up for the cooling system is readily available and usually obtained from the local water supply.

Radioactive gaseous effluents during normal operations are usually limited to argon-41. The release of radioactive liquid effluents can be carefully monitored and controlled. Liquid wastes are collected in storage tanks to allow for decay and monitoring prior to dilution and release to the sanitary sewer system or the environment. This liquid waste may also be solidified and disposed of as solid waste. Solid radioactive wastes are packaged and shipped offsite for storage or disposal at NRC-approved sites. The transportation of such waste is done in accordance with existing NRC–DOT regulations in approved shipping containers.

Chemical and sanitary waste systems are similar to those existing at other similar laboratories and buildings.

Environmental Effects of Site Preparation and Facility Construction

Construction of such facilities invariably occurs in areas that have already been disturbed by other building construction and, in some cases, solely within an already existing building. Therefore, construction would not be expected to have any significant effect on the terrain, vegetation, wildlife or nearby waters or aquatic life. The societal, economic and aesthetic impacts of construction would be no greater than those associated with the construction of an office building or similar research facility.

Environmental Effects of Facility Operation

Release of thermal effluents from a reactor of less than 2 MWt will not have a significant effect on the environment. This small amount of waste heat is generally rejected to the atmosphere by means of small cooling towers. Extensive drift and/or fog will not occur at this low power level. The small amount of waste heat released to sewers, in the case of heat exchanger secondary flow directly to the sewer, will not raise average water temperatures in the environment.

Release of routine gaseous effluents can be limited to argon-41, which is generated by neutron activation of air. In most cases, this will be kept as low as practicable by using gases other than air for supporting experiments. Experiments that are supported by air are designed to minimize production of argon-41. Yearly doses to persons in unrestricted areas will be at or below established 10 CFR part 20 limits. Routine releases of radioactive liquid effluents can be carefully monitored and controlled in a manner that will ensure compliance with the regulations. Solid radioactive wastes will be shipped in approved containers to an authorized disposal site or to a facility licensed to treat and consolidate radioactive waste. These wastes should not require more than a few shipping containers a year.

Based on experience with other research reactors, specifically TRIGA reactors operating in the 1 to 2 MWt range, the annual release of gaseous and liquid effluents to unrestricted areas should be less than 30 curies (1,110,000 MBq) and 0.01 curies (370 MBq), respectively.

No release of potentially harmful chemical substances will occur during normal operation. Small amounts of chemicals and/or high-solid content water may be released from the facility through the sanitary sewer during periodic blowdown of the cooling tower or from laboratory experiments. The quality of secondary cooling water may be maintained using biocides, corrosion inhibitors and pH control chemicals. The use of these chemicals for this purpose is approved by the Environmental Protection Agency (EPA). The small amounts of laboratory chemicals that may be used in research laboratories are disposed of in accordance with EPA and state requirements.

Other potential effects of the facility, such as aesthetics, noise, societal or impact on local flora and fauna are expected to be too small to measure.

Environmental Effects of Accidents

Accidents ranging from the failure of experiments up to the largest core damage and fission product release considered possible result in doses that are less than 10 CFR part 20 limits and are considered negligible with respect to the environment.

Unavoidable Effects of Facility Construction and Operation

The unavoidable effects of construction and operation involve the materials used in construction that cannot be recovered and the fissionable material used in the reactor. No adverse impact on the environment is expected from either of these unavoidable effects.

Alternatives to Construction and Operation of the Facility

To accomplish the objectives associated with research reactors, there are no suitable alternatives. Some of these objectives are training of students in the operation of reactors, production of radioisotopes, and use of neutron and gamma ray beams to conduct experiments.

Long-Term Effects of Facility Construction and Operation

The long-term effects of research facilities are considered to be beneficial as a result of the contribution to scientific knowledge and training. Because of the relatively small amount of capital resources involved and the small impact on the environment, very little irreversible and irretrievable commitment is associated with such facilities.

Costs and Benefits of Facility Alternatives

The costs are on the order of several millions of dollars with very little environmental impact. The benefits include, but are not limited to, some combination of the following: conduct of activation analyses, conduct of neutron radiography, training of operating personnel, and education of students. Some of these activities could be conducted using particle accelerators or radioactive sources which would be more costly and less efficient. There is no reasonable alternative to a nuclear research reactor for conducting this spectrum of activities.

Conclusion

The staff concludes that there will be no significant environmental impact associated with the licensing of research reactors or critical facilities designed to operate at power levels of 2 MWt or lower and that no environmental impact statements are required to be written for the issuance of construction permits, operating licenses or license renewals for such facilities.

Revised June 2001.

[FR Doc. 01–29447 Filed 11–26–01; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Sunshine Notice: Meeting

AGENCY HOLDING THE MEETING: Nuclear Regulatory Commission.

DATE: Weeks of November 26, December 3, 10, 17, 24, 31, 2001.

PLACE Commissioner's Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

MATTERS TO BE CONSIDERED:

Week of November 26, 2001

There are no meetings scheduled for the Week of November 26, 2001.

Week of December 3, 2001—Tentative

Monday, December 3, 2001

2:00 p.m. Briefing on Status of Steam Generator Action Plan (Public Meeting) (Contact: Maitri Banerjee, 301–415–2277)

Wednesday, December 5, 2001

1:25 p.m. Affirmation Session (Public Meeting) (if needed)

1:30 p.m. Meeting with Advisory Committee on Reactor Safeguards (ACRS) (Public Meeting) (Contact: John Larkins, 301–415–7360)

Week of December 10, 2001—Tentative

There are no meetings scheduled for the Week of December 10, 2001.

Week of December 17, 2001—Tentative

There are no meetings scheduled for the Week of December 17, 2001.

Week of December 24, 2001—Tentative

There are no meetings scheduled for the Week of December 24, 2001.

Week of December 31, 2001—Tentative

There are no meetings scheduled for the Week of December 31, 2001.

* The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings call (recording)—(301) 415–1292. Contact person for more information: David Louis Gamberoni (301) 415–1651.

* * * * *

ADDITIONAL INFORMATION: By a vote of 5–0 on November 15, the Commission determined pursuant to U.S.C. 552b(e) and § 9.107(a) of the Commission's rules that ''Discussion of Intragovernmental and Security Issues (Closed-Ex. 1 & 9)'' be held on November 15, and on less than one week's notice to the public.

* * * * *

The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov.*

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This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it, or would like to be added to the distribution, please contact the Office of the Secretary, Washington, DC 20555 (301–415–1969). In addition, distribution of this meeting notice over the Internet system is available. If your are interested in receiving this Commission meeting schedule electronically, please send an electronic message to *dkw@nrc.gov.*

Dated: November 21, 2001.

David Louis Gamberoni,

Technical Coordinator, Office of the Secretary.

[FR Doc. 01–29581 Filed 11–23–01; 12:51 pm]

BILLING CODE 7590–01–M

SECURITIES AND EXCHANGE COMMISSION

[Rel. No. IC–25274; File No. 812–12638]

Integrity Life Insurance Company, et al.

November 20, 2001.

AGENCY: Securities and Exchange Commission (''SEC'' or ''Commission'').

ACTION: Notice of application for an order pursuant to Section 6(c) of the Investment Company Act of 1940 (the ''Act'') granting exemptions from the provisions of sections 2(a)(32) and 37(i)(2)(A) of the Act and Rule 22c–1 thereunder.

Applicants: Integrity Life Insurance Company (''Integrity''), National Integrity Life Insurance Company (''National Integrity,'' together with Integrity, the ''Companies''), Separate Account I of Integrity Life Insurance Company, Separate Account I of National Integrity Life Insurance Company (together with Separate Account I of Integrity Life Insurance Company, the ''Account''), and Touchstone Securities, Inc. (''Touchstone'').

SUMMARY OF APPLICATION: Applicants seek an order of exemption pursuant to Section 6(c) of the Act to the extent necessary to permit the recapture, under specified circumstances, of credits applied to contributions made under certain flexible premium variable annuity contracts that the Companies will issue through the Accounts (the ''Contracts''), as well as other contracts that the Companies may issue in the future through their existing or future separate accounts (''Other Accounts'') that are substantially similar to the Contracts in all material respects (''Future Contracts''). Applicants also request that the order being sought extend to any other National Association of Securities Dealers, Inc. (''NASD'') member broker-dealer controlling or controlled by, or under common control or affiliated with, Touchstone, whether existing or created in the future, that serves as distributor or principal underwriter for the Contracts or Future Contracts (''Affiliated Broker-Dealers'').

Filing Date: The application was filed on September 20, 2001, and amended and restated on November 14, 2001.

Hearing or Notification of Hearing: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving Applicants with a copy of the request, personally or by mail. Hearing requests must be received by the SEC by 5:30 p.m. on December 17, 2001, 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 SEC's Secretary.

ADDRESSES: Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Applicants, c/o G. Stephen Wastek, Esq., Assistant General Counsel & Assistant Secretary, Integrity Life Insurance Company, 515 West Market Street, Louisville, Kentucky 40202.

FOR FURTHER INFORMATION CONTACT: Alison Toledo, Senior Counsel, or Lorna J. MacLeod, Branch Chief, Division of Investment Management, Office of Insurance Products, at (202) 942–0670.

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application is available for a fee from the SEC's Public Reference Branch, 450 Fifth Street, NW., Washington, DC 20549–0102 ((202) 942–8090).

Applicants' Representations

1. Integrity is a stock life insurance company organized under the laws of Ohio. It is authorized to sell life insurance and annuities in 47 states and the District of Columbia. Integrity is a subsidiary of Western and Southern Life Insurance Company (''Western and Southern''), a mutual life insurance company organized under the laws of Ohio.

2. National Integrity is a stock life insurance company organized under the laws of New York. It is authorized to sell life insurance and annuities in four

states and the District of Columbia. National Integrity is a direct subsidiary of Integrity and an indirect subsidiary of Western and Southern.

3. Separate Account I of Integrity Life Insurance Company was established in 1986 as a separate account under Ohio law for the purpose of funding variable annuity contracts issued by Integrity. It is a segregated asset account of Integrity and is registered with the Commission as a unit investment trust under the Act.

4. Separate Account I of National Integrity Life Insurance Company was established in 1986 as a separate account under New York law for the purpose of funding variable annuity contracts issued by National Integrity. It is a segregated assets account of National Integrity and is registered with the Commission as a unit investment trust under the Act.

5. The Accounts will fund the variable benefits available under the Contracts. Each Company's offering of the Contract is registered under the Securities Act of 1933. That portion of the assets of the Accounts that is equal to the reserves and other Contract liabilities with respect to the Account is not charageble with liabilities arising out of any other business of the Companies. Any income, gains or losses, realized or unrealized, from assets allocated to the Account are, in accordance with the Contracts, credited to or charged against the Accounts, without regard to other income, gains or losses of the Companies.

6. Touchstone is the principal underwriter of the Contracts. Touchstone is registered with the Commission as a broker-dealer under the Securities Exchange Act of 1934 and is a member of the NASD. The Contracts are sold by registered representatives of broker-dealer that have entered into distribution agreements with Touchstone. Touchstone is a wholly owned subsidiary of Western and Southern.

7. This application requests relief for two variable annuity Contracts both contained in a single registration statement previously filed on Form N–4 pursuant to the Securities Act of 1933. The Contracts are the IQ Smart Annuity (''IQ'') and the Grandmaster Annuity (''Grandmaster'').

8. The minimum initial contribution for both Contracts is $1,000 ($3,000 in Pennsylvania and South Carolina). An owner may make additional contributions of at least $100 at any time (except for the IQ New York Contract which is a single premium Contract). The Companies may limit total contributions to $1,000,000 if the owner is under age 76 and to $250,000 if the owner is over age 76.

9. The Added value Option is an optional credit to the Contracts of between 1% and 5% of the total first year contributions (the ''Credit''). If an owner selects the Added Value Option at the time of application, the Companies will credit an extra amount of the Contract each time the owner makes a contribution within the first twelve months after the Contract is issued. The owner may select a Credit from 1% to 5%. The Companies will allocate Credits pro rata among the investment options in the same ratio as the contribution. The Companies will fund Credits from their general account assets.

10. The annual charge for the Added Value Option is .15% for each percentage of Credit an owner selects. The charge is assessed against the Accounts and the fixed accounts. For example, if the owner selects the 3% Credit, the annual charge is .45%. The charge is subject to a minimum and maximum dollar amount. The minimum amount is .145% multiplied by first year total contributions. The maximum amount is .182% multiplied by first year total contributions. The prospectuses for the Contracts contain a chart of percentages the Companies will use in calculating the range of dollar amounts. The Companies assess the charge quarterly on the assets in the investment options to which the owner's contributions are allocated. The Companies will discontinue deducting the charge seven years from the date the Contract is issued.

11. The Credit is not part of the amount an owner will receive if he or she exercises the free look provision. In addition, all or part of the Credit will be recaptured if the owner makes a withdrawal during the first seven Contract years. Regardless of whether or not the Credit is vested, all gains or losses attributable to such Credit are part of the owner's Contract value and are immediately vested.

12. The free look period is the 10-day period (or longer if required by state law) during which an owner may return a Contract after it has been delivered and receive a full refund of the Contract value, less any Credits applied. Unless the law requires that the full amount of the contribution be refunded, less any withdrawals, the owner bears the investment risk from the time of purchase until he or she returns the Contract and the refund amount may be more or less than the contribution the owner made. The Credit is not part of the amount an owner will be paid if the free look provision is exercised.

13. An owner may make withdrawals from the Contract at any time before annuitization. The minimum withdrawal amount is $300. Assuming the owner has selected the Added Value Option, any withdrawal during the first seven Contract years will be subject to the recapture of all or part of any Credit applied to the Contract, and if applicable, contingent withdrawal charges. The IQ Contract contains no contingent withdrawal charges. The Grandmaster Contract does not contain contingent withdrawal charges. The amount that will be recaptured depends on the Contract year in which the withdrawal is made. The chart below shows what portion of the Added Value Option as credited will be recaptured in connection with a partial or a complete withdrawal.

AMOUNT OF CREDIT RECAPTURED

Contract year	Integrity and national integrity (In percent)
1	100
2	100
3	85
4	70
5	55
6	40
7	25
8+	0

The contingent withdrawal charge is a percentage of contribution withdrawal by the owner. The contingent withdrawal charge for the Grandmaster Contract for each Company is as follows:

Number of years from date of contribution	Integrity charge (In percent)	National integrity charge (%)
1	8	7
2	7	6
3	6	5
4	5	4
5+	0	0

For purposes of calculating the contingent withdrawal charge, the Companies treat withdrawals as coming from the oldest contribution first (*i.e.*, first-in, first-out). In the case of partial withdrawals, the Companies deduct the contingent withdrawal charge, if any, from the value remaining in the Contract, not from the withdrawal amount requested by the owner.

14. For the IQ product, owners of the Contracts may allocate their contributions among sixty-four investment options—fifty-seven variable investment options and seven fixed investment options. Each subaccount of the Accounts is a variable investment

option that will invest in shares of a corresponding portfolio of Fidelity's Variable Insurance Product Funds, Janus Aspen Series, The Legends Fund, MFS Variable Insurance Trust, Putnam Variable Trust Funds, Touchstone Variable Series Trust or Van Kampen Life Portfolios. For the Grandmaster product, owners of the Contracts may allocate their contributions among forty-seven investment options—forty variable investment options and seven fixed investment options. Each subaccount of the Accounts is a variable investment option that will invest in shares of a corresponding portfolio of Fidelity's Variable Insurance Product Funds, Janus Aspen Series, MFS Variable Insurance Trust or Putnam Variable Trust Funds.

15. The Companies, at a later date, may decide to create additional subaccounts to invest in any additional funding media as may now or in the future be available. The Companies, from time to time, also may combine or eliminate subaccounts or transfer assets to and from subaccounts.

16. The Contract provides for a death benefit, various death benefit options, annuity benefits and annuity payout options, as well as transfer privileges, dollar cost averaging, and other features. The IQ Contract has the following charges: (i) An annual administrative charge of $30 for contracts with account values of $50,000 or less; (ii) a mortality and expense risk charge of 1.30%; (iii) an administrative expense charge of .15%; (iv) a transfer fee of $20 after twelve transfers made during a Contract year; (v) any applicable charge for the Added Value Option; (vi) any applicable death benefit option fee; and (vii) any applicable state premium tax. The Grandmaster Contract has the following charges: (i) a deferred sales charge as a percentage of contribution withdrawn as described above; (ii) an annual administrative charge of $30 for contracts with account values of $50,000 or less; (iii) a mortality and expense risk charge of 1.20%; (iv) an administrative expense charge of .15%; (v) a transfer fee of $20 after twelve transfer made during a Contract year; (vi) any applicable charge for the Added Value Option; (vii) any applicable death benefit option fee; and (viii) any applicable state premium tax. In addition, assets invested in the subaccounts of either product are charged with the annual operating expenses of the underlying portfolios.

17. Applicants seek exemption pursuant to section 6(c) from sections 2(a)(32) and 27(i)(2)(A) of the Act and Rule 22c–1 thereunder to the extent deemed necessary to permit the Companies to recapture part or all of a Credit in the following instances: (i) when an owner exercises the Contract's free look provision; and (ii) when an owner makes a withdrawal in excess of the annual 10% free withdrawal amount within the first seven Contract years.

Applicants' Legal Analysis

1. Section 6(c) of the Act authorizes the Commission to exempt any person, security or transaction, or any class or classes of persons, securities or transactions from the provisions of the Act and the rules promulgated thereunder if and to the extent that 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 Act. Applicants request that the Commission pursuant to section 6(c) of the Act grant the exemptions requested below with respect to the Contracts and any Future Contracts issued by the Companies, funded by the Accounts or Other Accounts, and underwritten or distributed by Touchstone or Affiliated Broker-Dealers. Applicants undertake that Future Contracts will be substantially similar to the Contracts in all material respects. Applicants believe that the requested exemptions are 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.

2. Applicants represent that is not administratively feasible to track a Credit in the Accounts after the Credit is applied. Accordingly, the asset-based charges applicable to the Accounts will be assessed against the entire amount held in the Accounts, including the Credit, during the free look period and the recapture period. As a result, during such periods, the aggregate asset-based charges assessed against an owner's account value will be higher than those that would be charged if the owner's account value did not include the Credit. The account value includes all assets in the Accounts and the fixed accounts, including any Credit.

3. Subsection (i) of section 27 of the Act provides that section 27 does not apply to any registered separate account funding variable insurance contracts, or to the sponsoring insurance company and principal underwriter of such account, except as provided in paragraph (2) of the subsection. Paragraph (2) provides that it shall be unlawful for such a separate account or sponsoring insurance company to sell a contract by the registered separate account unless such contract is a redeemable security. Section 2(a)(32) defines ''redeemable security'' as any security, other than short-term paper, under the terms of which the holder, upon presentation to the issuer, is entitled to receive approximately his or her proportionate share of the issuer's current net assets, or the cash equivalent thereof.

4. Applicants submit that the recapture of a Credit in the circumstances set forth in the application would not deprive an owner of his her proportionate share of the issuer's current net assets. An owner's interest in a Credit allocated to his or her Contract value upon receipt of a contribution make during the first twelve months after issuance is not fully vested until the eighth Contract year. Unless and until the full amount of a Credit is vested, the Companies retain at least partial right and interest in the Credit, although not in the earnings attributable to that amount. Thus, Applicants argue that when the Companies recapture a Credit, in part or in full, they are merely retrieving their own assets and the owner has not been deprived of a proportionate share of the applicable Accounts' assets because his or her interest in the Credit has not vested.

5. In addition, Applicants state that permitting an owner to retain a Credit under a Contract upon the exercise of the free look provision would not only be unfair, but would also encourage individuals to purchase a Contract, with no intention of keeping it, and return it for a quick profit. Furthermore, Applicants state that the recapture of Credits applied to contributions made within the first twelve months after issuance is designed to provide the Companies with a measure of protection against anti-selection. The risk here is that, rather than spreading contributions over a number of years, an owner might make very large contributions during the first Contract year, thereby leaving the Companies little time to recover the cost of the Credits. As noted earlier, the amounts recaptured equal the Credits provided by the Companies from their general account assets and any gain would remain a part of the owner's Contract value.

6. Applicants represent that the Credit will be attractive to and in the interest of investors because it will permit owners to put between 101% and 105% of each of their contributions to work for them in the selected investment options. In addition, the owner will retain any earnings attributable to the Credit, as well as the principle amount of the Credit once vested.

7. Applicants further submit that the recapture of any Credit only applies in relation to the risk of anti-selection against the Companies. Anti-selection can generally be described as a risk that owners obtain an undue advantage based on elements of fairness to the Companies and the actuarial and other factors taken into account in designing the Contracts and Future Contracts. The Companies provide the Credit from their general account assets on a guaranteed basis. Thus, they undertake a financial obligation that contemplates the retention of the Contracts and Future Contracts by their owners over an extended period, consistent with the long-term nature of retirement planning. The Companies generally expect to recover their costs, including Credits, over an anticipated duration while a Contract or Future Contract is in force. The right to recapture Credits applied to contributions made within the first twelve months after issuance protects the Companies against the risk that an owner will purchase a Contract or Future Contract or make larger or additional contributions with the knowledge that the contingency that triggers payment of a benefit is likely or about to occur. With respect to refunds paid upon the return of a Contract or Future Contract during the free look period, the amount payable by the Companies must be reduced by the amount of the Credit. Otherwise, investors could purchase a Contract or Future Contract for the sole purpose of exercising the free look provision and making a quick profit.

8. Applicants submit that the provisions for recapture of Credits under the Contracts and Future Contracts do not violate sections 2(a)(32) and 27(i)(2)(A) of the Act. Sections 26(e) and 27(i) were added to the Act to implement the purposes of the National Securities Markets Improvement Act of 1996 and Congressional intent. The application of a Credit to contributions made under the Contracts should not raise any questions as to the Companies' compliance with the provisions of section 27(i). However, to avoid any uncertainly as to full compliance with the Act, Applicants request an exemption from sections 2(a)(32) and 27(i)(2)(A), to the extent deemed necessary, to permit the recapture of any Credit under the circumstances summarized herein without the loss of relief from section 27 provided by section 27(i).

9. Rule 22c–1 under the Act prohibits a registered investment company issuing any redeemable security, a person designated in such issuer's prospectus as authorized to consummate transactions in any such security, and a principal underwriter of, or dealer in, such security, from selling, redeeming, or repurchasing any such security except at a price based on the current net asset value of such security next computed after receipt of a tender of such security for redemption or of an order to purchase or sell such security.

10. The Companies' recapture of a Credit might arguably be viewed as resulting in the redemption of redeemable securities for a price other than one based on the current accumulation unit value of the Accounts. Applicants contend, however, that the recapture of the Credit does not violate Rule 22c–1. To effect a recapture of a Credit, the Companies will redeem interests in a Contract at a price determined on the basis of the current accumulation unit value(s) of the subaccount(s) to which the owner's Contract value is allocated. The amount recaptured will equal the amount of the Credit paid out of the Companies' general account assets. Although the owner will be entitled to retain any investment gain attributable to the Credit, the amount of that gain will be determined on the basis of the current accumulation unit values of the applicable subaccounts. Thus, no dilution will occur upon the recapture of the Credit. Applicants also submit that the second harm that Rule 22c–1 was designed to address, namely speculative trading practices calculated to take advantage of backward pricing, will not occur as a result of the recapture of the Credit. Because neither of the harms that Rule 22c–1 was meant to address is found in the recapture of the Credit, Rule 22c–1 should not apply to any Credit. However, to avoid any uncertainly as to full compliance with the Act, Applicants request an exemption from the provisions of Rule 22c–1 to the extent deemed necessary to permit them to recapture the Credit under the Contracts and Future Contracts.

Conclusion

Applicants submit that their request for an order that applies to the Accounts and any other Accounts established by the Companies, in connection with the issuance of the Contracts and Future Contracts, is appropriate and in the public interest. Applicants state that such an order would promote competitiveness in the variable annuity market by eliminating the need to file redundant exemptive applications, thereby reducing administrative expenses and maximizing the efficient use of Applicants' resources. Applicants undertake that Future Contracts funded by the Accounts or by Other Accounts will be substantially similar to the Contracts in all material respects. Applicants state that investors would not receive any benefit or additional protection by requiring Applicants to repeatedly seek exemptive relief that would present no issue under the Act that has not already been addressed in the application. Applicants submit that having Applicants file additional applications would impair Applicants' ability to take advantage of business opportunities as they arise. Further, Applicants state that if Applicants were required repeatedly to seek exemptive relief with respect to the same issues addressed in the application described herein, investors would not receive any benefit or additional protection thereby.

Applicants submit, based on the grounds summarized above, that their exemptive requests meet the standards set out in section 6(c) of the Act and that the Commission should, therefore, grant the requested order.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–45081; File No. S7–24–89]

Joint Industry Plan; Order Granting Approval of Amendment No. 12 to the Joint Self-Regulatory Organization Plan Governing the Collection, Consolidation, and Dissemination of Quotation and Transaction Information for Exchange-Listed Nasdaq/National Market System Securities and for Nasdaq/National Market System Securities Traded on Exchanges on an Unlisted Trading Privileges Basis; Submitted by the National Association of Securities Dealers, Inc., the Pacific Exchange, Inc. and the Boston, Chicago, Philadelphia, and Cincinnati Stock Exchanges

November 19, 2001.

I. Introduction

On August 29, 2001, the Cincinnati Stock Exchange Inc. (''CSE'') on behalf of itself and the National Association of Securities Dealers, Inc. (''NASD''), the Boston Stock Exchange, Inc. (''BSE''), the Chicago Stock Exchange, Inc. (''Chx''), the Pacific Exchange, Inc. (''PCX''), and the Philadelphia Stock

Exchange, Inc. (''PHLX'') (collectively, ''Participants''),[1] as members of the operating committee (''Operating Committee'')[2] of the Plan submitted to the Securities and Exchange Commission (''SEC'' or ''Commission'') Amendment No. 12 to the Plan, pursuant to Rule 11Aa3–2 under the Securities Exchange Act of 1934 (''Act'').[3] On September 18, 2001, the Participants submitted an amendment to Amendment No. 12.[4] Notice of the proposed 12th Amendment, as amended, was published for comment in the **Federal Register**.[5] The Commission received four comment letters on the proposed Plan Amendment[6] and a response to the comments from the Operating Committee,[7] as well as a response to the issues raised by Knight from the CSE and PCX/Archipelago.[8] This order approves the 12th Amendment to the Plan for nine months through August 19, 2002.

Extension of Unlisted Trading Privileges (''UTP'') In addtion, the PCX requested that the Commission extend UTP to all Nasdaq National Market securities (''Nasdaq/NM securities'')[9] and to Nasdaq SmallCap securities (''SmallCap securities'').[10] The Commission solicited comment on the request to extend UTP to Nasdaq/NM securities[11] and received four comment letters.[12] In connection with the publication of the 12th Amendment, the Commission solicited comment on extending UTP to SmallCap securities.

II. Background

The Plan governs the collection, consolidation, and dissemination of quotation and transaction information for Nasdaq/NM securities listed on an exchange or traded on and exchange pursuant to UTP.[13] The Plan provides for the collection from Participants, and the consolidation and dissemination to vendors, subscribers and others, of quotation and transaction information in ''eligible securities.''[14] The Plan also contains various provisions concerning its operation and sets out the responsibilities of the Participants with respect to each other and the Plan Processor.

The Commission approved the Plan on a pilot basis on June 26, 1990.[15] The parties did not begin trading until July 12, 1993, accordingly, the pilot period commenced on July 12, 1993. The Plan has since been in operation on a pilot basis.[16]

III. Description of the Amendment

The complete text of the Plan, as amended, was published in the **Federal Register**.[17] The following is a summary of the significant changes made by the 12th Amendment.

First, the name of the Plan has been changed. Second, the BSE and the Amex were added as Participants[18] and references in the Plan to the status of a Limited Participant[19] have been eliminated. Third, the definition of ''eligible security'' has been amended to include Small Cap securities.[20] Fourth, the Participants established the voting and quorum requirements for Committee meetings and the manner in which formal actions may be taken on behalf of the committee. Fifth, a process for selecting a new Securities information Processor (''SIP'' or ''Processor'') for the Plan was established.[21]

Sixth, the section of the Plan that discusses the functions of the Processor (Section VI) was amended to clarify the priority rules. Specifically, if an

[1] The CSE was elected chair of the Operating Committee for the Joint Self-Regulatory Organization Plan Governing the Collection, Consolidation, and Dissemination of Quotation and Transaction Information for Exchange-Listed Nasdaq/National Market System Securities and for Nasdaq/National Market System Securities Traded on Exchanges on an Unlisted Trading Privileges Basis (''Plan'') by the Participants.

[2] The Operating Committee is made up of all the Participants.

[3] 17 CFR 240.11Aa3–2.

[4] *See* letter from Jeffrey T. Brown, Committee Chairman, CSE, to Jonathan G. Katz, Secretary, SEC, dated August 29, 2001.

[5] Securities Exchange Act Release No. 44822 (September 20, 2001), 66 FR 50226 (October 2, 2001).

[6] *See* letters to Jonathan G. Katz, Secretary, SEC, from Jon Kroeper, Vice President, Regulatory Policy/Strategy, Instinet, dated October 25, 2001 (''Instinet''); Cameron Smith, General Counsel, Island, dated October 26, 2001 (''Island''); Michael T. Dorsey, Senior Vice President, General Counsel, and Secretary, Knight Trading Group, dated November 1, 2001 (''Knight''); and Michael J. Ryan, Jr., Executive Vice President and General Counsel, American Stock Exchange (''Amex''), dated November 14, 2001.

[7] *See* letter from Jeffrey T. Brown, Chairman, Operating Committee, to Jonathan G. Katz, Secretary, SEC, dated November 14, 2001.

[8] *See* letter from Jeffrey T. Brown, CSE and James P. Selway, PCX/Arca to Jonathan G. Katz, Secretary, SEC, dated November 14, 2001 (''CSE/Arca letter'').

[9] *See* letter from Thomas E. Connaghan, Senior Vice President, Equities, PCX, to Messrs. Robert L.D. Colby, Deputy Director, Division of Market Regulation, SEC and Robert E. Aber, Senior Vice President and General Counsel, The Nasdaq Stock Market, Inc., dated October 16, 2000.

[10] *See* letter from Mr. Connaghan to Messrs. Colby and Aber, dated November 20, 2000.

[11] *See* Securities Exchange Act Release No. 43545 (November 9, 2000), 65 FR 69581 (November 17, 2000).

[12] *See* letters from Roger Phillips to Mr. Colby, undated (''Phillips''); Steven E. Kamensky, Security Traders, Inc. to Secretary, SEC, dated December 4, 2000 (''Kamensky''); Richard G. Ketchum, President, The Nasdaq Stock Market, Inc., to Jonathan G. Katz, Secretary, SEC, dated December 5, 2000 (''Nasdaq''); and Michael T. Dorsey, Senior Vice President and General Counsel, and Knight Trading Group to Jonathan G. Katz, Secretary, SEC, dated December 13, 2000 (''Knight letter'').

[13] Section 12 of the Act generally requires an exchange to trade only those securities that the exchange lists, except that Section 12(f) of the Act permits UTP under certain circumstances. For example, Section 12(f) of the Act, among other things, permits exchanges to trade certain securities that are traded over-the-counter (''OTC/UTP''), but only pursuant to a Commission order or rule. 15 U.S.C. 78*l*(f). For a more complete discussion of the Section 12(f) requirement, *see* November 1995 Extension Order, *infra* note 16.

[14] Currently, the Plan defines ''eligible securities'' as any Nasdaq/NM security as to which UTP 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. The Participants propose to amend the definition of ''eligible security'' in this amendment to include SmallCap securities.

[15] *See* Securities Exchange Act Release No. 28146, 55 FR 27917 (July 6, 1990) (''1990 Plan Approval Order'').

[16] *See* Securities Exchange Act Release Nos 34371 (July 13, 1994), 59 FR 37103 (July 20, 1994); 35221 (January 11, 1995), 60 FR 3886 (January 19, 1995); 36102 (August 14, 1995), 60 FR 43626 (August 22, 1995); 36226 (September 13, 1995), 60 FR 49029 (September 21, 1995); 36368 (October 13, 1995), 60 FR 54091 (October 19, 1995); 36481 (November 13, 1995), 60 FR 58119 (November 24, 1995) (''November 1995 Extension Order''); 36589 (December 13, 1995), 60 FR 65696 (December 20, 1995); 36650 (December 28, 1995), 61 FR 358 (January 4, 1996); 36934 (March 6, 1996), 61 FR 10408 (March 13, 1996); 36985 (March 18, 1996), 61 FR 12122 (March 25, 1996); 37689 (September 16, 1996), 61 FR 50058 (September 24, 1996); 37772 (October 1, 1996), 61 FR 52980 (October 9, 1996); 38457 (March 31, 1997), 62 FR 16880 (April 8, 1997); 38794 (June 30, 1997) 62 FR 36586 (July 8, 1997); 39505 (December 31, 1997) 63 FR 1515 (January 9, 1998); 40151 (July 1, 1998) 63 FR 36979 (July 8, 1998); 40896 (December 31, 1998), 64 FR 1834 (January 12, 1999); 41392 (May 12, 1999), 64 FR 27839 (May 21, 1999) (''May 1999 Approval Order''); 42268 (December 23, 1999), 65 FR 1202 (January 6, 2000); 43005 (June 30, 2000), 65 FR 42411 (July 10, 2000); 44099 (March 23, 2001), 66 FR 17457 (March 30, 2001); and 44348 (May 24, 2001), 66 FR 29610 (May 31, 2001); 44552 (July 13, 2001), 66 FR 37712 (July 19, 2001); 44694 (August 14, 2001), 66 FR 43598 (August 20, 2001); 44804 (September 17, 2001), 66 FR 48299 (September 19, 2001); 44937 (October 15, 2001), 66 FR 53271 (October 19, 2001).

[17] *See* note 5 *supra.*

[18] This change was effective on filing. *See* note 5 *supra.*

[19] Section III had defined a Limited Participant to mean a registered national securities exchange whose participation in the Plan was restricted to reporting to the processor quotation information and transaction reports in Nasdaq/NM securities listed on that exchange. The only Limited Participant was the BSE.

[20] *See* NASD Rule 4200 for the definition of SmallCap security.

[21] The Committee included this section of the Plan pursuant to the discussion in the order approving the proposed rule change by the NASD relating to the establishment of the Nasdaq Order Display Facility and Order Collector Facility and modifications of the Nasdaq Trading Platform (''SuperMontage Order''). *See* Securities Exchange Act Release No. 43863 (January 19, 2001), 66 FR 8020 (January 26, 2001). In the SuperMontage Order, the Commission directed the Participants to negotiate a revised Plan to, among other things, provide for either a fully viable alternative exclusive SIP for all Nasdaq securities, or a fully viable alternative non-exclusive SIP.

exchange participant or Nasdaq market participant changes its bid and/or offer, it will be treated as a new quote for purposes of time priority. However, a change to only bid size and/or ask size will not change the time priority of the quote. Section VI also addresses how Participant quotes will be carried over from one trading day to the next, including the use of previous day's quotes in the calculation of the consolidated best bid and best offer (''BBO'').

Seventh, Section VI.C.1. specifies procedures for the Processor to follow when the BBO results in a locked or crossed market and states that the Processor shall normally cease calculation of the BBO at 6:30 p.m. Eastern Time (''ET''). It also contains a ''phase-in'' schedule for the addition of Nasdaq securities that will be eligible for trading pursuant to UTP by the Participants if the Commission extends UTP to all Nasdaq/NM securities and SmallCap securities. The Participants proposed the phase-in to minimize the threat to available Processor capacity that may arise as Participants trade additional Eligible Securities pursuant to UTP. The Committee believes that the phase-in period will allow the Processor to monitor the effects, if any, that the increased quote traffic and trading have upon Processor capacity. The phase-in schedule does not apply to Nasdaq, Nasdaq market participants acting in their capacity as Nasdaq market participants, or to any Participant that does not engage in auto-quoting.[22]

Eighth, the 12th Amendment limits the practice of auto-quoting if the Processor has made a determination that it is necessary to maintain adequate capacity and provides 30 days notice to Participants. If a Participant thereafter exceeds the auto-quoting limitations, the Processor may initiate proceedings, before the entire Committee, that will put the Participant on notice of the violation and afford ample time and procedures to rectify the situation.[23] The auto-quoting limitation ends once the Operating Committee selects a new Processor. The auto-quoting limitation includes a ''grandfather clause'' exempting a Participant from the auto-quoting limitations and the phase-in schedule for the number of securities that the Participant quoted, pursuant to the Plan, as of May 1, 2001.[24]

Ninth, the section on Operational Issues establishes Participant responsibilities with respect to the collection, validation, and transmission of data to the Processor. It also establishes operational procedures that the Processor must follow in collection data from Participants, such as performing gross validation processing for quotes and last sale messages and consolidating and disseminating trade and quote information from each Participant.

Finally, the 12th Amendment to the Plan amends Exhibit 1 to the Plan to eliminate the ''minimum-maximum'' payment formula and replace it with a formula for determining Participants' total trades, total share volume, operating expenses, and operating income for the purposes of distribution of gross operating revenue to the Participants, as well as a provision for reimbursing the Processor in the event that operating expenses exceed operating revenues.[25]

In addition, Exhibit 1 includes criteria and schedules for determining Participant eligibility for receiving distributions of gross operating revenue. Exhibit 1 also establishes procedures and cost allocations for retaining an independent auditor for the purpose of auditing the Processor's costs or other calculations used in the determination of operating expenses, operating revenues, and distribution shares, among other calculations.[26]

Thus, the Plan, as amended, will govern the collection, consolidation, and dissemination of quotation information and transaction reports in Nasdaq/NM securities and SmallCap securities.

IV. Summary of Comments

The Commission received four comment letters on Amendment No. 12.[27] Instinet raised several concerns about the Amendment. First, Instinet believes Amendment No. 12 does not fulfill the conditions the Commission set forth with respect to the Plan in the SuperMontage Order. Specifically, Amendment No. 12 does not provide a timeframe within which a new processor will be selected and does not require that Nasdaq step down as the processor. Second, Instinet notes that Amendment No. 12 does not provide for participation in decision-making by non-self-regulatory organizations. Instinet believes that this will inhibit its ability to compete. Instinet also assert that Section 11A of the Act requires the Commission to provide automated trading systems (''ATSs'') with the opportunity to directly participate in the Plan. Third, Instinet objects to the provision in the Plan that prohibits ECNs and ATSs in their role as Nasdaq market participants from imposing any access or execution fee or charge with respect to transactions with Participants and their members effected through the telephone. Instinet believes this provision is not consistent with the Act. Instinet also objects to a provision in Section IX of the Plan that states that an exchange Participant may charge for access, other than telephone access, to its floor or facilities. Fourth, Instinet argues that the provision in Section IX regarding what constitutes access is not clear.[28] Finally, Instinet favors extension of UTP to all Nasdaq/NM securities and SmallCap securities.

Island objects to the methodology and formula used to calculate costs submitted by Nasdaq in operating the Processor. Island also objects to some of the costs of the Processor that are subtracted from gross revenue before disbursements are made to the Participants. With respect to the Commission's request for comment on extending UTP to all Nasdaq/NM as well as SmallCap securities, Island urges the Commission to expand the number of securities that can be traded from 1,000 Nasdaq/NM securities to all Nasdaq/NM securities and also to expand UTP to SmallCap securities.

Knight objects to the concept of exchanges trading over-the-counter (''OTC'') securities because Knight believes that the rules that exchange members must comply with are not as demanding as the NASD's rules and therefore, the playing field is not level between exchanges and Nasdaq market makers trading the same securities. Knight specifically claims that exchanges do not have to comply with the NASD's firm quote rule.[29] Knight also raises concerns about the NASD's Trade or Move rule[30] and asserts that the Commission should not approve the 12th Amendment until either exchange participants are subject to the NASD's rules or they adopt comparable rules. Knight also argues that the Commission should not extend UTP to additional securities until the Commission has had

[22] *See* Section VI.C.2(a)(v) and Section VI.C.2(b).

[23] The Participants proposed a notice and cure period in which a Participant may rectify the situation on its own accord, as well as providing for formal proceedings to be held before the Committee before any remedial action may be taken against a violating Participant. *See* Section VI.C.2(e).

[24] *See* Section VI.C.2(f).

[25] The Commission put Exhibit 1 into effect summarily on October 2, 2001 on a temporary basis not to exceed 120 days. *See* note 5 *supra.*

[26] The 12th Amendment also contains numerous ''house-keeping'' corrections, such as changing the term ''NASDAQ'' to ''Nasdaq,'' officially removing the Chicago Board Options Exchange, and ensuring that references to amended sections are consistent with the amendments discussed above.

[27] *See* note 6 *supra.*

[28] *See* Instinet at p. 8.

[29] NASD Rule 4613(b)(1).

[30] NASD Rule 4613(b)(2).

a chance to review the impact of trading in a decimals environment on Nasdaq/NM and SmallCap securities.

Knight also raises concern that, under the 12th Amendment, UTP exchanges will be able to charge non-members access fees for interacting with their quotes that are included in the NASD'S montage. Finally, Knight believes that the Commission should not grant an extension of the exemption from Rule 11Ac1–2 under the Act [31] regarding calculation of the BBO. Knight opposes continuation of the exemption from calculating the BBO based on price, size, time priority. Currently, Nasdaq uses price, time, size to calculate the BBO. According to Knight, using the calculation required by Rule 11Ac1–2 under the Act [32] will encourage depth in the market.

Amex's main concern is with the ability of the Processor to determine that there is a capacity concern. Once the Processor makes this determination, the autoquoting restrictions are activated. Some Participants are grandfathered out of the limitaiton on autoquoting. Amex believes that these provisions are unfair and anticompetitive. Because Amex was not yet a Participant, it did not vote on the 12th Amendment.

In addition, the Commission received four comment letters in response to its request for comments regarding raising the number of Nasdaq/NM securities that can be traded pursuant to UTP consistent with Section 12(f) of the Act.[33] Two of the commenters (Phillips and Kamensky) supported extension of the UTP to all Nasdaq/NM securities. They both stated that extending UTP would add liquidity to the market for these securities and enhance competition. Kamensky stated that the earlier increases in the number of Nasdaq/NM securities that could be traded pursuant to UTP had increased the liquidity of the markets for these securities and enhanced competition. A third commenter, Knight, objected to the extension of the UTP to all Nasdaq/NM securities because of the level playing field argument raised in its comment on the 12th Amendment. Knight also stated that PCX had not demonstrated how the expansion of the number of securities that could be traded pursuant to UTP would help maintain fair and orderly markets and further the National Market System (''NMS'') goals. According to Knight, problems appeared in the market for Nasdaq/NM securities after the Commission raised the number of securities that could be traded pursuant to UTP from 500 to 1,000 in 1999.

Nasdaq stated that it did not object to the Commission raising the number of Nasdaq/NM securities that could be traded pursuant to UTP; however, it raised concerns about the capacity of the Nasdaq SIP to handle quote and trade reporting of all Nasdaq/NM securities given the potential new entrants to the Plan and the advent of decimal trading. Nasdaq also stated that the Commission should wait until Nasdaq and other interested market participants had resolved the issue of the exclusive SIP before granting PCX's request.

V. Discussion

The Commission has determined to approve the 12th Amendment, including Exhibit 1 to the Plan, on a pilot basis until August 19, 2001, to grant UTP to the Participants to trade all Nasdaq/NM securities as well as Small Cap securities pursuant to Section 12(f) of the Act,[34] and to continue the exemption from Rule 11Ac1–2 [35] regarding the calculation of the BBO.[36]

The Commission notes that the 12th Amendment to the Plan has been vigorously debated by the Participants and represents the result of good faith negotiations among the Participants. The Plan, as amended, is regarded by the Participants and the Commission as an interim plan. The Participants are currently negotiating a further amendment to the Plan to address the remaining outstanding items outlined in the Commission's SuperMontage order. In particular, the Commission notes that the Participants approved a proposed request for proposal (''RFP'') to select a new SIP. The Commission understand that the RFP has been issued. The Commission therefore believes that the Participants will continue to make progress in amending the Plan and responding to the concerns that the Commission noted in the SuperMontage Order.

Instinet argued that Section 11A of the Act requires the participation of ATSs in the Plan, and noted that the 12th Amendment does not contain provisions to permit the participation of non-self-regulatory organizations. As the Commission stated in the SuperMontage Order, the Commission believes that ATSs and ECNs should be given a role in the governance of the Plan; however, the Commission does not believe that Section 11A requires that the role of ECNs and ATSs be the same as the role of the SROs. While at this time the Plan does not contain a specific provision for receiving input from non-participants, the Commission notes that a number of ECNs have been represented at meeting of the Operating Committee over the past year, and the Commission expects that the Participants will address this issue in the next amendment to the Plan.[37]

Instinet also raised objections to Section IX of the Plan that prohibits Participants from charging any access or execution fee with respect to transactions with Participants and their members effected by telephone. The Commission notes that the Plan sets forth the terms of free telephone access to quotes of all market participants, including the ECNs, market makers, and specialists. The Commission therefore believes that the Plan establishes consistent standards for access to quotes displayed on any Participant by the members of other Participants.[38] Instinet also objects to a specific provision in Section IX of the Plan that permits exchange participants to charge for access, other than telephone access. Instinet believes that the Plan should jump NASD participant to charge for such access. As the Plan is silent on this matter, the Commission believes that, this provision is not meant to change the way that ECNs current operate.

Island objected to the methodology and formula used to calculate the costs of the Processor. In general, Island believes that some of the costs included are more properly associated with the costs of operating the Nasdaq market as opposed to the costs of operating the SIP. However, the Participants unanimously agreed to the cost for which the Processor will be reimbursed. Moreover, the Commission believes that the ambiguities related to the dual roles of Nasdaq supporting both the Process and the Nasdaq market will be resolved by the next amendment to the Plan and the selection of a new Processor.

Knight objects to exchanges being able to trade Nasdaq securities without either being subject to the NASD's rules or having comparable rules. The

[31] 17 CFR 240.11Ac1–2.

[32] *Id.*

[33] 15 U.S.C. 78l(f). *See* note 12, *supra. See also* Instinet at 4.

[34] 15 U.S.C. 781(f).

[35] 17 CFR 250.11Ac1–2.

[36] With this order, SmallCap securities will now be securities reported pursuant to a transaction reporting plan approved by the Commission. Accordingly, SmallCap securities will now be subject to all Commission rules that cover securities reported pursuant to a Commission approved transaction reporting plan.

[37] The Commission notes that the Participants are working on an amendment to add the NASD as a new Participant once Nasdaq's exchange registration is approved. Nasdaq will continue as a Participant.

[38] The Commission notes that, since its inception, the Plan approved by the Commission prohibited fees for telephone access to market makers. *See also* 17 CFR 242.301(b)(4).

Commission notes that all exchange participants, as well as the NASD's market participants, are subject to the Commission's Firm Quote Rule.[39] All exchange participants must comply with the Firm Quote Rule unless the exchange participant qualifies for one of the two exceptions in the Rule. In addition, Knight is concerned about not being able to open the market or trade because of a locking or crossing quote. The Commission notes that it recently approved an NASD proposal on a temporary basis, which provides, among other things, that SuperSOES may trade-through the superior quote of a UTP exchange that does not participate voluntarily in SuperSOES.[40] The Commission believes that this rule deals with the substance of Knight's objection.

Knight also raises concerns about the effects of decimal trading with minimum price increments on trading in the Nasdaq market and cautions the Commission not to approve the 12th Amendment or extent UTP until the Commission has reviewed the implications of decimalization. While the Commission is aware that decimalization has had a significant effect on the markets for securities, the Commission is not aware of any particular effect specific to UTP trading of Nasdaq/NM securities. The Commission will continue to monitor the impact of decimal trading on the securities markets. Knight also objects to the Commission extending the temporary exemption from Rule 11Ac1–2 [41] regarding the BBO calculation. Since the inception of this Plan, Nasdaq has calculated the BBO based on price, time, size priority. The Participants are currently discussing a change to the calculation to make it consistent with the requirement in Rule 11AC1–2. The Commission expects the issue to be resolved in connection with the next amendment to the Plan.

Finally, while the Commission understands Amex's concern with respect to the Processor (which is both an exclusive SIP and a competitor of the Amex's) making determinations regarding capacity, as an exclusive SIP, the Processor is subject to the provisions of Section 11A of the Act. Furthermore, the auto-quoting restrictions and the grandfather clause do not come into play until the Processor determines that there is a capacity concern. If the Processor determines that a capacity concern exists, it must provide Participants with 30 calendar days notice and the basis for the determination. After 30 days, the Processor can invoke the auto-quoting limitation. The Commission believes that the Plan contains adequate procedural safeguards surrounding the Processor's determination that a capacity concern exists. The Commission expects the Participants to move quickly to select a processor, consistent with the discussion in the SuperMontage Order.

Extension of UTP

Knight objected to the extension of UTP for two reasons. First, it stated that PCX had not made a case that extending UTP to all Nasdaq/NM securities would further the goals of NMS. The Commission notes that since 1993 there has been UTP trading of Nasdaq/NM securities and the Commission is not aware of any negative effects from having extending UTP to Nasdaq/NM securities. Indeed, two of the commenters stated that UTP for Nasdaq/NM securities had had a positive effect on the liquidity in the market and had provided additional competition. Second, Knight raised the issue that UTP exchanges do not have to comply with NASD rules. This argument is addressed above.

Nasdaq, the only other commenter to voice concerns, raised concerns about capacity of the SIP and the effects of the implementation of trading in decimals on Nasdaq/NM securities. It urged the Commission not to extend trading to all Nasdaq/NM securities until these issues had been addressed. Nasdaq also wanted the Commission to wait until a new SIP was in place. The Commission believes that the Participants to the Plan, including Nasdaq itself, addressed these concerns adequately in the 12th Amendment.

VI. Commission Findings and Conclusion

Plan Amendment

For the reasons discussed above, the Commission finds that the 12th Amendment, including Exhibit 1, to the Plan is consistent with the requirements of the Act and the rules and regulations thereunder and, in particular, Section 11A(a)(1) and Rules 11Aa3–1 and 11Aa3–2. The Commission finds that the 12th Amendment to the Plan is necessary and appropriate in the public interest, for the protection of investors and the maintenance of fair and orderly markets, to remove impediments, to, and perfect the mechanisms of, a national market system.

Extension of UTP

The Commission finds that extending UTP to all Nasdaq/NM securities and SmallCap securities is consistent with Section 12(f) of the Act. Specifically, extending UTP to these securities is consistent with the maintenance of fair and orderly markets, the protection of investors and the public interest, and otherwise in furtherance of the purposes of the Act. The Commission has taken into account the public trading activity in these securities, the character of the trading, the impact of the extension on existing markets for the securities, and the desirability of removing impediments to, and the progress that has been made toward, the development of a national market system.

Exemptive Relief

For the reasons discussed above, the Commission has determined to grant an exemption for Nasdaq/NM and SmallCap securities from the requirement in Rule 11Ac1–2 under the Act regarding calculation of the BBO. The Commission has determined that granting exemptive relief for the duration of the 12th Amendment is consistent with the public interest and the protection of investors. The Commission notes that the Participants have undertaken to address this issue in the next amendment to the Plan and the Commission urges that Participants to act quickly to implement the amendment.

It is therefore ordered, pursuant to Section 11A of the Act and paragraph (c)(2) of Rule 11Aa3–2, thereunder, that the 12th Amendment to the Plan described above be, and hereby is, approved on a pilot basis until August 19, 2002. Further, the Commission hereby extends UTP pursuant to Section 12(f) of the Act to all Nasdaq/NM securities and SmallCap securities. Finally, the Commission hereby grants a temporary exemption from the requirement in Rule 11Ac1–2 that the BBO be calculated based on price, size, time priority for the duration of the 12th Amendment.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[42]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–29458 Filed 11–26–01; 8:45 am]

BILLING CODE 8010–01–M

[39] 17 CFR 240.11Ac1–1.

[40] *See* Securities Exchange Act Release No. 45047 (November 8, 2001).

[41] 17 CFR 240.11Ac1–2.

[42] 17 CFR 200.30–3(a)(27); 17 CFR 200.30–3(a)(2); 17 CFR 200.30–3(a)(36).

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Federal Register Citation of Previous Announcement: [66 FR 58543, November 21, 2001]

STATUS: Open/Closed Meetings.

PLACE: 450 Fifth Street, NW., Washington, DC.

DATE AND TIME OF PREVIOUSLY ANNOUNCED MEETING: Thursday, November 29, 2001, at 10 a.m.

CHANGE: Additional Meeting and Time Change.

An open meeting will be held on Thursday, November 29, 2001 at 10 a.m.

The closed meeting scheduled for Thursday, November 29, 2001 at 10 a.m., will follow the 10 a.m. open meeting.

The subject matter of the open meeting scheduled for Thursday, November 29, 2001, at 10 a.m., will be:

The Commission will consider whether to extend a stay relating to the application of certain requirements contained in Regulation ATS under the Securities Exchange Act of 1934 to alternative trading systems that facilitate trading in investment grade and non-investment grade corporate debt securities. Those requirements relate to fair access and systems capacity, security, and integrity. The current stay of those requirements expires on December 1, 2001.

For further information contact: Gordon Fuller, Counsel to the Assistant Director, at (202) 942–0792, Office of Market Supervision, Division of Market Regulation.

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact:

The Office of the Secretary at (202) 942–7070.

Dated: November 21, 2001.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–29514 Filed 11–21–01; 4:06 pm]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–45074; File No. SR–Amex–2001–99]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the American Stock Exchange LLC Relating to the Withdrawal of Continued Approval for Securities Underlying Options Traded on the Exchange

November 16, 2001

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 16, 2001, the American Stock Exchange LLC (''Amex'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Amex. The proposed rule change has been filed by the Amex as a ''non-controversial'' rule change under Rule 19b–4(f)(6) under the Act.[3] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Amex proposes to amend Amex Rule 916 governing the withdrawal of approval for securities underlying options traded on the Exchange.

The text of the proposed rule change is available at the Amex and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Amex included statements concerning the purpose of and statutory basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6)

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Commentary .01 to Amex Rule 916 currently provides guidelines to be used in determining whether an underlying security previously approved for options trading meets requirements for continuance of such approval. Specifically, one guideline states that the Exchange may not list additional series for an option class if the underlying security has failed to close above $5 for the majority of business days during the preceding six calendar months as measured by the highest closing price reported in any market in which the underlying security traded. If the underlying security does not meet the guideline price then the Exchange will not open for trading additional series of that class and may take other actions such as prohibiting opening purchase transactions in existing series. There is a limited exception from this guideline for highly capitalized, actively-traded securities whose options have significant investor open interest. The exception allows series to be added if such underlying securities closed at or above an initial standard of $3 and a subsequent standard of $4.

Change in Guideline Price. The Exchange is proposing to amend Commentary .01 to Rule 916 in the following manner. First, the Exchange proposes to change the guideline price from $5 to $3, which is used to determine whether an underlying security previously approved for options transactions meets the requirements for continued approval. Second, the Exchange proposes to shorten the time period used to determine the guideline price from the majority of business days during the preceding six calendar months to whether the underlying security closed above the guideline price on just the preceding trading day. And, third, the Exchange proposes to use the highest closing price reported in the primary market in which the underlying security trades rather than the closing price in ''any market'' to determine whether the $3 guideline has been met. The other criteria set forth in Commentary .01 used to determine whether a class of options meets the requirements for continued approval (such as, the number of shares outstanding and held by non-insiders, the number of holders, and trading volume) will remain the same.

Additions of Series. Commenter .02 to Amex rule 916 prohibits the opening of

trading any additional series of options on an underlying security at any time when the market price per share of such security is less than $5, as measured by the highest closing price reported in any market in which the underlying security trades. The Exchange proposes to amend Commentary .02 to Amex Rule 916 by reducing from $5 to $3 the price above which the underlying security must be traded before the Exchange may add additional series of options. This means if the Exchange is adding a series intra-day, the underlying security must have closed above $3 the previous day (in order to meet the proposed requirement of Commentary .01) and must be at $3 or above at the time the new series is added (in order to meet the proposed requirement of Commentary .02 to Amex Rule 916). In addition, the Exchange proposes to use the highest closing price reported in the primary market, as that term is defined in Rule 900(26), in which the underlying security trades, rather than the closing price in ''any market'' to determine whether the $3 guideline has been met. Finally, for purposes of Commentary .02, the Exchange proposes to use the market price for each underlying security as measured by (i) for intra-day series additions, the last reported trade in the primary market in which the underlying security trades at the time the Exchange determines to add these additional series; and (ii) for next-day and expiration series additions, the closing price reported in the primary market in which the underlying security traded on the last trading day before the series are added.

Exemption from Commentaries .01 and .02. Commentary .04 to Amex Rule 916 provides an exemption from the $5 guideline for highly capitalized, actively traded underlying securities whose options have significant customer open interest. The Exchange may add series if: (1) The closing price of the underlying security was at or over $3 for a majority of the days during the six calendar month period preceding the addition, and (2) the closing price of the underlying security was at or over $4 for a majority of the days during a subsequent six calendar month period. Since the Exchange is proposing to reduce the guideline from $5 to $3 in Commentaries .01 and .02, the exemption provided in Commentary .04 no longer needed.

When many of the maintenance criteria were first implemented, the list options market was in its infancy. Now more than twenty-six years later, the listed options market is a mature market with sophisticated investors. The Exchange does not believe that the $5 guideline is necessary to accomplish its presumed intended purposes: (1) To provide for the listing of options on securities that are not susceptible to manipulation; and (2) to prevent the proliferation of option classes on underlying securities that lack liquidity needed to maintain fair and orderly markets. The Exchange believes that it should allow the desires of its customers and the workings of the marktplace determine the securities on which options will continue to be traded. The Exchange represents that it will continue to apply its other guidelines, which assure that there are a large number of shares outstanding and held by non-affiliates of the issuer, the underlying security is actively traded, there are a large number of holders of the security, and the underlying security continues to be listed on a national securities exchange or traded through the facilities of a national securities association. The Exchange represents that the use of the revised guidelines will continue to ensure that options will be traded on securities of companies that are financially sound and are still subject to adequate minimum standards. In addition, the Exchange asserts that it will ensure that its own systems and those of the Options Price Reporting Authority can handle any increased capacity requirements due to the listing of new option series under the proposed less restrictive guidelines.

2. Statutory Basis

The Amex believes that the proposed rule change is consistent with Section 6 of the Act,[4] in general, and with Section 6(b)(5) of the Act,[5] specifically, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition.

[4] 15 U.S.C. 78f.

[5] 15 U.S.C. 78f(b)(5).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change, as amended: (1) Does not significantly affect the protection of investors or the public interest; (2) does not impose any significant burden on competition; and (3) does not become operative for 30 days after the date of filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest; provided that the self-regulatory organization has given the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission,[6] the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[7] and Rule 19b–4(f)(6)[8] thereunder.

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative prior to 30 days after the date of filing. However, Rule 19b–4(f)(6)(iii) permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Amex seeks to have the proposed rule change become operative immediately. The Commission, consistent with the protection of investors and the public interest, has determined to make the proposed rule change operative as of November 16, 2001.[9] The Commission notes that the proposed rule change is substantially similar in all material respects to the rule of another exchange that the Commission has already noticed for public comment and

[6] *See* Letter from Claire P. McGrath, Vice President and Deputy General Counsel, Amex, to Nancy Sanow, Assistant Director, Division of Market Regulation, Commission, dated November 2, 2001.

[7] 15 U.S.C. 78s(b)(3)(A).

[8] 17 CFR 240.19b–4(f)(6).

[9] For purposes only of accelerating the operative date of this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

approved [10] and, therefore, the proposed rule change raises no new issues of regulatory concern. At any time within 60 days of the filing of the proposed rule change the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.[11]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Amex.

All submissions should refer to File No. SR–Amex–2001–99 and should be submitted by December 18, 2001.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[12]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–29404 Filed 11–26–01; 8:45 am]

BILLING CODE 8010–01–M

[10] *See* Securities Exchange Act Release No. 44964 (October 19, 2001), 66 FR 54559 (October 29, 2001) (order approving File No. SR–CBOE–2001–29).

[11] *See* Section 19(b)(3)(C) of the Act, 15 U.S.C. 78(b)(3)(C).

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–45077; File No. SR–PCX–2001–39]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Pacific Exchange, Inc. To Eliminate References to Fractional Pricing From PCX and PCXE Rules

November 19, 2001.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 30, 2001, the Pacific Exchange, Inc. (''PCX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Exchange filed the proposal pursuant to Section 19(b)(3)(A) of the Act,[3] and Rule 19b–4(f)(6) [4] thereunder, which renders the proposal effective upon filing with the Commission.[5] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Rules and those of its subsidiary, the PCX Equities, Inc. (''PCXE''), so that prices for securities traded on the Exchange and trading differentials for bids and offers made on the Exchange may be expressed in decimal form. The Exchange proposes these amendment in anticipation of the industry-wide conversion to quoting and trading in decimals. The text of the proposed rule change is available at the PCX and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the PCX included statements concerning the purpose of and basis of its proposal and discussed any comments it received regarding the proposal. The text of these statements may be examined at the places specified in Item IV below. The PCX has prepared summaries, set forth in Sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On June 8, 2000, the Commission provided a framework for the national securities exchanges and the National Association of Securities Dealers, Inc. (collectively ''Participants'') to convert quotation pricing in equity securities and options from fractions to decimals.[6] The Commission's Order required that: (i) by June 8, 2001, Participants submit studies analyzing how decimal conversion affects systems capacity, liquidity and trading behavior, and (ii) by July 9, 2001, Participants submit rule filings that individually establish the minimum price variation (''MPV'') for each market. On May 22, 2001, the Commission extended the deadlines to September 10, 2001 (for submitting studies) and to November 5, 2001 (for submitting rule filings). On September 25, 2001, in view of the market disruption caused by the attacks of September 11, 2001, the Commission extended the deadline for rule filings to January 14, 2002.

Participants Submitted an implementation plan and successfully completed the phasing-in of decimal pricing in all equity securities and options by April 9, 2001. In connection with the full implementation, the Exchange modified its Rules to include pricing in decimal format with cross-references to fractional pricing. This was done to allow the Exchange to trade, during the phase-in, some securities in decimals and some in fractions. The Exchange also established an MPV scheme for each market (equities and options) and submitted its study of the results on September 10, 2001.[7] The Exchange now proposes to eliminate references to fractional pricing.

Equity Trading Rules

PCXE Rule 7.10(a)—Trading Differentials: The PCX is amending PCXE Rule 7.10(a) to delete text relating to trade differential increments priced in fractions and to eliminate references to fractions currently present in the Commentary examples.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

[5] The Exchange provided the Commission with written notice of its intent to file the proposal on or about October 22, 2001. *See* Rule 19b–4(f)(6). 17 CFR 240.19b–4(f)(6).

[6] *See* Securities Exchange Act Release No. 42914 (June 8, 2000), 65 FR 38101.

[7] *See* The Pacific Exchange, Report on Decimal Trading (September 10, 2001).

PCXE Rule 7.12(b)—Firm Quotations: The PCX is amending PCXE Rule 7.12(b), Commentary .05 for the purpose of deleting reference to fractional pricing in the example.

PCXE Rule 7.66(b)(8)(i)(A)(1)—Intermarket Trading System: The PCX is modifying PCXE Rule 7.66(b)(8)(A)(1) relating to price changes that trigger obligations in order to delete cross-references to fractional pricing in the ''applicable price change.''

The PCX is modifying PCXE Rule 7.70(h) relating to the Pacific Computerized Order Access System (''P/COAST'') in order to replace the fractional pricing in the example to decimal values.

The PCX is modifying Rule 7.79(e) relating to information on tape in order to replace the fractional pricing to a decimal value.

Options Trading Rules

PCX Rule 1.15(b)—Point to Point Testing: The PCX is deleting PCX Rule 1.15(b) in its entirety because it relates to testing requirements for the conversion of fractional pricing to decimal pricing. Because the Exchange has fully implemented decimal pricing, the Rule is no longer applicable or necessary.

PCX Rules 637(b)(1) and 6.37(b)(3)—Obligations of Market Makers: The PCX is modifying the maximum bid/ask spread differentials to eliminate the cross-references to fractional pricing.

PCX Rules 6.47(b)(4)(A) and 6.47(b)(4)(B)—Crossing Orders: The PCX is modifying the examples relating to crossing markets in order to eliminate cross-references to fractional pricing.

PCX Rule 6.64 Commentary .01(c) and (d)—Trading Rotations: The PCX is modifying the examples relating to the determination of opening prices in order to eliminate cross-references to fractional pricing.

PCX Rule 6.72(a)(2) and Commentary .01—Trading Differentials: The PCX is amending its Rules to delete text relating to treatment of option issues quoted in fractions. Because the Exchange and all Member and Member Organizations have fully-implemented decimal pricing, the contingency language is no longer applicable.

PCX Rule 6.75(a)–(e)—Priority of Bids and Offers: The PCX is modifying the example relating to bids and offers in order to eliminate cross-references to fractional pricing.

PCX Rule 6.80 Commentary .01—Accommodation Transactions: The PCX is modifying its Rules on cabinet securities to delete cross-references to fractions.

PCX Rule 7.9—Meaning of Premium and Offers: The PCX is modifying its Rules on bids and offers to change the example by deleting cross-references to fractional pricing.

PCX Rule 8.102(f)—Terms of FLEX Options: The PCX is amending its Rules to delete text relating to percentage pricing and to delete cross-references to fractional pricing.

2. Statutory Basis

The Exchange believes the proposal is consistent with the requirements of Section 6(b) of the Act,[8] in general, and furthers the objectives of Section 6(b)(5),[9] in particular, in that it is designed to promote just and equitable principles of trade, prevent fraudulent and manipulative acts and practices, protest investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments on the proposed rule change were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

(i) Significantly affect the protection of investors or the public interest;

(ii) impose any significant burden on competition; and

(iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[10] and Rule 19b–4(f)(6) thereunder.[11] At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appear to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposal is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the PCX. All submissions should refer to file number SR–PCX–2001–39 and should be submitted December 18, 2001.

For the Commission, by the division of Market Regulation, pursuant to delegated authority.[12]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–29403 Filed 11–26–01; 8:45 am]

BILLING CODE 8010–01–M

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6).

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–45080; File No. SR–PCX–2001–24]

Self-Regulatory Organizations; Pacific Exchange, Inc.; Order Granting Approval to Proposed Rule Change Relating to Synchronization of Member Organization Business Clocks

November 19, 2001.

On June 18, 2001, the Pacific Exchange, Inc. (''PCX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change requiring all PCX member organization business clocks, used for purposes of recording order or trade data to the Exchange, to be synchronized to a single time designated by the PCX, and that member organizations adopt those procedures as may be necessary to maintain such synchronization during each trading day.

The proposed rule change was published for comment in the **Federal**

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Register on October 18, 2001.[3] The Commission received no comments on the proposal.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange[4] and, in particular, the requirements of Section 6 of the Act[5] and the rules and regulations thereunder. The Commission finds specifically that the proposed rule change is consistent with Section 6(b)(5)[6] because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, and in general, to protect investors and the public interest.

The Commission notes that it has previously supported a move toward industry-wide synchronization of clocks.[7] The Commission further notes that the PCX has the regulatory responsibility to design and implement an audit trail sufficient to enable the Exchange to reconstruct markets promptly, conduct efficient surveillance, and enforce its rules.[8] The Commission believes that the reliability and usefulness of the Exchange's audit trail information should be enhanced by the synchronization of its member organizations' business clocks. In addition, synchronization will be important in evaluating members' compliance with the rules of the Exchange and the Act, including best execution obligations, firm quote rules, and prohibitions on frontrunning customer orders.

It Is Therefore Ordered, pursuant to Section 19(b)(2) of the Act,[9] that the proposed rule change (File No. SR–PCX–2001–24) be, and it hereby is, approved.

[3] *See* Securities Exchange Act Release No. 44922 (October 11, 2001), 66 FR 52954.

[4] In approving this proposed rule change, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[5] 15 U.S.C. 78f.

[6] 15 U.S.C. 78f(b)(5).

[7] *See* Securities Exchange Act Release No. 39279 (March 6, 1998), 63 FR 12559 (March 13, 1998) (File No. SR–NASD–97–56) (Order approving the National Association of Securities Dealers' proposed audit trail system).

[8] *See* In the Matter of Certain Activities of Options Exchanges, Securities Exchange Act Release No. 37538 (September 11, 2000), Administrative Proceeding File No. 3–10282.

[9] 15 U.S.C. 78s(b)(2).

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[10]

Margaret H. McFarland,

Deputy Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–45082; File No. SR–Phlx–2001–92]

Self-Regulatory Organizations; Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change and Amendments Nos. 1 and 2 by the Philadelphia Stock Exchange, Inc. Relating to the Listing and Trading of Index-Linked Exchangeable Notes

November 19, 2001.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'' or ''Exchange Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 4, 2001, the Philadelphia Stock Exchange, Inc. (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. Amendment No. 1 was filed on November 2, 2001.[3] Amendment No. 2 was filed on November 19, 2001.[4] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons and to grant accelerated approval to the proposed rule change.

[10] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* letter from John Dayton, Assistant Secretary and Counsel, Phlx, to Nancy Sanow, Assistant Director, Division of Market Regulation (''Division''), Commission, dated November 1, 2001 (''Amendment No. 1''). In Amendment No. 1, the Phlx stated that it would highlight in its circular to members concerning the proposed new product, index-linked exchangeable notes, the various call and redemption features that makes this product different from other products listed on the Exchange. The Phlx also stated that rules applying to members trading for their own account, specialists, odd-lot brokers, and the handling of orders and reports would also apply to the trading of these products.

[4] *See* letter from John Dayton, Assistant Secretary and Counsel, Phlx, to Nancy Sanow, Assistant Director, Division of Market Regulation (''Division''), Commission, dated November 16, 2001 (''Amendment No. 2''). In Amendment No. 2, the Phlx amended subsection (ii) in proposed rule 803(m)(4)(ii) to add the requirement that in addition to the standards stated there, such index qualifying under that subsection will also meet the requirements of Phlx Rule 1009A(b)(12). In addition, the Exchange represents that with respect to any future rules adopted by the Exchange pursuant to Rule 19b–4(e), the Exchange commits, in its Section 19(b)(2) filings to adopt such new rules, to state and discuss whether or not it proposes to apply the new rule standards to index-linked exchangeable notes.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to adopt listing standards for a new product to be known as index-linked exchangeable notes. The text of the proposed rule change, as amended, follows. Additions are in *italics*.

* * * * *

Rule 803(a)–(1) No Change.

(m) Index-Linked Exchangeable Notes

Index-linked exchangeable notes which are exchangeable debt securities that are exchangeable at the option of the holder (subject to the requirement that the holder in most circumstances exchange a specified minimum amount of notes), on call by the issuer or at maturity for a cash amount (the ''Cash Value Amount'') based on the reported market prices of the Underlying Stocks of an Underlying Index will be considered for listing and trading on the Exchange pursuant to Rule 19b–4(e) under the Securities Exchange Act of 1934, provided:

(1) Both the issue and the issuer of such security meet the criteria set forth in Rule 803(f)1–4, except that the minimum public distribution shall be 150,000 notes with a minimum of 400 public note-holders, except, if traded in thousand dollar denominations, then no minimum number of holders.

(2) The issue has a minimum term of one year.

(3) The issuer will be expected to have a minimum tangible net worth in excess of $250,000,000, and to otherwise substantially exceed the earnings requirements set forth in Rule 803(f). In the alternative, the issuer will be expected:

(i) to have a minimum tangible net worth of $150,000,000 and to otherwise substantially exceed the earnings requirements set forth in Rule 803(f); and

(ii) not to have issued index-linked exchangeable notes where the original issue price of all the issuer's other index-linked exchangeable note offerings (combined with other index-linked exchangeable note offerings of the issuer's affiliates) listed on a national securities exchange or traded through the facilities of Nasdaq exceeds 25% of the issuer's net worth.

(4) The Index to which an exchangeable-note is linked shall either be (i) indices that have been created by a third party and been reviewed and

have been approved for the trading of options or other derivative securities (each, a ''Third-Party Index'' either by the Commission under Section 19(b)(2) of the Securities Exchange Act of 1934, as amended (the ''Exchange Act'') and rules thereunder or by the Exchange under rules adopted pursuant to Rule 19b–4(e); in addition, the Third-Party Index's underlying securities shall meet Rule 803(h)(3)(B) and the Third-Party Index shall comply with Rule 1009A(b)(12); or (ii) indices which the issuer has created and for which an exchange will have obtained approval from either the Commission pursuant to Section 19(b)(2) and rules thereunder or from the Exchange under rules adopted pursuant to Rule 19b–4(e) (each, an ''Issuer Index''). The Issuer Indices and their underlying securities must meet one of the following:

(i) the procedures and criteria set forth in Rule 1009A(b)–(c); or

(ii) the criteria set forth in Rule 803(h)(3)(A)(i)–(iii), (h)(3)(B)–(D), (h)(4) and Rule 1009A(b)(12) and the index concentration limits set forth in Rule 1009A(b)(6) and in Rule 1009A(c)(1) insofar as it relates to Rule 1009A(b)(6).

(5) Index-linked Exchangeable Notes will be treated as equity instruments.

(6) Beginning twelve months after the initial issuance of a series of index-linked exchangeable notes, the Exchange will consider the suspension of trading in or removal from listing of that series of index-linked exchangeable notes under any of the following circumstances:

(i) If the series has fewer than 50,000 notes issued and outstanding;

(ii) if the market value of all index-linked exchangeable notes of that series issued and outstanding is less than $1,000,000; or

(iii) if such other event shall occur or such other condition exists which in the opinion of the Exchange makes further dealings on the Exchange inadvisable.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposal Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item III below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this proposed rule change is to enact listing standards for index-linked exchangeable notes. Under Exchange Rule 803(f), the Exchange may approve for listing and trading securities which cannot be readily categorized under the listing criteria for common and preferred stocks, bonds, debentures, or warrants. The Exchange now proposes to list for trading, under new Exchange Rule 803(m), index-linked exchangeable notes that are intended to allow investors to hold a single, exchange-listed note exchangeable for the cash value of the underlying stocks index (''Underlying Stocks'') of an index (''Underlying Index,'' ''Index,'' ''Underlying Indices,'' and ''Indices''), and thereby to acquire—in a single security and a single trade—exposure to a specific index of equity securities.

Each Underlying Index must be:

- an index that has been created by a third party and approved for the trading of options or other derivative securities (each, a ''Third-Party Index'') by the Commission under Section 19(b)(2) of the Act,[5] and the rules thereunder, or by the Exchange under rules adopted pursuant to Rule 19b–4(e)[6]; or
- an index which the issuer has created and for which an Exchange will have obtained approval from the Commission pursuant to Section 19(b)(2)[7] and the rules thereunder, or from the Exchange under rules adopted pursuant to Rule 19b–4(e)[8] (each, and ''Issuer Index'').

In addition, each Underlying Stock will meet the following criteria:

- each issuer of an Underlying Stock shall be an Exchange Act reporting company which is listed on a national securities exchange or is traded through the facilities of a national securities association and is subject to last sale reporting;
- each Underlying Stock of a Third-Party Index will meet the standards set forth in the Commission's Section 19(b)(2) order approving the index, or the Exchange rules under which it was approved, as the case may be; and
- each Underlying Stock of an Issuer Index will meet (with minor modifications set forth below) the criteria in Phlx Rules 1009A(b)–(c), or (with minor modifications set forth below) the criteria for underlying securities in Phlx Rule 803(h)(3)(A)(i)–(iii), (h)(3)(B)–(D), and (h)(4) and Phlx Rule 1009A(b)(12) and the index concentration limits in Phlx Rule 1009A(b)(6) and in Rule 1009A(c)(1) insofar as it relates to Rule 1009A(b)(6).

Description of Index-Linked Exchangeable Notes

Index-linked exchangeable notes are exchangeable debt securities that are exchangeable at the option of the holder (subject to the requirement that the holder in most circumstances exchange a specified minimum amount of notes), on call by the issuer or at maturity for a cash amount (the ''Cash Value Amount'') based on the reported market prices of the Underlying Stocks of an Underlying Index. Each index-linked exchangeable note is intended to provide investors with an instrument that closely tracks the Underlying Index. Notwithstanding that the notes are linked to an index, they will trade as a single security. The linkage is on a 1-to-1 basis so that a holder of notes is fully exposed to depreciation and appreciation of the Underlying Stocks. The Exchange will disseminate, on a real time basis for each series of index-linked exchangeable notes, an estimate, updated every 15 seconds, of the value of a note of that series.[9] This will be based, for example, upon current information regarding the value of the Underlying Index. The value for any newly created index shall be disseminated by the Exchange on a real time basis and updated every 15 seconds.

Index-linked exchangeable notes are expected to trade at a lower cost than the cost of trading each of the Underlying Stocks separately (because of reduced commission and custody costs), and also to give investors the ability to maintain index exposure without any management or administrative fees and ongoing expenses. The initial offering price for an index-linked exchangeable note will be established on the date the note is priced for sale to the public. In addition, unlike many hybrid products, index-linked exchangeable notes will not include embedded options or leverage. Because index-linked exchangeable notes are debt securities, holders will

[5] 15 U.S.C. 78s(b)(2).

[6] 17 CFR 240.19b–4(e).

[7] 15 U.S.C. 78s(b)(2).

[8] 17 CFR 240.19b–4(e).

[9] In cases where the Issuer of the index-linked exchangeable note disseminates the estimate of the value of the note through another exchange, the Phlx will ensure that such value is being disseminated by such other exchange on a real-time basis and updated every 15 seconds. Telephone conversation between John Dayton, Assistant Secretary and Counsel, Phlx, and Christopher Solgan, Law Clerk, Division, Commission, on November 19, 2001.

not be recognized by issuers of the Underlying Stocks as the owner of those stocks and will have no rights as a stockholder with respect to those stocks.

Additional issuances of a series of index-linked exchangeable notes may be made subsequent to the initial issuance of that series (and prior to the maturity of that series) for purposes of providing market liquidity. Each series of index-linked exchangeable notes may or may not provide for quarterly interest coupons based on dividends or other cash distributions paid on the Underlying Stocks during a prescribed period and an annual supplemental coupon based on the value of the Underlying Index during a prescribed period. Index-linked exchangeable notes will generally be acquired, held, or transferred only in round-lot amounts (or round-lot multiples) of 100 notes, although odd-lot orders are permissible.

Beginning on a specified date and up to a specified date prior to the maturity date or any call date, the holder of an index-linked exchangeable note may exchange some or all of its index-linked exchangeable notes for their Cash Value Amount, plus any accrued but unpaid quarterly interest coupons. Holders will generally be required to exchange a certain specified minimum amount of index-linked exchangeable notes, although this minimum requirement may be waived following a downgrade in the issuer's credit rating below specified thresholds or the occurrence of other specified events.

Index-linked exchangeable notes may be subject to call by the issuer on specified dates or during specified periods, upon at least 30, but not more than 60, days notice to holders. The call price would be equal to the Cash Value Amount, plus any accrued but unpaid quarterly interest coupons.

At maturity, the holder of an index-linked exchangeable note will receive a cash amount equal to the Cash Value Amount, plus any accumulated but unpaid quarterly and annual supplemental interest coupons. Although a specific maturity date will not be established until the time of the initial offering of a series of index-linked exchangeable notes, the index-linked exchangeable notes will provide for maturity within a period of not less than one nor more than thirty years from the date of issue.

In connection with the initial listing of each series of index-linked exchangeable notes, the Exchange has established that a minimum of 150,000 notes held by at least 400 holders be required to be outstanding when trading begins. Beginning twelve months after the initial issuance of a series of index-linked exchangeable notes, the Exchange will consider the suspension of trading in or removal from listing of that series of index-linked exchangeable notes under any of the following circumstances: (i) If the series has fewer than 50,000 notes issues and outstanding; (ii) if the market value of all index-linked exchangeable notes of that series issued and outstanding is less than $1 million; or (iii) if such other event shall occur or such other condition exists which in the opinion of the Exchange makes further dealings on the Exchange inadvisable.

Eligibility Standards for Issuers

The following standards shall apply to each issuer of index-linked exchangeable notes:

(A) Assets/Equity—The issuer shall have assets in excess of $100 million and stockholders' equity of at least $10 million. In the case of an issuer that is unable to satisfy the earnings criteria set forth in the first sentence of Phlx Rule 803(f)2, the Exchange generally will require the issuer to have the following: (i) Assets in excess of $200 million and stockholders' equity of at least $10 million; or (ii) assets in excess of $100 million and stockholders' equity of at least $20 million.

(B) Distribution—Minimum public distribution of 150,000 notes with a minimum of 400 public noteholders, except, if traded in thousand dollar denominations, then no minimum number of holders.

(C) Principal Amount/Aggregate Market Value—Not less than $4 million.

(D) Tangible Net Worth—The issuer will be expected to have a minimum tangible net worth in excess of $250 million, and to otherwise substantially exceed the earnings requirements set forth in the first sentence of Phlx Rule 803(f)2. In the alternative, the issuer will be expected: (i) To have a minimum tangible net worth of $150 million, and to otherwise substantially exceed the earnings requirements set forth in the first sentence Phlx Rule 803(f)2; and (ii) not to have issued index-linked exchangeable notes where the original issue price of all the issuer's other index-linked exchangeable note offerings (combined with other index-linked exchangeable note offerings of the issuer's affiliates) listed on a national securities exchange or traded through the facilities of Nasdaq exceeds 25% of the issuer's net worth.

Description of the Underlying Indices

Underlying Indices will either be: (i) Indices that have been created by a third party and have been reviewed and approved for the trading of options or other derivative securities (each, a ''Third-Party Index'') either by the Commission under Section 19(b)(2) of the Act,[10] and the rules thereunder, or by the Exchange under rules adopted pursuant to Rule 19b–4(e),[11] or (ii) indices which the issuer has created and for which an Exchange will have obtained approval either from the Commission pursuant to Section 19(b)(2) of the Act [12] and rules thereunder or from the Exchange under rules adopted pursuant to Rule 19b–4(e) [13] (each, an ''Issuer Index'').

All changes to an Underlying Index, including the deletion and addition of Underlying Stocks, index rebalancing, and changes to the calculation of the index, will be made in accordance with the Commission's Section 19(b)(2) order or the Exchange rules under which that index was approved, as the case may be.

The Underlying Index will be calculated based on either the market capitalization, modified market capitalization, price, equal-dollar, or modified equal-dollar weighting methodology. If the issuer or a broker-dealer is responsible for maintaining (or has a role in maintaining) the Underlying Index, it would be required to erect and maintain a ''Fire Wall,'' in a form satisfactory to the Exchange, to prevent the flow of information regarding the Underlying Index from the index production personnel to the sales and trading personnel, and the index must be calculated by a third party who is not a broker-dealer.

Eligibility Standards for Underlying Stocks

The following standards shall apply to each Underlying Stock:

(A) General Criteria—Each issuer of an Underlying Stock shall be an Exchange Act reporting company that is listed on a national securities exchange or is traded through the facilities of a national securities association and is subject to last sale reporting.

(B) Criteria Applicable to Underlying Stocks of Third-Party Indices—In addition to meeting the ''General Criteria'' set forth under clause (A) above, each Underlying Stock of a Third-Party Index shall also meet the criteria specified for Underlying Stocks of that index in the Commission's Section 19(b)(2) order approving that index or the Exchange rules under which it was approved.

(C) Criteria Applicable to Underlying Stocks of Issuer Indices—In addition to

[10] 15 U.S.C. 78s(b).

[11] 17 U.S.C. 240.19b–4(e).

[12] 15 U.S.C. 78s(b).

[13] 17 CFR 240.19b–4(e).

meeting the ''General Criteria'' set forth under clause (A) above, each Underlying Stock of an Issuer Index shall also meet the criteria specified in (1) or (2) below:

(1) Each Underlying Stock of an Issuer Index shall meet each of the following criteria:

(a) A minimum market value of at least $75 million, except that for each of the lowest weighted Underlying Stocks in the index that in the aggregate account for no more than 10% of the weight of the index, the market value can be at least $50 million;

(b) trading volume in each of the last six months of not less than 1 million shares, except that for each of the lowest weighted Underlying Stocks in the index that in the aggregate account for no more than 10% of the weight of the index, the trading volume shall be at least 500,000 shares in each of the last six months;

(c) in a capitalization-weighted index, the lesser of the five highest weighted Underlying Stocks in the index or the highest weighted Underlying Stocks in the index that in the aggregate represent at least 30% of the total number of Underlying Stocks in the index, each have an average monthly trading volume of at least 2 million shares over the previous six months;

(d) 90% of the index's numerical index value and at least 80% of the total number of Underlying Stocks will meet the then current criteria for standardized option trading set forth in Exchange Rule 1009;

(e) American Depositary Receipts (''ADRs'') that are not subject to comprehensive surveillance agreements do not in the aggregate represent more than 20% of the weight of the index;

(f) all component stocks or ADRs will either be listed on the American Stock Exchange or the New York Stock Exchange or traded through the facilities of the National Association of Securities Dealers Automated Quotation System and reported National Market System securities; and

(g) no Underlying Stock will represent more than 25% of the weight of the index, and the five highest weighted Underlying Stocks in the index will not in the aggregate account for more than 50% of the weight of the index (60% for an index consisting of fewer than 25 Underlying Stocks).

The standards set forth in clauses (a) to (g) above must be continuously maintained, except that:

(a) The criteria that no single Underlying Stock represent more than 25% of the weight of the index and the five highest weighted Underlying Stocks in the index cannot represent more than 50% (or 60% of indices with less than 25 Underlying Stocks) of the weight of the index, need only be satisfied for capitalization-weighted and price-weighted indices as of the first day of January and July in each year;

(b) the total number of Underlying Stocks in the index may not increase or decrease by more than 33⅓% from the number of Underlying Stocks in the index at the time of its initial listing, and in no event may be fewer than nine Underlying Stocks;

(c) the trading volume of each Underlying Stock in the index must be at least 500,000 shares for each of the last six months, except that for each of the lowest weighted Underlying Stocks in the index that in the aggregate account for no more than 10% of the weight of the index trading volume must be at least 400,000 shares for each of the last six months; and

(d) in a capitalization-weighted index, the lesser of the five highest weighted Underlying Stocks in the index or the highest weighted Underlying Stocks in the index that in the aggregate represent at least 30% of the total number of stocks in the index have had an average monthly trading volume of at least 1 million shares over the previous six months.

(2) In the alternative, each Underlying Stock of an Issuer Index shall meet each of the following criteria:

(a)(i) a minimum market capitalization of $3 billion and during the 12 months preceding listing is shown to have traded at least 2.5 million shares; (ii) a minimum market capitalization of $1.5 billion and during the 12 months preceding listing is shown to have traded at least 10 million shares; or (iii) a minimum market capitalization of $500 million and during the 12 months preceding listing is shown to have traded at least 15 million shares;

(b) no Underlying Stock will represent more than 25% of the weight of the index, and the five highest weighted component securities in the index do not in the aggregate account for more than 50% of the weight of the index (60% for an index consisting of fewer than 25 component securities), except that for capitalization-weighted and price-weighted indices these standards need be satisfied only as of the first day of January and July in each year;

(c) if any Underlying Stock is the stock of a non-U.S. company that is traded in the U.S. market as sponsored American Depositary Shares (''ADS'') or ADRs then for each such security the Exchange shall either;

(i) have in place a comprehensive surveillance sharing agreement with the primary exchange on which each security underlying the ADS or ADR is traded;

(ii) the combined trading volume of each non-U.S. security and other related non-U.S. securities occurring in the U.S. market or in markets with which the Exchange has in place a comprehensive surveillance sharing agreement represents (on a share equivalent basis for any ADSs) at least 50% of the combined worldwide trading volume in each non-U.S. security, other related non-U.S. securities, and other classes of common stock related to each non-U.S. security over the six-month period preceding the date of listing of the related index-linked exchangeable note; or

(iii)(A) the combined trading volume of each non-U.S. security and other related non-U.S. securities occurring in the U.S. market represents (on a share equivalent basis) at least 20% of the combined world-wide trading volume in each non-U.S. security and in other related non-U.S. securities over the six-month period preceding the date of listing of the related index-linked exchangeable note; (B) the average daily trading volume for each non-U.S. security in the U.S. markets over the six months preceding the date of listing of the related index-linked exchangeable note is 100,000 or more shares; and (C) the trading volume is at least 60,000 shares per day in the U.S. markets on a majority of the trading days for the six months preceding the date of listing of the related index-linked exchangeable note.

(d) An Underlying Stock may not exceed 5% of the total outstanding common shares of the issuer of that Underlying Stock, however, if any Underlying Stock is a non-U.S. security represented by ADSs, common shares, or otherwise, then for each such index-linked exchangeable note the instrument may not exceed:

(i) 2% of the total shares outstanding worldwide provided at least 20% of the worldwide trading volume in each non-U.S. security and related non-U.S. security during the six-month period preceding the date of listing occurs in the U.S. market;

(ii) 3% of the total worldwide shares outstanding provided at least 50% of the worldwide trading volume in each non-U.S. security and related non-U.S. security during the six-month period preceding the date of listing occurs in the U.S. market; and

(iii) 5% of the total shares outstanding worldwide provided at least 70% of the worldwide trading volume in each non-U.S. security and related non-U.S. security during the six-month period

preceding the date of listing occurs in the U.S. market.

(e) if any non-U.S. security and related securities has less than 30% of the worldwide trading volume occurring in the U.S. market during the six-month period preceding the date of listing, then the instrument may not be linked to that non-U.S. security.

If an issuer proposes to list an index-linked exchangeable note that relates to more than the allowable percentages set forth above, the Exchange, with the concurrence of the staff of the Division, will evaluate the maximum percentage of index-linked exchangeable note that may be issued on a case-by-case basis.

If an Underlying Stock to which an index-linked exchangeable note is to be linked is the stock of a non-U.S. company which is traded in the U.S. market as a sponsored ADS, ordinary shares or otherwise, then the minimum number of holders of such Underlying Stock shall be 2,000.

Exchange Rules Applicable to Index-Linked Exchangeable Notes

Index-linked exchangeable notes will be treated as equity instruments. Index-linked exchangeable notes will be subject to all Exchange rules governing the trading of equity securities, including, among others, rules governing priority, parity and precedence of orders, market volatility related trading halt provisions pursuant to Phlx Rule 133, and responsibilities of specialists. Exchange equity margin rules and the regular equity trading hours of 9:30 am to 4 pm will apply to transactions in index-linked exchangeable notes.

In addition, consistent with other structured products, the Exchange will distribute a circular to its membership, prior to the commencement of trading, providing guidance with respect to, among other things, the fact that the notes are subject to call by the issuer, and the member firm responsibilities under Exchange Rules 746 and 747. Lastly, as with other structured products, the Exchange will closely monitor activity in index-linked exchangeable notes to identify and deter any potential improper trading activity in the index-linked exchangeable notes.

2. Statutory Basis

The proposed rule change, as amended, is consistent with Section 6(b) of the Act [14] in general and furthers the objectives of Section 6(b)(5) [15] in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All submissions should refer to File No. SR–Phlx–2001–92 and should be submitted by December 18, 2001.

IV. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

The Commission finds that the proposed rule change and Amendment No. 1 and 2 are consistent with the requirements of Section 6(b)(5) of the Act [16] and the rules and regulations thereunder applicable to a national securities exchange. In particular, the Commission believes the Exchange's proposal to list and trade index-linked exchangeable notes will provide an instrument for investors to achieve desired investment objectives through the purchase of debt securities—index-inked exchangeable notes—exchangeable for the cash value of the Underlying Stocks of an Underlying Index.[17] Accordingly, the Commission finds that the Exchange's proposal will facilitate transactions in securities, remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.[18]

The Commission notes that the initial offering price of an index-linked exchangeable note will be determined on the date that the note is priced for sale to the public. The Commission believes that index-linked exchangeable notes will be attractive to investors because they are expected to trade at lower cost than the cost of trading each of the Underlying Stocks separately. The Commission also notes that the Exchange will disseminate an estimate of the value of a note for each series of index-linked exchangeable notes, on a real time basis, every 15 seconds. The value of any Underlying Index will also be publicly available to investors on a real time basis. The Phlx, for example, has stated that to the extent there is an existing Index, it will ensure its value is publicly available, and if it is a new Index, that the Phlx would publish the value itself on a real time basis. This will ensure investors receive up-to-date information on the value of the note and the Underlying Index. Accordingly,

[14] 15 U.S.C. 78f(b).

[15] 15 U.S.C. 78f(b)(5).

[16] 15 U.S.C. 78f(b)(5). In approving this rule, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[17] Index-linked exchangeable notes will generally be acquired, held or transferred only in round-lot amounts (or round-lot multiples) of 100 notes although odd-lot orders are permissible. Although these notes will have features similar to other index related products, they differ from other products with respect to their exchangeability feature. The Commission notes that the holder of the note may exchange the notes at his or her option, on call by the issuer, or at maturity for the cash value based upon the reported market prices of the Underlying Stocks of an Underlying Index. Holders, however, will generally be required to exchange a certain specified minimum amount of index-linked exchangeable notes, although this minimum requirement may be waived following a downgrade in the issuer's credit rating below specified thresholds or the occurrence of other specified events.

[18] Pursuant to Section 6(b)(5) of the Act, the Commission must predicate approval of exchange trading for new products upon a finding that the introduction of the product is in the public interest. Such a finding would be difficult with respect to a product that served no investment, hedging or other economic functions, because any benefits that might be derived by market participants would likely be outweighed by the potential for manipulation, diminished public confidence in the integrity of the markets, and other valid regulatory concerns.

index-linked exchangeable notes should allow investors to: (i) Respond quickly to market changes through intra-day trading opportunities; (ii) engage in hedging strategies not currently available to retail investors; and (iii) reduce transaction costs for trading a group or index of securities.

Although the value of index-linked exchangeable notes will be based on the value of the Underlying Stocks in an Underlying Index, index-linked exchangeable notes are not leveraged instruments.[19] In essence, index-linked exchangeable notes are debt securities based on the Underlying Stocks of an Underlying Index; the holders of such notes will not be considered owners of the Underlying Stocks and will not have the rights of a stockholder in those stocks. However, index-linked exchangeable notes will be regulated as equity instruments and will be subject to all of the Exchange's rules governing the trading of equity securities. Nevertheless, the Commission believes that the unique nature of index-linked exchangeable notes, related to, among other things, the exchangeability feature,[20] raise certain product design, disclosure, trading, and other issues that must be addressed.

A. Index-Linked Exchangeable Notes Generally

The Commission believes that the proposed index-linked exchangeable notes are reasonably designed to provide investors with an investment vehicle that substantially reflects the value of the Underlying Stocks of an Underlying Index. Index-linked exchangeable notes will be treated as equity instruments subject to Phlx rules governing the trading of equity securities. As such, the Commission finds that adequate rules and procedures exist to govern the trading of index-linked exchangeable notes. In this regard, the Commission notes that the Exchange will impose specific criteria in the selection of issuers, the Underlying Stocks, and the Underlying Indices.

As noted above, the Phlx rules for index-linked exchangeable notes contain specific criteria for issuers. For example, the issuer must have a minimum tangible net worth in excess of $250 million and substantially exceed the earnings requirements in the first sentence of Phlx Rule 803(f)2; or a minimum tangible value of $150 million, substantially exceed the earnings requirements in the first sentence of Phlx Rule 803(f)2, and not to have issued index-linked exchangeable notes where the original issue price of all the issuer's other index-linked exchangeable note offerings (combined with other index-linked exchangeable note offerings of the issuer's affiliates) listed on a national securities exchange or traded through the facilities of Nasdaq exceeds 25% of the issuer's net worth. These criteria are in part intended to ensure that the issuer has enough assets to meet its obligations under the terms of the note and should help to reduce systematic risk.

The minimum issue requirements for the issue of index-linked exchangeable notes should also serve to establish a minimum level of liquidity for the product. These issue requirements include: (i) A minimum public distribution of 150,000 notes with a minimum of 400 public noteholders (no minimum number of holders if traded in one thousand dollar denominations), and (ii) market value of $4 million.

The Phlx rules applicable to the index-linked exchangeable notes also contain minimum requirements for the Indices the note can be linked to and the underlying components of those Indices. For example, because all components of an Underlying Index must be a U.S. reporting company, there will be information of available Index component stocks. Further, the Phlx's proposed rules for the Indices underlying index-lined exchangeable notes are linked to other approved criteria for index related products. Accordingly, any Underlying Index would have to follow the criteria adopted by the Commission for that Index, including the criteria for component stocks already in Phlx's rules. These requirements will generally contain, among other things, minimum market capitalization, trading volume, and concentration requirements that are designed to reduce manipulation concerns and ensure a minimum level of liquidity for component securities.

In summary, the rules for selecting components of Indices are intended to make the Underlying Stocks and the Underlying Indices representatives of the market they are intended to reflect as well as to reduce manipulation concerns by setting forth minimum liquidity standards for Underlying Stocks. Accordingly, the Commission believes that these criteria should serve to ensure that the Underlying Stocks of Underlying Indices are well capitalized and actively traded.

B. Disclosure

The Commission believes that the Exchange's proposal should ensure that investors have information that will allow them to be adequately apprised of the terms, characteristics, and risks of trading index-lined exchangeable notes. The Commission notes that upon the initial listing of any class of index-linked exchangeable notes, the Exchange will issue a circular to its members explaining the unique characteristics and risk of this type of security.[21] The circular will also note Exchange members' responsible under Exchange Rules 746 and 747 regarding transactions in index-linked exchangeable notes. Exchange Rule 746 generally requires that members use due diligence to learn the essential facts relative to every customer, every order or account accepted.[22] Exchange Rule 747 generally requires that members be personally informed of the essential facts of each customer prior to giving the required written approval for the opening of that customer account.[23]

C. Trading of Index-Linked Exchangeable Notes

The Commission finds that adequate rules and procedures exist to govern the trading of index-linked exchangeable notes. Index-linked exchangeable notes will be treated as equity instruments subject to all Phlx rules governing the trading of equity securities. These rules include; rules governing priority, parity and precedence of orders, market volatility related trading halt provisions pursuant to Exchange Rule 133, responsibilities of specialists, members dealing for their own accounts, odd-lot brokers, and registered traders, and handling of orders and reports.[24] In addition, the Exchange's equity margin rules and regular equity trading hours of 9:30 am to 4 pm will apply to transactions in index-linked exchangeable notes.

The Commission is satisfied with Phlx's development of specific listing and delisting criteria for index-linked exchangeable notes. For example, in connection with the initial listing of each series of index-linked exchangeable notes, the Exchange has established that a minimum of 150,000

[19] In contrast, proposals to list exchange-traded derivative products that contain a built-in leverage feature or component raise additional regulatory issues, including heightened concerns regarding manipulation, market impact, and customer suitability. *See, e.g.,* Securities Exchange Act Release No. 36165 (August 29, 1995), 60 FR 46653 (September 7, 1995) (relating to the establishment of uniform listing and trading guidelines for stock index, currency, and currency index warrants).

[20] *See supra* note 15.

[21] The Exchange represents that it will highlight the exchangeability feature of index-linked exchangeable notes in its circular to members. Amendment No. 1, *supra* note 3.

[22] Phlx Rule 746.

[23] Phlx Rule 747.

[24] Amendment No. 1, *supra* note 3.

notes held by at least 400 holders be required to be outstanding when trading begins. These criteria should help ensure that a minimum level of liquidity will exist in each series of index-linked exchangeable notes to allow for maintenance of fair and orderly markets. The delisting criteria also allows the Exchange of consider suspension of trading and the delisting of a series of index-linked exchangeable notes if an event were to occur that made further dealings in such series inadvisable. This will give the Phlx flexibility to delist index-linked exchangeable notes if circumstances warrant such action. Further, Phlx rules have specific criteria that allow them to delist if there is fewer than 50,000 notes issued and outstanding, of if the market value of the index-exchangeable notes is less than $100,000. This should ensure a minimum level of liquidity for these products. Accordingly, the Commission believes that the rules governing the trading of index-linked exchangeable notes, consistent with Section 6(b)(5) of the Act,[25] provide adequate safeguards to protect investors and the public interest. While the index-linked exchangeable notes have certain call and redemption features that make them different from other products, the Phlx has addressed any concerns by adopting the existing criteria used in other index related products. In addition, the Phlx will highlight these different features in the circular to members.

D. Dissemination of Information

The Commission believes that the value of index-linked exchangeable notes that the Exchange proposes to disseminate will provide investors with timely and useful information concerning the value of the index-linked exchangeable notes based on current information regarding the value of the Underlying Index. The value of the Underlying Index will also be publicly disseminated. This information will be disseminated and updated every 15 seconds during regular Phlx trading hours of 9:30 am to 4:00 pm, Philadelphia time.

E. Surveillance

The Commission believes that the surveillance procedures developed by the Phlx for index-linked exchangeable notes should be adequate to address concerns associated with the listing and trading of such notes. In this regard, the Phlx has developed procedures to monitor activity in index-linked exchangeable notes to identify and deter improper trading activity.

[25] 15 U.S.C. 78f(6)(5).

The Commission also notes that concerns are raised when a broker-dealer is involved in the development and maintenance of an Underlying Index upon which a product, such as index-linked exchangeable notes is based, in that case, the broker-dealer and its affiliate should have procedures designed specifically to address the improper sharing of information. The Commission notes that the Exchange requires the implementation of procedures that are satisfactory to the Exchange to prevent the misuse of material, non-public information regarding changes to Underlying Stocks of an Underlying Index in a particular series of index-linked exchangeable notes. In addition, the Commission notes that if a broker-dealer is involved in developing or maintaining an Underlying Index, the Index must be calculated by a third party who is not a broker-dealer.[26] The Commission believes that such information barrier procedures will address the unauthorized transfer and misuse of material, non-public information.

F. Scope of the Commission's Order

The Commission is approving the Exchange's proposed listing and trading standards for the index-linked exchangeable notes as discussed herein. Index-linked exchangeable notes addressed in this order can be listed pursuant to Rule 19b–4(e) [27] if they meet the standards discussed above in the Phlx rules. The Commission notes that with respect to any future rules adopted by the Exchange pursuant to Rule 19b–4(e),[28] the Exchange has indicated that in its Section 19(b)(2) filings to adopt such new rules, it will state and discuss whether or not it proposes to apply the new rule standards to index-linked exchangeable notes.[29]

G. Accelerated Approval

The Commission finds good cause for approving the proposal prior to the thirtieth day after the date of the publication of notice of filing thereof in the **Federal Register**. The proposal establishes listing and trading standards for a new product, index-linked exchangeable notes. Granting accelerated approval will allow the Exchange to immediately begin listing and trading series of index-linked exchangeable notes under these new standards. While the structure of the product is different from those previously reviewed by the Commission, the Phlx proposes to apply existing criteria used for other index related products. Accordingly, the Commission believes that there is good cause, consistent with Sections 6(b)(5) and 19(b) of the Act,[30] to approve the proposal on an accelerated basis.

[26] *See* Phlx Rule 1009A(b)(12).

[27] 17 CFR 240.19b–4(e).

[28] *Id.*

[29] *See* Amendment No. 2, *supra* note 4.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[31] that the proposed rule change and Amendments No. 1 and 2 (SR–Phlx–2001–92) is hereby approved on an accelerated basis.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[32]

Margaret H. McFarland,

Deputy Secretary.

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[30] 15 U.S.C. 78f(b)(5) and 78s(b).

[31] 15 U.S.C. 78s(b)(2).

[32] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–45083; File No. SR–Phlx–2001–93]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change and Amendment No. 1 by the Philadelphia Stock Exchange, Inc. Relating to the Listing Agreement for Index-Linked Exchangeable Notes

November 19, 2001.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 [2] thereunder, notice is hereby given that an October 22, 2001, the Philadelphia Stock Exchange, Inc. (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change is described in Items I, II, and III below, which Items have been prepared by the Exchange. Amendment No. 1 was filed on November 2, 2001.[3] The Commission is publishing this notice to solicit comments on he proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* letter from John Dayton, Assistant Secretary and Counsel, Phlx, to Nancy Sanow, Assistant Director, Division of Market Regulation (''Division''), Commission, dated November 1, 2001 (''Amendment No. 1''). In Amendment No. 1, the Phlx requested that the Commission waive the 30-day period under which the proposal would become operative under Rule 19b–4(f)(6)(iii). 17 CFR 240.19b–4(f)(6)(iii).

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Pursuant to Rule 19b–4 under the Act, the Phlx proposes to adopt a modified listing agreement for a new product to be known as index-linked exchangeable notes.[4]

The text of the proposed rule change appears below. New text is in italics.

Listing Agreement

Nothing in the following agreement shall be so construed as to require the issuer to do any act in contravention of law or in violation of any rule or regulation of any public authority exercising jurisdiction of the Issuer.

_____; (hereinafter called the ''Corporation''), in consideration of the listing of its securities covered by this application, hereby agrees with the Philadelphia Stock Exchange (hereinafter called the ''Exchange''), as follows:

I. The Corporation Will

1. promptly notify the Exchange as soon as it becomes aware that it does not meet the maintenance listing standards.

2. promptly notify the Exchange of any change in the general character or nature of its business.

3. promptly notify the Exchange of any changes of officers or directors.

4. promptly notify the Exchange in the event that it or any company controlled by it shall dispose of any property or of any equity interest in any of its subsidiary companies.

5. promptly notify the Exchange of any change in, or removal of, collateral deposited under any mortgage or trust indenture, under which listed securities of the Corporation have been issued.

6. file two copies of all material mailed by the Corporation to its stockholders with respect to any amendment to its Certificate of Incorporation.

7. file with the Exchange two copies of any amendment to the Certificate of Incorporation (one of which will be certified) as soon as the amendment has the approval of the appropriate state agencies.

8. file with the Exchange two copies of any amendments to the By-Laws of the Corporation (one if which will be certified) as soon as the amendment has the approval of the appropriate state agencies.

9. disclose in its annual report for the Corporation's fiscal year:

a. the number of unoptioned shares available at the beginning and at the close of the year for the granting of options under an option plan;

b. any changes in the exercise price of outstanding options, through cancellation and reissuance or otherwise, except price changes resulting from the normal operation of anti-dilution provisions of the options; and

c. any changes, cancellations or exercises of any options or warrants.

10. *notify the Exchange within ten business days following the end of the month in which the change occurred if the Corporation reacquires or disposes of, directly or indirectly, any of its previously listed stock.*

11. receive the approval of the Exchange before it purchases, directly or indirectly, any of its securities listed on the Exchange at a price in excess of its market value.

12. not redeem any of its listed securities in a manner other than pro rata without prior approval of the Exchange. The Corporation will notify the Exchange at least fifteen days in advance of any such redemption and will provide any information requested in reference to such redemption to the Exchange in a prompt manner.

13. promptly notify the Exchange of any corporate action which will result in the redemption, cancellation or retirement, in whole or in part, of any security of the Corporation listed on the Exchange as soon as the Corporation's management initiates such action.

14. give the Exchange at least ten business days notice in advance of the closing of the transfer books, or of the taking of a record of its stockholders for any purpose.

15. not make any change in the form or nature of any of its securities that are listed on the Exchange or in the rights or privileges of its holders, without having given twenty business days prior notice to the Exchange of the proposed change and having applied for the listing of the changed securities if required by the Exchange.

16. furnish to the Exchange on demand any information concerning the Corporation as the Exchange may reasonably require.

17. promptly notify the Exchange of any depletion in the supply of stock available for trading caused by the deposit of stock under any voting trust, tender offer or any other deposit agreement.

18. apply to the Exchange for the listing of additional amounts of listed securities at least fifteen business days prior to their issuance in order to afford the Exchange adequate time to properly evaluate the application.

II. The Corporation Will

1. publish and mail to the holders of listed securities (and file copies with the Exchange), at least ten business days before the annual meeting and not later than four months after the close of the fiscal year, an annual report containing audited financial statements prepared in conformity with the requirements of the Securities and Exchange Commission.

2. establish and maintain an Audit Committee, which will consist of at least two independent directors. Such directors will not act as officers of the Corporation nor will they own more than ten percent of common shares outstanding.

3. promptly notify the Exchange of any change of their designated independent auditors which regulatory audit the books and accounts of the Corporation.

4. publish quarterly statements of earnings on the basis of the same degree of consolidation as in the Annual Report. Such statements will show net profits before and after Federal taxes and disclose any substantial items of unusual or nonrecurrent nature.

III. The Corporation Will

1. maintain in accordance with the requirements of the Exchange:

a. an office or agency where the principal of and interest on all bonds of the Corporation listed on the Exchange shall be payable and where any such bonds which are registerable as to principal of interest may be registered;

b. an office or agency where:

1. all stock of the Corporation listed on the Exchange shall be transferable;

2. checks for dividends and other payments with respect to stock listed on the Exchange may be presented for immediate payment;

3. scrip issued to holders of a security listed on the Exchange and representing a fractional interest in a security listed on the Exchange will, during the period provided for consolidation thereof, be accepted for such purpose; and

4. a security listed on the Exchange which is convertible will be accepted for conversion.

c. *a registrar where stock of the Corporation listed on the Exchange shall be registerable. Such registrar shall be a bank or trust company not acting as transfer agent for the same security.*

[4] On October 4, 2001, the Exchange filed with the Commission SR–Phlx–2001–92, a proposed rule change requesting accelerated approval of new listing standards for index-linked exchangeable notes. This filing was approved November 19, 2001. The Exchange states that the listing standards in SR–Phlx–2001–92 are substantially identical to the listing standard adopted by the American Stock Exchange LLC for index-linked exchangeable notes. *See* Securities Exchange Act Release No. 44621 (July 30, 2001), 66 FR 41064 (August 6, 2001).

If the transfer books for a security of the Corporation listed on the Exchange should be closed permanently, the Corporation will continue to split up certificates for such security into certificates of smaller denominations in the same name so long as that security continues to be dealt in on the Exchange.

2. not add to the number of its transfer agencies nor make any change of a transfer agency, trustee or fiscal agent of any of the Corporation's listed securities without prior notice to the Exchange.

3. not add to the number of registrants of its listed stock, nor change a registrar of that stock, without the prior approval of the Exchange.

4. not select an officer or director of the Corporation as a trustee of a mortgage or other listed security.

5. have on hand at all times a sufficient supply of certificates to meet the demands for transfer.

6. promptly notify its security holders of any corporate action taken in connection to dividends or purchase rights listed on the Exchange. The Corporation will also contact the Exchange as to such developments.

7. solicit proxies for all meetings of stockholders.

8. pay when due any applicable Listing Fees established from time to time by the Exchange.

9. promptly notify the Exchange whenever any other exchange or market place takes steps to remove their issues from trading.

10. comply with Exchange rules, policies and procedures as in effect and as they may be amended from time to time.

The above agreement has been signed by me as _____ of _____ (Title) (Name of Company) pursuant to authority granted me by resolution of the Board of Directors of _____ (Corporate Seal) said corporation adopted on _____ Dated: By:

(2) Listing agreement for issuers of index-listed exchangeable notes

Listing Agreement

Nothing in the following agreement shall be so construed as to require (hereinafter called the ''Corporation) to do any act in contravention of law or in violation of any rule or regulation of any public authority exercising jurisdiction over the Corporation.

The Corporation, in consideration of the listing of its (its ''Issue;), hereby agrees with the Philadelphia Stock Exchange (hereinafter called the ''Exchange), as follows:

I. The Corporation Will

1. promptly notify the Exchange as soon as it becomes aware that it does not meet the maintenance listing standards;

2. promptly notify the Exchange of any material change in the general character or nature of its business;

3. promptly notify the Exchange of any changes of executive officers of the Corporation (as defined by Rule 3b–7 under the Securities Exchange Act of 1934) or directors;

4. promptly notify the Exchange in the event that it or any company controlled by it makes a material disposition of any property or of any equity interest in any of its subsidiary companies;

5. promptly notify the Exchange of any change in, or removal of, collateral deposited under any mortgage or trust indenture, under which the Issue of the Corporation have been issued;

6. file two copies of all proxy statements mailed by the Corporation to its stockholders with respect to any amendment to its Certificate of Incorporation;

7. file with the Exchange two copies of any amendment to the Certificate of Incorporation (one of which will be certified) as soon as the amendment has the approval of the appropriate state agencies;

8. file with the Exchange two copies of any amendments to the By-Laws of the Corporation (one of which will be certified) as soon as the amendment has the approval of the appropriate state agencies;

9. disclose in its annual report for the Corporation's fiscal year:

a. the number of unoptioned shares available at the beginning and at the close of the year for the granting of employee stock options under an employee stock option plan and

b. changes, cancellations or exercises of any employee stock options;

10. inform the Exchange within ten business days following the end of each month of the total amount of the Issue outstanding at the end of such month;

11. receive the approval of the Exchange before it purchases, directly or indirectly, any of the Issue listed on the Exchange at a price in excess of its market value;

12. not redeem any of the Issue in a manner other than pro rata without prior approval of the Exchange (the Corporation will notify the Exchange at least fifteen days in advance of any such redemption and will provide any information requested in reference to such redemption to the Exchange in a prompt manner);

13. promptly notify the Exchange of any corporate action which will result in the redemption, cancellation or retirement, in whole or in part, of the Issue as soon as the Corporation's management initiates such action;

14. not make any change in the form or nature of any of the Issue listed on the Exchange or in the rights or privileges of holders of the Issue, without having given twenty business days prior notice to the Exchange of the proposed changed and having applied for the listing of such changed securities if required by the Exchange;

15. promptly furnish to the Exchange any other publicly available information concerning the Corporation as the Exchange may reasonably require;

16. promptly notify the Exchange of any depletion in the supply of the listed Issued available for trading caused by the deposit of the listed Issue under any voting trust, tender offer or any other deposit agreement; and

17. apply to the Exchange for the listing of additional amounts of the Issue as soon as reasonably practicable and at latest on the business day prior to listing.

II. The Corporation Will

1. publish and file with [the entity or entities required to receive an annual report containing audited financial statements under the law or rules of the Commission], (and file copies with the Exchange) an annual report containing audited financial statements prepared in conformity with the requirements of the Securities and Exchange Commission (the ''Commission'') within fifteen days after the Corporation is required to file such annual report with the Commission;

2. establish and maintain an Audit Committee which will consist of at least two independent directors (such directors will not act as officers of the Corporation nor will they own more than ten percent of common shares outstanding);

3. promptly notify the Exchange of any change of their designated independent auditors which regularly audit the books and accounts of the Corporation and

4. publish quarterly statements of earnings on the basis of the same degree of consolidation as in the Annual Report (such statements will show net profits before and after Federal taxes and disclose any substantial items of unusual or nonrecurrent nature).

III. The Corporation Will

1. maintain in accordance with the requirements of the Exchange:

a. an office or agency where the principal of, and interest on, all bonds of the Corporation listed on the

Exchange shall be payable and where any such bonds which are registerable as to principal of interest may be registered;

b. an office or agency where a security listed on the Exchange which is convertible will be accepted for conversion;

2. not add to the number of its transfer agencies nor make any change of a transfer agency, trustee or fiscal agent of the Issue without prior notice to the Exchange;

3. not select an officer or director of the Corporation as a trustee of a mortgage or in connection with the issuance of the Issue listed with the Exchange;

4. have on hand at all times a sufficient supply of certificates to meet the demands for transfer;

5. pay when due any applicable Listing Fees established from time to time by the Exchange;

6. promptly inform the Exchange if the Corporation's common stock or Issue is delisted by the New York Stock Exchange, American Stock Exchange or Pacific Exchange and

7. comply with Exchange rules, policies and procedures as in effect and as they may be amended from time to time.

The above agreement has been signed by me as pursuant to authority granted me by resolution of the Board of Directors of said corporation adopted on [DATE].

(Corporate Seal)

Dated: ; By:

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(1) Purpose

The purpose of this proposed rule change is to modify its present listing agreement to accommodate issuers of a new product to be known as index-linked exchangeable notes. Under Phlx Rule 803(f), the Exchange may approve for listing and trading securities which cannot be readily categorized under the listing criteria for common and preferred stocks, bonds, debentures, or warrants. The Phlx, in proposed rule change SR–Phlx–2001–92,[5] proposed new Phlx Rule 803(m), creating listing standards for index-linked exchangeable notes that are intended to allow investors to hold a single, exchange-listed note exchangeable for the cash value of the underlying stocks of an index, and thereby to acquire—in a single security and a single trade—exposure to a specific index of equity securities.

The Exchange intends to list at least one index-linked exchangeable note under these new proposed standards. In reviewing its listing materials, the Exchange decided to propose a modified listing agreement for issuers of index-linked exchangeable notes. The Exchange requires listing agreements with issuers to better ensure receipt of information from the issuer about the issue and the issuer itself.

The proposed listing agreement is substantially similar to the current listing agreement with the following modifications. In Section I, the proposed agreement does not contain a reference to the closing of transfer books or the taking of a record of stockholders because index-linked exchangeable notes are debt instruments and consequently holders of the notes do not participate in issuer corporate governance.

In Section II, the proposed agreement contains a provision that an annual report containing audited financial statements to be sent to those required to receive them under the law or rules of the Commission. Finally, in Section III, the proposed agreement does not include references to dividends and proxies for stockholder meetings, since these items are not applicable to these debt instruments.

The Exchange notes that its proposed listing agreement retains the provision against construing the agreement in such a way as requiring the issuer to act in violation of law or regulation. Also, the proposed listing agreement retains the provision, in Section III, item 7, requiring the issuer to comply with Exchange rules, policies and procedures as in effect and as they may be amended from time to time.

The Exchange believes that these modifications to its current listing agreement reflect the nature of the index-linked exchangeable note and issuer of such notes and do not require such issuers to provide or Exchange staff to receive non-applicable information. Nevertheless, the Exchange believes that the modifications retain the elements of the current agreement that apply universally to any Exchange issuer.

(2) Statutory Basis

The exchange believes that the proposed rule change is consistent with section 6(b) of the Act,[6] in general, and furthers the objectives of section 6(b)(5),[7] in particular, in that that an exchange have rules that are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any inappropriate burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to section 19(b)(3)(A) of the Act[8] and subparagraph (f)(6) of Rule 19b–4[9] thereunder because it does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate; and the Exchange has given the Commission written notice of its intention to file the proposed rule change at least five business days prior to filing. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise

[5] *See supra* footnote number 4.

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(4).

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f)(6).

in furtherance of the purposes of the Act.[10]

The Commission notes that under Rule 19b–4(f)(6)(iii), the proposal does not become operative for 30 days after the date of its filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative date.[11] Accelerating the operative date to October 22, 2001, will enable the Exchange to modify its listing agreement in order to begin to list its new product, index-linked exchangeable notes. For this reason, the Commission finds good cause to designate that the proposal become operative on October 22, 2001.[12]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All submissions should refer to File No. SR–Phlx–2001–93 and should be submitted by December 18, 2001.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[13]

Margaret H. McFarland,

Deputy Secretary.

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[10] For purposes of calculating the 60-day abrogation date, the Commission considers the 60-day period to have commenced on November 2, 2001, the date the Phlx filed Amendment No. 1.

[11] *See supra* footnote 3.

[12] For purposes only of accelerating the operative date of this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–45079; File No. SR–Phlx–2001–102]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Philadelphia Stock Exchange, Inc. To Extend a PACE Order Execution and Price Protection Pilot Program

November 19, 2001.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 5, 2001, the Philadelphia Stock Exchange, Inc. (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange filed this proposal under Section 19(b)(3)(A) of the Act,[3] and Rule 19b–4(f)(6)[4] thereunder, which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend through January 14, 2002, its Philadelphia Stock Exchange Automated Communication and Execution System (''PACE'')[5] order execution and price protection pilot program (''pilot program''). The pilot program, which is found in Supplementary Material .05 and .07(c)(ii) to Phlx Rule 229, incorporates decimal pricing into two PACE provisions—immediate execution of certain market orders through the Public Order Exposure System (''POES'') and mandatory double-up/double-down price protection for equities quoting in decimals. The pilot program has been in effect since August 25, 2000.[6]

The only substantive change the Phlx proposes at this time is to extend the pilot program through January 14, 2002. The text of the proposed rule change is available at the Phlx and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Phlx proposes to extend, through January 14, 2002, the Exchanges' Rule 229 pilot program that incorporates immediate execution of certain orders and mandatory double-up/double-down price protection for equities quoting in decimals over PACE. No other substantive changes to the pilot program are proposed at this time.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6 of the Act[7] in general, and in particular, with Section 6(b)(5),[8] in that it is designed to promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and protect investors and the public interest by providing for automatic execution of certain market orders and mandatory double-up/double-down price protection for equities traded in decimals.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any inappropriate burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6). The Phlx requested that the Commission waive the 5-day pre-filing notice requirement, and the 30-day operative delay.

[5] PACE is the Exchange's automated order delivery, routing, execution and reporting system for equities.

[6] The pilot program was established in SR–Phlx–00–08. *See* Securities Exchange Act Release No. 43206 (August 25, 2000), 65 FR 53250 (September 1, 2000).

[7] 15 U.S.C. 78f.

[8] 15 U.S.C. 78f(b)(5).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

(i) Significantly affect the protection of investors or the public interest;

(ii) impose any significant burden on competition; and

(iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[9] and Rule 19b–4(f)(6) thereunder.[10] At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

The Exchange has requested that the Commission waive the 5-day pre-filing notice requirement, and accelerate the operative date. The Commission finds good cause to waive the pre-filing notice requirement, and to designate the proposal to be both effective and operative upon filing because such designation is consistent with the protection of investors and the public interest. Waiver of these requirements will allow the pilot program to continue uninterrupted through January 14, 2002. For these reasons, the Commission finds good cause to designate that the proposal is both effective and operative upon filing with the Commission.[11]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposal is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All submissions should refer to file number SR–Phlx–2001–102, and should be submitted by December 18, 2001.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[12]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–29401 Filed 11–26–01; 8:45 am]

BILLING CODE 8010–01–M

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6).

[11] For purposes only of accelerating the operative date of this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–45078; File No. SR–Phlx–2001–101]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Philadelphia Stock Exchange, Inc. Relating to Automatic Price Improvement for Equities Trading in Decimals

November 19, 2001.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 5, 2001, the Philadelphia Stock Exchange, Inc. (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange filed this proposal under Section 19(b)(3)(A) of the Act,[3] and Rule 19b–4(f)(6)[4] thereunder, which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend through January 14, 2002 its Philadelphia Stock Exchange Automated Communication and Execution System (''PACE'')[5] price improvement pilot program (''pilot program''). The pilot program, which is found in Supplementary Material .07 to Phlx Rule 229, consists of an automated price improvement feature based on decimal quoting, including a percentage of the spread between the bid and the offer. The current pilot program, established in SR–Phlx–2001–12, has been in effect since January 29, 2001.[6] The only substantive change the Phlx proposes at this time is to extend the pilot program through January 14, 2001. The text of the proposed rule change is available at the Phlx and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Phlx proposes to extend, through January 14, 2002, the Phlx's pilot program that incorporates automatic price improvement for equities quoting in decimals based on certain decimal parameters, including a percentage of the spread between the bid and offer. The Phlx proposes no substantive changes to the pilot program other than extending its date of operation through January 14, 2002.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6 of the Act[7] in general, and in particular, with Section 6(b)(5),[8] in that it is designed to promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6). The Phlx requested that the Commission waive the 5-day pre-filing notice requirement, and the 30-day operative delay.

[5] PACE is the Exchange's automated order delivery, routing, execution and reporting system for equities.

[6] *See* Securities Exchange Act Release No. 43901 (January 30, 2001), 66 FR 8988 (February 5, 2001).

[7] 15 U.S.C. 78f.

[8] 15 U.S.c. 78f(b)(5).

and protect investors and the public interest by extending automatic price improvement more widely to equities trading in decimals.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any inappropriate burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

(i) Significantly affect the protection of investors or the public interest;

(ii) Impose any significant burden on competition; and

(iii) Become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[9] and Rule 19b–4(f)(6) thereunder.[10] At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

The Exchange has requested that the Commission accelerate the operative date. The Commission finds good cause to designate the proposal to be both effective and operative upon filing because such designation is consistent with the protection of investors and the public interest. Waiver of the 30-day operative delay will allow the pilot program to continue uninterrupted through January 14, 2002. For these reasons, the Commission finds good cause to designate that the proposal is both effective and operative upon filing with the Commission.[11]

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposal is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All submissions should refer to file number SR–Phlx–2001–101, and should be submitted by December 18, 2001.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[12]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–29402 Filed 11–26–01; 8:45 am]

BILLING CODE 8010–01–M

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(6).

[11] For purposes only of accelerating the operative date of this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 35–27468]

Filings Under the Public Utility Holding Company Act of 1935, as Amended (''Act'')

November 20, 2001.

Notice is hereby given that the following filing(s) has/have been made with the Commission pursuant to provisions of the Act and rules promulgated under the Act. All interested persons are referred to the application(s) and/or declaration(s) for complete statements of the proposed transaction(s) summarized below. The application(s) and/or declaration(s) and any amendment(s) is/are available for public inspection through the Commission's Branch of Public Reference.

Interested persons wishing to comment or request a hearing on the application(s) and/or declaration(s) should submit their views in writing by December 14, 2001, to the Secretary, Securities and Exchange Commission, Washington, DC 20549–0609, and serve a copy on the relevant applicant(s) and/or declarant(s) at the address(es) specified below. Proof of service (by affidavit or, in the case of an attorney at law, by certificate) should be filed with the request. Any request for hearing should identify specifically the issues of facts or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in the matter. After December 14, 2001, the application(s) and/or declaration(s), as filed or as amended, may be granted and/or permitted to become effective.

American Electric Power Company, Inc. (70–6126)

American Electric Power Company, Inc. (''AEP''), 1 Riverside Plaza, Columbus, Ohio 43215, a registered holding company, has filed a post-effective amendment under sections 6(a) and 7 of the Act and rule 54 under the Act to its application-declaration filed under sections 6(a), 7, 9(a), 10, 12(b), 32 and 33 of the Act and rules 45 and 54 under the Act.

By prior Commission orders dated April 25, 1978, April 27, 1979, June 24, 1980, June 30, 1981, June 28, 1982, March 8, 1988, December 12, 1990, December 6, 1993, May 10, 1996, December 1, 1997 and June 14, 2000 (HCAR Nos. 20516, 21022, 21639, 22112, 22549, 24594, 25210, 25939, 26516, 26786 and 27186) (''Orders''), AEP was authorized to issue and sell up to 11.44 million shares of its common stock, $6.50 par value (''Common''), to the American Electric Power System Employees Savings Plan (''Plan''), through December 31, 2001. AEP issued and sold 5,293,642 of the authorized number of shares of Common to the Plan, through September 28, 2001.

AEP now proposes to extend the time in which it may issue and sell the remaining authorized shares of Common to the Plan, equaling approximately 6.1 million shares, through September 30, 2006. All shares of Common will be issued and sold to the Plan on the same terms and conditions as provided in the Orders.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–29456 Filed 11–26–01; 8:45 am]

BILLING CODE 8010–01–M

UNITED STATES SENTENCING COMMISSION

Sentencing Guidelines for United States Courts

AGENCY: United States Sentencing Commission.

ACTION: Notice of final amendments to the Sentencing Commission's Rules of Practice and Procedure.

SUMMARY: This notice sets forth amendments to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Michael Courlander, Public Affairs Officer, Telephone: (202) 502–4590.

SUPPLEMENTARY INFORMATION: Section 995(a)(1) of Title 28, United States Code, authorizes the Commission to establish general policies and promulgate rules and regulations as necessary for the Commission to carry out the purposes of the Sentencing Reform Act of 1984. The Commission originally adopted the Rules of Practice and Procedure in July 1997 and has now made amendments to these rules. Specifically, the amendments clarify various rules pertaining to public access and generally provide updated information regarding how the public can contact the Commission.

Authority: 28 U.S.C. § 995(a)(1); USSC Rules of Practice and Procedure 1.2.

Diana E. Murphy,

Chair.

Amendment: Part I of the Rules of Practice and Procedure is amended by striking the introduction in its entirety.

Part I of the Rules of Practice and Procedure is amended in Rule 1.1 by striking the last sentence and inserting the following:

''These rules are not intended to create or enlarge legal rights for any person.''.

Part II of the Rules of Practice and Procedure is amended in Rule 2.2 in the first paragraph by striking ''public'' following ''and vote in''; and in the fourth paragraph by striking the last sentence and inserting the following:

''Such matters include the approval of budget requests, legal briefs, staff reports, analyses of legislation, administrative and personnel issues, notices regarding Commission amendment priorities, technical and clerical amendments to these rules, and decisions to hold a nonpublic meeting.''.

Part III of the Rules of Practice and Procedure is amended in Rule 3.1 by adding at the end the following paragraph:

''Members may participate in meetings from remote locations by electronic means, including telephone, satellite, and video conference devices.''.

Part III of the Rules of Practice and Procedure is amended in Rule 3.2 by adding at the end of the first paragraph the following:

''Except as provided in Rule 3.3, meetings of the Commission with outside parties shall be conducted in public.''.

Rule 3.3 is amended to read as follows:

Rule 3.3—Nonpublic Meetings

The Commission may hold nonpublic meetings (*i.e.,* meetings closed to the public) for purposes of the following: (1) to transact business of the Commission that is not appropriate for a public meeting (*e.g.,* discussion and resolution of personnel and budget issues); (2) to receive information from, and participate in discussions with, Commission staff and any person designated by an ex-officio commissioner as support staff for that commissioner; and (3) upon a decision by a majority of the members then serving, to receive or share information, from or with any other person, that is inappropriate for public disclosure (one example of which would be information from a law enforcement agency, the public disclosure of which would reveal confidential investigatory techniques or jeopardize an ongoing investigation).''.

Part III of the Rules of Practice and Procedure is amended by striking Rule 3.4 in its entirety; and by redesignating Rules 3.5 and 3.6 as Rules 3.4 and 3.5, respectively.

Part V of the Rules of Practice and Procedure is amended in Rule 5.1 by striking ''Office of Legislative and Public Affairs'' and inserting ''Office of Publishing and Public Affairs''; and by striking the second paragraph in its entirety and inserting the following:

'' 'Public comment' means (1) any written comment submitted by an outside party, including an agency represented by an ex-officio commissioner, pursuant to a solicitation by the Commission; and (2) any other written submission, from an outside party, that the Chair or a majority of the members then serving has not precluded from being made available to the public. 'Public comment' does not include any internal communication between and among commissioners, Commission staff, and any person designated by an ex-officio commissioner as support staff for that commissioner.''.

Part V of the Rules of Practice and Procedure is amended in Rule 5.2 by adding at the end the following paragraph:

''Subsequent to the deadline for comment on the tentative priorities, the Commission shall publish in the **Federal Register**, and make available to the public for inspection, a notice of priorities for Commission inquiry and possible action.''.

Part V of the Rules of Practice and Procedure is amended in Rule 5.3 by striking ''Data and Reports'' in the title and inserting ''Information''; by striking ''relevant data and reports for consideration'' and inserting ''relevant data, reports, and other information for consideration''; and by striking the last sentence and inserting the following:

''Upon authorization by the Staff Director, the Office of Publishing and Public Affairs shall make the data, reports, and other information available to the public as soon as practicable.''.

Part VI of the Rules of Practice and Procedure is amended in Rule 6.1 by striking ''(202) 273–4500'' and inserting ''(202) 502–4500''; by striking ''(202) 273–4529'' and inserting ''(202) 502–4699''; and by adding at the end ''The e-mail address is pubaffairs@ussc.gov.''.

Rule 6.2 is amended to read as follows:

Rule 6.2—Availability of Materials for Public Inspection; Office of Publishing and Public Affairs

The Office of Publishing and Public Affairs is the repository of all materials that are available to the public.

Generally, the Office of Publishing and Public Affairs will maintain for public inspection the following: (1) Agendas and schedules for Commission public meetings and public hearings; (2) approved minutes of Commission public meetings; (3) transcripts of public hearings; (4) public comment as defined in Rule 5.1; (5) data, reports, and other information made available pursuant to Rule 5.3; and (6) with respect to nonpublic meetings described in Rule 3.3(3), a list of outside parties attending the meeting, a list of issues upon which the Commission was briefed, and, unless otherwise directed by the Chair or a majority of the members then serving, copies of written materials submitted by outside parties.

The Office of Publishing and Public Affairs also will make available upon request (1) information available pursuant to the Commission's policy on public access to Commission data; and (2) *A Guide to Publications & Resources* that lists all publications and datasets available from the Commission.''.

Part VI of the Rules of Practice and Procedure is amended in Rule 6.4 by striking ''http://www.access.gpo.gov/su_docs; 'Information Available for Free Public Use in Federal Depository Libraries' should be selected. The listing may be searched by state or by area code.'' and inserting ''http://www.access.gpo.gov/su_docs/locators/findlibs/index.html.''.

Part VI of the Rules of Practice and Procedure is amended in Rule 6.5 by striking ''http://www.ICPSR.umich.edu/

NACJD/home.html.'' and inserting ''http://www.ICPSR.umich.edu/NACJD/archive.html.''.

[FR Doc. 01–29466 Filed 11–26–01; 8:45 am]

BILLING CODE 2210–40–P

TENNESSEE VALLEY AUTHORITY

Environmental Impact Statement for 500-kV Transmission Line in Middle Tennessee

AGENCY: Tennessee Valley Authority.

ACTION: Notice of intent.

SUMMARY: The Tennessee Valley Authority (TVA) will prepare an environmental impact statement (EIS) addressing the proposed construction and operation of a new 500-kV transmission system in northern Middle Tennessee. This 500-kV transmission line would be located within a study area extending from near Cumberland City northeast to Clarksville and southeast to near Nashville, and including parts of seven counties in Tennessee. The EIS will evaluate the potential environmental impacts of the construction, operation, and maintenance of the line. TVA will use the EIS process to obtain public involvement on this proposal. Public comment is invited concerning both the scope of the EIS and environmental issues that should be addressed as a part of this EIS.

DATES: Comments on the scope and environmental issues for the EIS must be postmarked or e-mailed no later than December 31, 2001 to ensure consideration. Late comments will receive every consideration possible.

ADDRESSES: Written comments should be sent to Charles P. Nicholson, NEPA Specialist, Environmental Policy and Planning, Tennessee Valley Authority, mail stop WT 8C, 400 West Summit Hill Drive, Knoxville, Tennessee 37902–1499. Comments may be e-mailed to *cpnicholson@tva.gov.*

FOR FURTHER INFORMATION CONTACT: Hugh S. Barger, Transmission/Power Supply, Tennessee Valley Authority, mail stop MR 4G–C, 1101 Market Street, Chattanooga, Tennessee 37402–2801. Telephone (423) 751–3131. E-mail may be sent to *hsbarger@tva.gov.*

SUPPLEMENTARY INFORMATION:

Background

Electric loads in the Nashville and surrounding areas of Middle Tennessee have grown steadily in the recent past and are projected to continue to grow. In addition, new electrical generation is being connected to the TVA system, particularly in the western portion of the TVA service area. These two factors have combined to create two potentially serious problems: transmission system overloading and damage to electrical generating units.

TVA has studied this problem and has tentatively concluded that the best method of remedying these problems is the construction of a new 500-kV transmission line that would allow the additional movement of large quantities of power from the western part of its system to the Middle Tennessee area.

Project Description

The project would involve the construction of a new 500-kV transmission line from TVA's Cumberland Fossil Plant to one of two locations; either TVA's Montgomery, TN 500-kV substation located northeast of Clarksville, or TVA's Davidson, TN 500-kV substation located southwest of Nashville. The line would likely be built using self-supporting, laced steel towers on right-of-way 175 feet in width. A line to the Montgomery substation would be around 30 miles long, and a line to the Davidson substation would be around 45 miles long. Neither detailed routing studies nor line design studies have yet been conducted. The line structure type, right-of-way characteristics, and line length remain to be determined and could change when additional information is gathered.

Line construction would require removal of trees within the line right-of-way as well as any other nearby tall trees which would endanger the safe operation of the line. Construction of the support structures would require the excavation of foundations for each of the tower legs. Cranes and other heavy equipment would be needed to construct the towers and pull the electrical conductor into place. After construction, the land disturbed would be restored and the right-of-way would be periodically maintained to prevent the growth of tall vegetation which would endanger the line. The EIS will provide a detailed description of these activities, as well as applicable and appropriate environmental protection measures.

After the completion of scoping, TVA will begin its detailed line routing studies using maps, aerial photography and other relevant data. When the studies have progressed sufficiently, potentially affected landowners will be contacted directly, and additional field surveys will be conducted.

Proposed Issues To Be Addressed

The EIS will describe the existing environmental and socioeconomic resources within the area that would be affected by construction and operation of a transmission line. TVA's evaluation of environmental impacts to these resources will include, but not necessarily be limited to, the potential impacts on water quality, aquatic and terrestrial ecology, endangered and threatened species, wetlands, aesthetics and visual resources, land use, historic and archaeological resources, and socioeconomic resources.

Alternatives

The results of evaluating the potential environmental impacts and other important issues identified in the scoping process, as well as, engineering and economic considerations will be used by TVA in selecting a preferred alternative. At this time, the range of alternatives TVA has identified for detailed evaluation include no action and construction and operation of a 500-kV transmission line from Cumberland Fossil Plant to one of two possible sites.

Scoping Process

Scoping, which is integral to the NEPA process, is a procedure that solicits public input to the EIS process to ensure that: (1) Issues are identified early and properly studied; (2) issues of little significance do not consume substantial time and effort; (3) the draft EIS is thorough and balanced; and (4) delays caused by an inadequate EIS are avoided. TVA's NEPA procedures require that the scoping process commence soon after a decision has been reached to prepare an EIS in order to provide an early and open process for determining the scope and for identifying the significant issues related to a proposed action. The scope of alternatives and issues to be addressed in the draft EIS will be determined, in part, from written comments submitted by mail or e-mail, and comments presented orally or in writing at public meetings. The preliminary identification in this notice of reasonable alternatives and environmental issues is not meant to be exhaustive or final.

The scoping process will include both interagency and public scoping. The public is invited to submit written comments or e-mail comments on the scope of this EIS no later than the date given under the **DATES** section of this notice.

TVA will conduct two public scoping meetings within the project study area. The first meeting will be held at the Tennsco Community Center, 115 Tennsco Drive in Dickson, Tennessee on November 28, 2001 and the second will be held at the Burt-Cobb Community Center, 1011 Franklin Street in

Clarksville, Tennessee on November 29, 2001. These informal meetings will begin at 1 p.m. and end at 7 p.m. At each meeting, TVA management and project staff will present overviews of the EIS process and the proposed transmission line project, answer questions, and solicit comments on the issues that the public would like addressed in the EIS. These meetings will be publicized through notices in local newspapers, by TVA press releases, on the TVA Web site at *http://www.tva.gov/environment/calendar.htm* and in letters to local elected officials preceding the public meetings.

The agencies to be included in the interagency scoping are U.S. Army Corps of Engineers, U.S. Army—Fort Campbell, U.S. Fish and Wildlife Service, Tennessee Department of Environment and Conservation, the Tennessee State Historic Preservation Officer and other federal, state, and local agencies, as appropriate. After consideration of the scoping comments, TVA will further identify alternatives and environmental issues to be addressed in the EIS. Following analysis of the environmental consequences of each alternative, TVA will prepare a draft EIS for public review and comment. Notice of availability of the draft EIS will be published by the Environmental Protection Agency in the **Federal Register**. TVA will solicit written comments on the draft EIS, and information about possible public meetings to comment on the draft EIS will be announced. TVA expects to release a draft EIS by late summer, 2002 and a final EIS by June 2003.

Dated: November 20, 2001.

Kathryn J. Jackson,

Executive Vice President, River System Operations & Environment.

[FR Doc. 01–29490 Filed 11–26–01; 8:45 am]

BILLING CODE 8120–08–P

TENNESSEE VALLEY AUTHORITY

Meetings; Sunshine Act

AGENCY HOLDING THE MEETING: Tennessee Valley Authority (Meeting No. 1536).

TIME AND DATE: 8:30 a.m. (EST), November 30, 2001.

PLACE: TVA West Tower Auditorium, 400 West Summit Hill Drive, Knoxville, Tennessee.

STATUS: Open.

Agenda

Approval of minutes of meeting held on October 24, 2001.

New Business

A—Budget and Financing

A1. Approval of Fiscal year 2001 Financial Statements.

A2. Approval of tax-equivalent payments for Fiscal Year 2001 and estimated payments in Fiscal Year 2002 in accordance with Section 13 of the TVA Act.

B—Purchase Awards

B1. Supplement to Contract No. 999997641 with Marsh USA Inc., to provide coverage for the integrated risk insurance program.

B2. Supplements to contracts with United HealthCare of Tennessee and Cigna HealthCare of Tennessee for health maintenance organization benefit plan options.

B3. Supplement to Contract No. 99999115 with Connecticut General Life Insurance Company for dental health services.

C—Energy

C1. Contract with Guy F. Atkinson Construction, LLC, for the design and construction of a low-level outlet at the Blue Ridge Dam.

C2. Contract with General Electric International, Inc., to provide combustion turbine parts and services for TVA's new combustion turbine units located at Gallatin, Johnsonville, Lagoon Creek, and Kemper sites.

C3. Contract with ALSTOM Power, Inc., to provide large steam turbine/generator parts and services.

C4. Sale at public auction of a coal lease on the TVA Koppers property and delegation of authority to the Vice President of Fuel Supply and Engineering Services to administer and amend the lease.

C5. Proposed increases in prices under Dispersed Power Price Schedule—CSPP.

E—Real property Transaction

E1. Abandonment of an easement affecting approximately .5 acre of land on Wautauga Reservoir (a portion of Tract Nos. WAR–587F, War–592F, and WAR–594F) in Carter County, Tennessee.

Information Items

1. Winning Performance Team Incentive Plan payout.

2. Delegation of interim approval authority to the President and Chief Operating Officer, or a designee, for certain power purchase agreements for small renewable fueled generation projects.

3. Approval of the modification of contracts with Lodestar Energy, Inc., for coal supply to Johnsonville, Colbert Unit 5, the Cumberland Fossil Plants.

4. Renegotiation of Contract No. P96P06–190951 under a reopener provision with Ingram Barge Company for coal transportation services to Colbert, Cumberland, Johnsonville, and Widows Creek Fossil Plants.

5. Delegation of authority to the Manager, Watershed Technical Services, or a designee, and the Chief Financial Officer, or a designee, to grant leases concerning eight combustion turbines and related facilities located at Lagoon Creek Combustion Turbine Plant and take other actions with respect to the transfer of real property interests related to the lease arrangements.

6. Release of a restrictive covenant affecting approximately 28.3 acres of TVA land on Wheeler Reservoir in Morgan County, Alabama (Tract No. XWR–384).

7. Contract with The Buntin Group for marketing services primarily for the Energy Right® and Green Power Switch® programs.

8. Cooperative agreement with Memphis Light, Gas and Water to support low-income energy conservation demonstration in the MLGW service area.

9. Enhancements to TVA's efforts to recruit and retain employees and reward excellence in business performance and public service (''the 3Rs'').

For more information: Please call TVA Media Relations at (865) 632–6000, Knoxville, Tennessee. Information is also available at TVA's Washington Office (202) 898–2999. People who plan to attend the meeting and have special needs should call (865) 632–6000.

Dated: November 21, 2001.

Maureen H. Dunn,

General Counsel and Secretary.

[FR Doc. 01–29582 Filed 11–23–01; 12:30 pm]

BILLING CODE 8120–08–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Public Notice for Waiver of Aeronautical Land-Use Assurance; Greater Kankakee Airport, Kankakee, IL

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of intent of waiver with respect to land.

SUMMARY: The Federal Aviation Administration (FAA) is considering a proposal to change a portion of airport land from aeronautical use to non-

aeronautical use and to authorize the sale of the airport property. The proposal consists of a 16.5-acre portion of Parcel A and all of Parcel P (1.6 acres). Presently the land is vacant and used as open land for control of FAR Part 77 surfaces and compatible land use and is not needed for aeronautical use, as shown on the Airport Layout Plan. There are no impacts to the airport by allowing the airport to dispose of the property. Parcel A (36 acres) was acquired in 1962 under FAAP grant 9–11–040–05. Parcel P (1.6 acres) was acquired in 1964 under FAAP grant 5–12–0057–03. It is the intent of the Kankakee Valley Airport Authority (KVAA) to sell Parcel A–1 and Parcel P in fee to the County of Kankakee. This notice announces that the FAA intends to authorize the disposal of the subject airport property at Greater Kankakee Airport, Kankakee, IL. Approval does not constitute a commitment by the FAA to financially assist in disposal of the subject airport property nor a determination that all measures covered by the program are eligible for grant-in-aid funding from the FAA. The disposition of proceeds from the disposal of the airport property will be in accordance FAA's Policy and Procedures Concerning the Use of Airport Revenue, published in the **Federal Register** on February 16, 1999.

In accordance with section 47107(h) of title 49, United States Code, this notice is required to be published in the **Federal Register** 30 days before modifying the land-use assurance that requires the property to be used for an aeronautical purpose. The proposed land will be used by County of Kankakee for the construction of a new correctional facility. The construction of a new correctional facility will benefit the community. The proceeds from the sale of the land will be maintained in an interest bearing account and used for reimbursement of land transfer costs and future Airport Improvement Program eligible development.

DATES: Comments must be received on or before November 27, 2001.

FOR FURTHER INFORMATION CONTACT: Denis Rewerts, Program Manager, 2300 East Devon Avenue, Des Plaines, IL, 60018. Telephone Number 847–294–7195/FAX Number 847–294–7046. Documents reflecting this FAA action may be reviewed at this same location by appointment or at the Kankakee Valley Airport Authority, Greater Kankakee Airport, 813A E. 4000 South Road, Kankakee, Illinois 60901.

SUPPLEMENTARY INFORMATION: The following legal description of the proposed land sale is:

That part of the West Half of the Northwest Quarter of the Northeast Quarter of Section 20, Township 30 North, Range 13 West of the 2nd P.M. in Kankakee County, Illinois, lying South of the Southerly right-of-way line of I–57, containing approximately 18.1 acres, subject to rights-of-way for roads, drainage, and easements apparent or of record, and subject to survey.

This legal description does not represent a boundary survey and is based on a suggested land description provided by the KVAA.

Issued in Des Plaines, Illinois on October 25, 2001.

Philip M. Smithmeyer,

Manager, Chicago Airports District Office FAA, Great Lakes Region.

[FR Doc. 01–29483 Filed 11–26–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Acceptance of Noise Exposure Maps for Reno Tahoe International Airport, Reno, NV

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces its determination that the Noise Exposure Maps submitted by the Airport Authority of Washoe County for the Reno/Tahoe International Airport, Reno, Nevada under the provisions of Title I of the Aviation Safety and Noise Abatement Act of 1979 (Pub. L. 96–193) and Title 14, Code of Federal Regulations (CFR), Part 150, are in compliance with applicable requirements.

EFFECTIVE DATE: The effective date of the FAA's acceptance of the Noise Exposure Maps for the Reno/Tahoe International Airport, Reno, Nevada is November 15, 2001.

FOR FURTHER INFORMATION CONTACT: Elisha Novak, Airport Planner, Airports Division, SFO–611, Federal Aviation Administration, San Francisco Airports District Office. Mailing address: 831 Mitten Road, Burlingame, California 94010–1303. Telephone (650) 876–2928. 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 the Reno/Tahoe International Airport, Reno, Nevada are in compliance with applicable requirements of Federal Aviation Regulation (FAR) Part 150, effective November 15, 2001.

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 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 in introduction of additional noncompatible uses.

The FAA has completed its review of the Noise Exposure Maps and supporting documentation submitted by the Airport Authority of Washoe County. The specific maps under consideration are Exhibit 1, ''2000 Noise Exposure Map'' and Exhibit 2, ''2005 Noise Exposure Map'' in the submission. The FAA has determined that these maps for the Reno/Tahoe International Airport are in compliance with applicable requirements. This determination is effective on November 15, 2001. FAA's acceptance of 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 acceptance 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 FAR part 150 or through FAA's review of the 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 150.21 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, 800 Independence Avenue, SW., Room 617, Washington, DC 20591.

Federal Aviation Administration, Western-Pacific Region, Airports Division, AWP–600, 15000 Aviation Boulevard, Hawthorne, CA 90261.

Airport Authority of Washoe County, Reno/Tahoe International Airport, P.O. Box 12490, Reno, NV 89510–2490.

Questions may be directed to the individual named above under the heading **FOR FURTHER INFORMATION CONTACT**.

Issued in Hawthorne, California on November 15, 2001.

Herman C. Bliss,

Manager, Airports Division, AWP–600, Western-Pacific Region.

[FR Doc. 01–29481 Filed 11–26–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Approval of Noise Compatibility Program, Orlando International Airport, Orlando, FL

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces its findings on the noise compatibility program submitted by the Greater Orlando Aviation Authority under the provisions of Title I of the Aviation Safety and Noise Abatement Act of 1979 (Pub. L. 96–193) and 14 CFR Part 150. These findings are made in recognition of the description of Federal and nonfederal responsibilities in Senate Report No. 96–52 (1980). On April 23, 2001, the FAA determined that the noise exposure maps submitted by the Greater Orlando Aviation Authority under Part 150 were in compliance with applicable requirements. On October 22, 2001, the Administrator approved the Orlando International Airport noise compatibility program. All of the recommendations of the program were approved. No program measures relating to new or revised flight procedures for noise abatement were proposed by the airport operator.

EFFECTIVE DATE: The effective date of the FAA's approval of the Orlando International Airport noise compatibility program is October 22, 2001.

FOR FURTHER INFORMATION CONTACT: Bonnie L. Baskin, Federal Aviation Administration, Orlando Airports District Office, 5950 Hazeltine National Dr., Suite 400, Orlando Florida 32822, (407) 812–6331, Extension 30. Documents reflecting this FAA action may be reviewed at this same location.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA has given its overall approval to the noise compatibility program for Orlando International Airport, effective October 22, 2001.

Under Section 104(a) of the Aviation Safety and Noise Abatement Act of 1979 (hereinafter referred to as ''the Act''), an airport operator who has previously submitted a noise exposure map may submit to the FAA a noise compatibility program which sets forth the measures taken or proposed by the airport operator for the reduction of existing noncompatible land uses and prevention of additional noncompatible land uses within the area covered by the noise exposure maps. The Act requires such programs to be developed in consultation with interested and affected parties including local communities, government agencies, airport users, and FAA personnel.

Each airport noise compatibility program developed in accordance with Federal Aviation Regulations (FAR) Part 150 is local program, not a Federal Program. The FAA does not substitute its judgment for that of the airport proprietor with respect to which measure should be recommended for action. The FAA's approval or disapproval of FAR Part 150 program recommendations is measured according to the standards expressed in Part 150 and the Act, and is limited to the following determinations:

a. The noise compatibility program was developed in accordance with the provisions and procedures of FAR Part 150;

b. Program measures are reasonably consistent with achieving the goals of reducing existing noncompatible land uses around the airport and preventing the introduction of additional noncompatible land uses;

c. Program measures would not create an undue burden on interstate or foreign commerce, unjustly discriminate against types or classes of aeronautical users, violate the terms of airport grant agreements, or intrude into areas preempted by the Federal government; and

d. Program measures relating to the use of flight procedures can be implemented within the period covered by the program without derogating safety, adversely affecting the efficient use and management of the navigable airspace and air traffic control systems, or adversely affecting other powers and responsibilities of the Administrator prescribed by law.

Specific limitations with respect to FAA's approval of an airport noise compatibility program are delineated in FAr Part 150 Section 150.5. Approval is not a determination concerning the acceptability of land uses under Federal, state, or local law. Approval does not by itself constitute an FAA implementing action. A request for Federal action or approval to implement specific noise compatibility measures may be required, and an FAA decision on the request may require an environmental assessment of the proposed action. Approval does not constitute a commitment by the FAA to financially assist in the implementation of the program nor a determination that all measures covered by the program are eligible for grant-in-aid funding from the FAA. Where Federal funding is sought, requests for project grants must be submitted to the FAA Airports District Office in Orlando, Florida.

The Greater Orlando Aviation Authority submitted to the FAA on March 30, 2001, the noise exposure maps, descriptions, and other documentation produced during the noise compatibility planning study conducted from July 1, 1997, through March 30, 2001. The Orlando International Airport noise exposure maps were determined by FAA to be in compliance with applicable requirements on April 23, 2001. Notice of this determination was published in the **Federal Register** on April 23, 2001.

The Orlando International Airport study contains a proposed noise compatibility program comprised of

actions designed for phased implementation by airport management and adjacent jurisdictions from the date of study completion to the year 2006. It was requested that FAA evaluate and approve this material as a noise compatibility program as described in Section 104(b) of the Act. The FAA began its review of the program on April 23, 2001, and was required by a provision of the Act to approve or disapprove the program within 180 days (other than the use of new flight procedures for noise control). Failure to approve or disapprove such program within the 180-day period shall be deemed to be an approval of such program.

The submitted program contained four (4) proposed actions for noise mitigation on and off the airport. The FAA completed its review and determined that the procedural and substantive requirements of the Act and FAR Part 150 have been satisfied. The overall program, therefore, was approved by the Administrator effective October 22, 2001.

Out right approval was granted for all four (4) of the specific program elements. The approval action was for the following program measures:

Measure	Description/Land Use Measures	NCP Pages
1. Incorporation of the Overlay Zone in Land Development Codes.	Zone C includes the DNL 65 dB noise contour and recommends avoiding new residential development, and does not permit new mobile home development. Zone D, corresponding to the DNL 60 dB noise contour, includes sound attenuation requirements, a waiver of claim, and notification to be provided for any new residential development. The Overlay Zone was incorporated into the respective land development codes of the City of Orlando and Orange County during the preparation of the FAR Part 150 Study. It is expected that land development code modifications will also be established during 2001 by Osceola County for the portion of the Overlay Zone that falls within their jurisdiction. FAA Action: Approved.	Pages 11–1—11–8, 13–1; exhibits 11–1—11–6; and tables 11–1—11–4.
2. Sound Insulation Program with Avigation Easement.	It is recommended that the Greater Orlando Aviation Authority offer to provide sound insulation, only where feasible and cost effective and in exchange for an avigation easement to homeowners located within the DNL 65+dB noise contour of the 2001 Noise Exposure Map. Sound insulation would only be beneficial to those residences where sound insulation can be effectively applied. Sound insulation for mobile homes, for example, would not be beneficial. This project includes 30 homes. It is also recommended that this program include insulation of Shenandoah Elementary School, which is located within the DNL 65 dB for the forecast NEM timeframe. This will reduce existing non-compatible land uses. FAA Action: Approved.	Pages 12–1, 13–2, and 14–2.
3. Property Acquisition Program.	It is recommended that the Greater Orlando Aviation Authority offer to provide voluntary acquisition of residential properties meeting the eligibility requirements of the FAA and those located within the 65 DNL contour. As indicated previously some of the these residences are mobile homes and are not suitable for sound insulation. Acquisition would be the only applicable noise mitigation action for these types of homes. In addition, others owning non-mobile home residences may prefer that their homes be acquired in lieu of sound insulation. Any offers of acquisition would be limited to those who acquired the residence prior to October 1, 1998. It is planned that any fixed residence purchased through this program will be, in turn, sound insulated and sold with an avigation easement. Mobile home owners who are renting property will be moved and the park land purchased. Mobile home owners who also own the property and wish to participate in this program will be required to sell the home and the underlying property. As with the sound insulation program, the acquisition of residences would be purely on a voluntary basis. FAA Action: Approved. Relocation must be consistent with 49 Code of Federal Regulation, Part 24 to be eligible for Federal financial assistance.	Pages 12–2, 13–2, and 14–2; GOAA letter dated 9/24/01.
4. Acquisition of Noise Monitoring Equipment.	The current noise and operations monitoring system has been an effective addition to the noise abatement program. The information provided by the system has helped to develop operational noise abatement measures, has allowed the accurate identification of the source of noise complaints and improved the resolutions of problems through follow-ups with those who registered the noise complaints. The benefit of future enhancements to the system (upgraded field monitors or improvements to system software and hardware) would allow GOAA to stay current with future technological advancements. All current equipment is anticipated to remain in place over the next five years. The acquisition of new noise monitoring equipment is not expected in the short term (less than five years). Justification for replacement equipment will be determined at the time of the proposed replacement. FAA Action: Approved. For purposes of aviation safety, this approval does not extend to the use of monitoring equipment for enforcement purposes by in-situ measurement of any pre-set noise thresholds.	Pages 13–3, 14–2.

These determinations are set forth in detail in a Record of Approval endorsed by the Administrator on October 22, 2001. The Record of Approval, as well as other evaluation materials and the documents comprising the submittal, are available for review at the FAA office listed above and at the administrative office of the Greater Orlando Airport Authority.

Issued in Orlando, Florida on November 15, 2001.

John W. Reynolds, Jr.,

Acting Manager, Orlando Airports District Office.

[FR Doc. 01–29482 Filed 11–26–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Aviation Rulemaking Advisory Committee Meeting on Transport Airplane and Engine Issues

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of public meeting.

SUMMARY: This notice announces a public meeting of the FAA's Aviation Rulemaking Advisory Committee (ARAC) to discuss transport airplane and engine (TAE) issues.

DATES: The meeting is scheduled for December 4, 2001, beginning at 8:30 a.m. Arrange for oral presentations by November 30.

ADDRESSES: National Transportation Safety Board Room and Conference Center, Conference Room A&B, 429 L'Enfant Plaza, SW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Effie M. Upshaw, Office of Rulemaking, ARM–209, FAA, 800 Independence Avenue, SW., Washington, DC 20591, Telephone (202) 267–7626, FAX (202) 267–5075, or e-mail at *effie.upshaw@faa.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C. app. III) notice is given of an ARAC meeting to be held December 4, in Washington, DC.

The agenda will include:

- Opening Remarks
- FAA Report
- Joint Aviation Authorities Report
- Transport Canada Report
- Executive Committee Report
- Harmonization Management Team Report
- ARAC Tasking Priorities Discussion
- Design for Security Harmonization Working Group (HWG) Report
- Ice Protection HWG Report
- Loads & Dynamics HWG Report
- Engine HWG Report and Approval
- Mechanical Systems HWG Report
- General Structure HWG Report
- Airworthiness Assurance Working Group Report
- Human Factors HWG Report
- Electrical Systems HWG Report
- System Design and Analysis Report
- Written working group reports may be provided for the following HWG's: Electromagnetic Effects, Flight Test, Powerplant Installation, Seat Test, Flight Guidance, Flight Control, and Avionics Systems. An update also may be provided for the Extended Range with Two-Engine Aircraft Tasking.

The Engine HWG plans to seek approval of its bird management recommendations.

Attendance is open to the public, but will be limited to the availability of meeting room space and telephone lines. Details for participating in the teleconference will be available after November 28 by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Callers outside the Washington metropolitan area will be responsible for paying long distance charges.

The public must make arrangements by November 30 to present oral statements at the meeting. Written statements may be presented to the committee at any time by providing 25 copies to the Assistant Executive Director for Transport Airplane and Engine issues or by providing copies at the meeting. Copies of the documents to be presented to ARAC for decision or as recommendations to the FAA may be made available by contacting the person listed under the heading **FOR FURTHER INFORMATION CONTACT.**

If you are in need of assistance or require a reasonable accommodation for the meeting or meeting documents, please contact the person listed under the heading **FOR FURTHER INFORMATION CONTACT.** Sign and oral interpretation, as well as a listening device, can be made available if requested 10 calendar days before the meeting.

Issued in Washington, DC on November 20, 2001.

Tony F. Fazio,

Director, Office of Rulemaking.

[FR Doc. 01–29396 Filed 11–26–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

Office of Hazardous Materials Safety; Notice of applications for exemptions

AGENCY: Research and Special Progrmas Administration, DOT.

ACTION: List of Applicants for Exemptions.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, exemptions from the Department of Transportation's Hazardous Materials Regulations (49 CFR part 107, subpart B), notice is hereby given that the Office of Hazardous Materials Safety has received the applications described herein. Each mode of transportation for which a particular exemption is requested is indicated by a number in the ''Nature of Application'' portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft.

DATES: Comments must be received on or before December 27, 2001.

ADDRESS COMMENTS TO: Records Center, Research and Special Programs Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the exemption application number.

FOR FURTHER INFORMATION CONTACT: Copies of the applications (See Docket Number) are available for inspection at the New Docket Management Facility, PL–401, at the U.S. Department of Transportation, Nassif Building, 400 7th Street, SW., Washington, DC 20590 or at *http://dms.dot.gov.*

This notice of receipt of applications for new exemptions is published in accordance with Part 107 of the Federal hazardous materials transporation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on November 20, 2001.

J. Suzanne Hedgepeth,

Director, Office of Hazardous Materials, Exemptions and Approvals.

Application No.	Docket No.	Applicant	Regulation(s) affected	Nature of exemption thereof
12858–N	RSPA–01–10977	Union Carbide Corporation, South Charlestown, WV.	49 CFR 172.203, 179.13	To authorize the transportation in commerce of a DOT specification 105J400W tank car having a gross weight on rail of 286,000 pounds, for use in transportation Division 2.1, 2.3, Poison-Inhalation Hazard/Zone D. (Mode 2)
12859–N	RSPA–01–10942	Atlantic Research Corporation, Gainesville, VA.	49 CFR 173.320, 173.56(b), 173.56(e)(3).	To authorize the transportation in commerce of unapproved air bag inflators or air bag modules or seatbelt pretensioners, Division 1.4C in specially designed packaging. (Mode 1)

[FR Doc. 01–29476 Filed 11–26–01; 8:45 am]

BILLING CODE 4910–60–M

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

Office of Hazardous Materials Safety; Notice of Applications for Modification of Exemption

AGENCY: Research and Special Programs Administration, DOT.

ACTION: List of applications for modification of exemptions.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, exemptions from the Department of Transportation's Hazardous Materials Regulations (49 CFR part 107, subpart B), notice is hereby given that the Office of Hazardous Materials Safety has received the applications described herein. This notice is abbreviated to expedite docketing and public notice. Because the sections affected, modes of transportation, and the nature of application have been shown in earlier **Federal Register** publications, they are not repeated here. Requests for modifications of exemptions (e.g. to provide for additional hazardous materials, packaging design changes, additional mode of transportation, etc.) are described in footnotes to the application number. Application numbers with the suffix ''M'' denote a modification request. These applications have been separated from the new applications for exemptions to facilitate processing.

DATES: Comments must be received on or before December 12, 2001.

ADDRESS COMMENTS TO: Records Center, Research and Special Programs Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the exemption number.

FOR FURTHER INFORMATION CONTACT: Copies of the applications are available for inspection in the Records Center, Nassif Building, 400 7th Street SW., Washington, DC or at *http://dms.dot.gov.*

This notice of receipt of applications for modification of exemptions is published in accordance with part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on November 20, 2001.

J. Suzanne Hedgepeth,

Director, Office of Hazardous Materials, Exemptions and Approvals.

Application No.	Docket No.	Applicant	Modification of exemption
10440–M		MASS Systems (A Unit of Ameron Global, Inc.), Baldwin Park, CA (See Footnote 1).	10440
11186–M		Chart Industries, Inc. (Storage Systems Div.), Denver, CO (See Footnote 2).	11186
11993–M	RSPA–97–3100	BREED Technologies, Inc., Lakeland, FL (See Footnote 3).	11993
12196–M	RSPA–98–4939	HR Textron, Pacoima, CA (See Footnote 4)	12196

[1] To modify the exemption to authorize an alternative maintenance/inspection program for welded austenitic stainless steel non-DOT specification cylinders, conforming with DOT Specification 4DS, for the transportation of Division 2.2 materials.

[2] To modify the exemption to authorize the addition of new vessel assemblies for the non-DOT specification vacuum insulated portable tanks, comparable to DOT Specification MC 338 cargo tank motor vehicle, for the transportation of Division 2.2 materials.

[3] To modify the exemption to authorize a new design style of the non-DOT specification cylinders used as components of automobile vehicle safety systems for the transportation of Division 2.1 and 2.2 materials.

[4] To modify the exemption to authorize the hydrostatic retest period from 5 to 18 years for non-DOT specification stainless steel alloy cylinders used for the transportation of Division 2.2 materials.

[FR Doc. 01–29477 Filed 11–26–01; 8:45 am]
BILLING CODE 4910–60–M

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

Office of Hazardous Materials Safety; Notice of Delays in Processing of Exemption Applications

AGENCY: Research and Special Programs Administration, DOT.

ACTION: List of applications delayed more than 180 days.

SUMMARY: In accordance with the requirements of 49 U.S.C. 5117(c), RSPA is publishing the following list of exemption applications that have been in process for 180 days or more. The reason(s) for delay and the expected completion date for action on each application is provided in association with each identified application.

FOR FURTHER INFORMATION CONTACT: J. Suzanne Hedgepeth, Director, Office of Hazardous Materials, Exemptions and Approvals, Research and Special Programs Administration, U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590–0001, (202) 366–4535.

Key to ''Reasons for Delay''

1. Awaiting additional information from applicant.
2. Extensive public comment under review.
3. Application is technically complex and is of significant impact or precedent-setting and requires extensive analysis.
4. Staff review delayed by other priority issues or volume of exemption applications.

Meaning of Application Number Suffixes

N—New application.

M—Modification request.

PM—Party to application with modification request.

Issued in Washington, DC, on November 20, 2001.

J. Suzanne Hedgepeth,

Director, Office of Hazardous Materials, Exemptions and Approvals.

NEW EXEMPTION APPLICATIONS

Application Number	Applicant	Reason for delay	Estimated date of completion
11862–N	The BOC Group, Murray Hill, NJ	4	12/31/2001
11927–N	Alaska Marine Lines, Inc., Seattle, WA	4	12/31/2001
12353–N	Monson Companies, South Portland, ME	4	12/31/2001
12381–N	Ideal Chemical & Supply Co., Memphis, TN	4	12/31/2001
12406–N	Occidental Chemical Corporation, Dallas, TX	4	12/31/2001
12412–N	Great Western Chemical Company, Portland, OR	4	12/31/2001
12434–N	Salmon Air, Salmon, ID	4	12/31/2001
12440–N	Luxfer Inc., Riverside, CA	4	12/31/2001
12456–N	Baker Hughes, Houston, TX	4	12/31/2001
12571–N	Air Products & Chemicals, Inc., Allentown, PA	4	12/31/2001
12586–N	Wilsonart International Inc., Temple, TX	4	12/31/2001
12588–N	El Dorado Chemical Co., Creve Ceour, MO	4	12/31/2001
12629–N	Western Sales & Testing of Amarillo, Inc., Amarillo, TX	4	01/31/2002
12630–N	Chemetall GmbH Gesellschaft, Langelsheim, DE	4	01/31/2002
12634–N	Norman International, Los Angeles, CA	4	01/31/2002
12648–N	Stress Engineering Services, Inc., Houston, TX	4	12/01/2001
12650–N	Coleman Powermate, Inc., Kearney, NE	4	01/31/2002
12670–N	Taylor-Wharton, Theodore, AL	4	12/31/2001
12674–N	G&S Aviation, Donnelly, ID	4	12/31/2001
12690–N	Air Liquide America Corporation, Houston, TX	4	01/31/2002
12696–N	Phibro-Tech, Inc., Fort Lee, NJ	4	01/31/2002
12701–N	Fuel Cell Components & Integrators, Inc., Hauppauge, NY	4	01/31/2002
12702–N	Los Crespos Cylinders, Anasco, PR	4	12/31/2001
12706–N	Raufoss Composites AS, Raufoss, NO	4	01/31/2002
12716–N	Air Liquide America Corporation, Houston, TX	4	01/31/2002
12718–N	Weldship Corporation, Bethlehem, PA	4	01/31/2002
12724–N	E. I. DuPont de Nemours & Co., Inc., Wilmington, DE	4	01/31/2002
12751–N	Defense Technology Corporation, Casper, WY	4	01/31/2002
12753–N	Praxair, Inc., Danbury, CT	4	01/31/2002
12756–N	Department of Energy, Oak Ridge, TN	4	01/31/2002
12819–N	BBI–Biotech Research Laboratories, Inc., Gaithersburg, MD	4	12/31/2001
12827–N	Department of Energy (DOE), Washington, DC	4	12/31/2001
4453–M	Dyno Nobel, Inc., Salt Lake City, UT	4	12/31/2001
4884–M	Matheson Tri-Gas, East Rutherford, NJ	4	12/31/2001
6805–M	Air Liquide America Corporation, Houston, TX	4	12/31/2001
7060–M	Federal Express, Memphis, TN	4	12/31/2001
7954–M	Voltaix, Inc., North Branch, NJ	4	12/31/2001
8308–M	Tradewind Enterprises, Inc., Hillsboro, OR	4	12/31/2001
8308–M	American Courier Express Corporation, Miramar, FL	4	01/31/2002
8554–M	Orica USA Inc., Englewood, CO	4	12/31/2001
8554–M	Dyno Nobel, Inc., Salt Lake City, UT	4	01/31/2002
8723–M	Dyno Nobel, Inc., Salt Lake City, UT	4	01/31/2002
9421–M	Taylor-Wharton (Harsco Corporation), Harrisburg, PA	4	01/31/2002
11244–M	Aerospace Design & Development, Inc., Longmont, CO	4	12/31/2001
111537–M	JCI Jones Chemicals, Inc., Milford, VA	4	12/31/2001
11769–M	Great Western Chemical Company, Portland, OR	4	12/31/2001
11769–M	Great Western Chemical Company, Portland, OR	4	01/31/2002
11769–M	Hydrite Chemical Company, Brookfield, WI	4	01/31/2002

NEW EXEMPTION APPLICATIONS—Continued

Application Number	Applicant	Reason for delay	Estimated date of completion
11911–M	Transfer Flow, Inc., Chico, CA	4	12/31/2001
12084–M	Honeywell International, Inc., Morristown, NJ	4	01/31/2002

[FR Doc. 01–29478 Filed 11–26–01; 8:45 am]

BILLING CODE 4910–60–M

DEPARTMENT OF VETERANS AFFAIRS

Poverty Threshold

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Department of Veterans Affairs (VA) hereby gives notice of the weighted average poverty threshold established for 2000 for one person (unrelated individual) as established by the Bureau of the Census. The amount is $8,794.

DATES: For VA determinations, the 2000 poverty threshold is effective September 25, 2001, the date on which it was established by the Bureau of the Census.

FOR FURTHER INFORMATION CONTACT: Paul Trowbridge, Consultant, Compensation and Pension Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 273–7218.

SUPPLEMENTARY INFORMATION: We published a final rule amending 38 CFR 4.16(a) in the **Federal Register** of August 3, 1990, 55 FR 31579. The amendment provided that marginal employment generally shall be deemed to exist when a veteran's earned annual income does not exceed the amount established by the Bureau of the Census as the poverty threshold for one person. The provisions of 38 CFR 4.16(a) use the poverty threshold as a standard in defining marginal employment when considering total disability ratings for compensation based on unemployability of an individual. We stated we would publish subsequent poverty threshold figures as notices in the **Federal Register**.

The Bureau of the Census recently published the weighted average poverty thresholds for 2000. The threshold for one person (unrelated individual) is $8,794.

Dated: November 15, 2001.

Anthony J. Principi,

Secretary of Veterans Affairs.

[FR Doc. 01–29442 Filed 11–26–01; 8:45 am]

BILLING CODE 8320–01–P

Federal Register

Tuesday,
November 27, 2001

Part II

Social Security Administration

20 CFR Part 404

Revised Medical Criteria for Evaluating Hematological Disorders and Malignant Neoplastic Diseases; Proposed Rule

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

[Reg. No. 4]

RIN 0960–AD67

Revised Medical Criteria for Evaluating Hematological Disorders and Malignant Neoplastic Diseases

AGENCY: Social Security Administration.

ACTION: Proposed rules.

SUMMARY: We are proposing to revise the criteria in the Listing of Impairments (the listings) that we use to evaluate claims involving hematological disorders and malignant neoplastic diseases at the third step of our sequential evaluation processes for adults and children under title II and title XVI of the Social Security Act (the Act). The proposed revisions reflect advances in medical knowledge, treatment, and methods of evaluating hematological disorders and malignant neoplastic diseases.

DATES: To be sure your comments are considered, we must receive them by January 28, 2002.

ADDRESSES: Give us your comments using our Internet site facility (i.e., Social Security Online) at: *http://www.ssa.gov/regulations/*. If that facility is unavailable or not desired, you may send us your comments: by e-mail to regulations@ssa.gov; by telefax to (410) 966–2830; or, by letter to the Commissioner of Social Security, P.O. Box 17703, Baltimore, Maryland 21235–7703. You may also deliver them to the Office of Process and Innovation Management, Social Security Administration, L2109 West Low Rise Building, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, between the 8:00 a.m. and 4:30 p.m. on regular business days. Comments are posted on our Internet site, or you may inspect them on regular business days by making arrangements with the contact person shown in this preamble.

Electronic Version: The electronic file of this document is available on the date of publication in the **Federal Register** on *http://www.access.gpo.gov/su_docs/aces/aces140.html.* It is also available on the Internet site for SSA (i.e., Social Security Online): *http://www.ssa.gov/regulations/*. Electronic copies of public comments may also be found on this site.

FOR FURTHER INFORMATION CONTACT: Suzanne DiMarino, Social Insurance Specialist, Office of Process and Innovation Management, Social Security Administration, L2109 West Low Rise, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, (410) 965–1769 or TTY (410) 966–5609. For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213 or TTY 1–800–325–0778, or visit our Internet web site, *SSA Online,* at *www.ssa.gov.*

SUPPLEMENTARY INFORMATION:

What Programs Would Be Affected by These Proposed Regulations?

These proposed regulations would affect disability determinations and decisions we make for individuals under title II and title XVI of the Act. In addition, to the extent that Medicare and Medicaid eligibility are based on title II and title XVI eligibility, these proposed regulations also would affect the Medicare and Medicaid programs.

Who Can Get Disability Benefits?

Under title II of the Act, we provide for the payment of disability benefits to three groups of individuals:

- Workers insured under the Act.
- Children of insured workers.
- Widows, widowers, and surviving divorced spouses of insured individuals.

Under title XVI of the Act, we provide for SSI payments on the basis of disability to adults and children who have limited income and resources.

How Do We Define Disability?

Under both the title II and title XVI programs, disability must be the result of any medically determinable physical or mental impairment or combination of impairments that can be expected to result in death or that has lasted or can be expected to last for a continuous period of at least 12 months. Our definition of disability is shown in the following table:

If you file a claim under * * *	And you are * * *	Disability means you have a medically determinable impairment(s) that meets the statutory duration requirement and results in * * *
title II	an adult or a child	the inability to do any substantial gainful activity (SGA)
title XVI	an adult	the inability to do any SGA
title XVI	a child	marked and severe functional limitations

What Are the Listings?

The listings contain examples of impairments that we consider severe enough to prevent an adult from doing any gainful activity, or that cause marked and severe functional limitations in a child. Although the listings are contained only in appendix 1 to subpart P of part 404, we incorporate them by reference in the SSI program by § 416.925 of our regulations.

How Do We Use the Listings?

We divide the listings into part A and part B. We apply the medical criteria in part A when we assess the claims of adults. We may also use the medical criteria in part A when we evaluate the claims of children, if the disease processes have a similar effect on adults and children. However, we first use the criteria in part B to evaluate claims by children. If the criteria in part B do not apply, we then use the criteria in part A. (See §§ 404.1525, 404.1526, 416.925 and 416.926.)

We use the criteria in the listings only to make favorable determinations or decisions regarding disability. We never deny a claim or find that an individual's disability has ceased because an impairment(s) does not meet or medically equal a listing. When an individual has a severe impairment(s) that does not meet or medically equal a listing, we may still find him or her disabled (or still disabled) based on other rules. For more information about our sequential evaluation processes for adults and children, see §§ 404.1520, 416.920, and 416.924 of our regulations regarding initial claims, and §§ 404.1594, 416.994, and 416.994a of our regulations regarding continuing disability reviews.

Why Are We Proposing To Revise the Listings for Hematological Disorders and Malignant Neoplastic Diseases?

We last published final rules revising the listings for the hemic and lymphatic system and the malignant neoplastic diseases system in the **Federal Register** on December 6, 1985 (50 FR 50068). In the preamble to those rules, we indicated that due to medical advances in disability evaluation and treatment and program experience we would periodically review and update the listings. The current listings for the

hemic and lymphatic system and malignant neoplastic diseases will no longer be effective on July 2, 2003. We are proposing to update the listings in part A, 7.00 and 13.00, and in part B, 107.00 and 113.00. We propose to make the rules effective for 5 years from their effective date, unless we extend them, or revise and issue them again.

We will continue to apply our current listings until we evaluate the public comments on these proposed rules and determine whether they should be issued as final rules. If we finalize these proposed rules, when any final rules become effective, we will apply them to new applications filed on or after the effective date of the final rules, and to cases that are pending in the administrative review process. In accordance with our usual practice, we would explain how we would apply any final rules in greater detail in the preamble to the final rules.

When we conduct reviews to determine whether your disability continues, we would not find that your disability has ended based only on any changes in the listings. Our regulations explain that we continue to use our prior listings when we review your case if you receive disability benefits or SSI payments based on our determination or decision that your impairment(s) met or equaled the listings. In these cases, we determine whether you have experienced medical improvement, and if so, whether the medical improvement is related to the ability to work. If your impairment(s) still meets or equals the same listing section that we used to make our most recent favorable determination or decision, we will find the medical improvement is not related to the ability to work. If your condition has medically improved so that you no longer meet or equal the prior listing, we evaluate your case further to determine whether you are currently disabled. We may find that you are currently disabled, depending on the full circumstances of your case. See 20 CFR 404.1594(c)(3)(i), 416.994(b)(2)(iv)(A). If you are a child who is eligible for SSI payments, we follow a similar rule when we decide whether you have experienced medical improvement in your condition. 20 CFR 416.994a(b)(2).

What Revisions Are We Proposing That Affect Both the Hematological Disorders and Malignant Neoplastic Diseases Listings?

To present the listing criteria in a more logical order, and make the listings easier to use, we propose to:

- Renumber the listings in part A and part B for the hematological disorders and malignant neoplastic diseases body systems. To the extent possible, we number the listings in part B to correspond with listings addressing the same impairments in part A.
- Reorganize these listings by grouping related impairments under broader medical diagnostic categories. For example, we would group chronic thrombocytopenia (current listings 7.06 and 107.06) and coagulation defects (current listings 7.08 and 107.08) under the category ''Disorders of hemostasis'' (proposed listings 7.03 and 107.03); and we would group sarcoma of skin (current listing 13.03) and malignant melanoma (current listing 13.05) under the category ''Skin'' (proposed listing 13.03).
- Further reorganize these listings to place all listings for malignant neoplastic diseases under that body system. To do this, we would move the criteria for acute leukemia, chronic leukemia, myeloma, and malignant brain tumors, current listings 7.11, 7.12, 7.16, 11.05, 107.11, and 111.05, to proposed listings 13.06, 13.07, 13.13, 113.06 and 113.13. We would also move the guidance for evaluating macroglobulinemia or heavy chain disease, current listing 7.14, to section 13.00K(3) of the proposed preface. The current listing for this disorder is a reference listing. In accordance with the discussion below, we propose to eliminate reference listings.
- Replace reference listings in these areas with guidance in the preface. Reference listings are listings that are met by satisfying the criteria of another listing. For example, current listing 7.16B, for myeloma with evidence of renal impairment, is a reference listing that requires evaluation under current listing 6.02, for impairment of renal function. Instead of using reference listings, we propose to provide general guidance in the preface to each of these body systems stating that resulting impairments should be evaluated under the criteria for the affected body system. Where appropriate, we would also provide references to specific listings. For example, in proposed section 13.00K(3) we indicate that macroglobulinemia or heavy chain disease should be evaluated under the criteria of proposed listings 7.03 or 7.04, or under the criteria of any other affected body system.

We also propose to use the phrase ''bone marrow or stem cell transplantation'' in proposed listings 7.06, 107.06, 13.28, and 113.28 instead of ''bone marrow transplantation'' as used in current listing 7.17. The purpose of bone marrow transplantation is to transplant stem cells, but stem cells from other sources, such as peripheral blood or cord blood, may also be used. Because of this, the phrase ''stem cell transplantation'' more accurately represents the type of transplantation addressed in the proposed listings. However, as ''bone marrow transplantation'' is still in common usage, we would also retain it in our listings in order to avoid confusion.

In several of the proposed listings, such as listings 7.03A2, 13.28, and 113.11D, we provide that we will consider the individual disabled for a specified period of time, such as for 12 months from the date of diagnosis. After that time, we will evaluate any residual impairment(s) under the criteria for the affected body system. In these situations, the beginning date specified is not related to the onset date; it is used only to calculate the period of time we would presume the impairment is disabling. We can establish an earlier onset date if the individual is not engaging in SGA and the evidence in file supports the earlier onset date.

We also propose to make nonsubstantive editorial changes to update the medical terminology in the listings and to make the language clearer.

How Are We Proposing To Change the Preface to the Listings for Evaluating Hematological Disorders in Adults?

7.00 Hematological Disorders

We propose to change the name of this body system from Hemic and Lymphatic System to Hematological Disorders because we are proposing to move the lymphatic impairments now contained in 7.00 to 13.00, Malignant Neoplastic Diseases.

Because we are proposing to move the criteria for evaluating leukemia to proposed listing 13.06, we propose to move the guidance contained in current 7.00E, ''Acute leukemia,'' to proposed 13.00K(2)(a). We discuss our revisions to that guidance in the explanation of proposed 13.00K(2)(a).

We also propose to expand and reorganize the introductory material in 7.00 to provide additional guidance and reflect the new listings. The following is a detailed explanation of the proposed material.

Proposed 7.00A—What Do We Consider When We Evaluate Hematological Disorders Under These Listings?

In this new section, we list the factors we consider.

Proposed 7.00B—What Documentation Do We Need?

To clarify the first sentence of current 7.00B, ''Chronicity,'' we explain that we

generally need a longitudinal clinical record covering a period of at least 3 months of observations and treatment unless we can make a fully favorable determination or decision without it.

We expand the second sentence of current 7.00B to provide examples of the types of laboratory findings that should be in the longitudinal clinical record.

We also clarify, in 7.00B(2) and 7.00B(3), what additional information the longitudinal clinical record should contain.

Proposed 7.00C—How Do We Evaluate Impairments That Do Not Meet One of the Hematological Disorders Listings?

In this new section, we state our basic adjudicative principle that if the individual's impairment(s) does not meet or medically equal the requirements of a listing, we will continue the sequential evaluation process to determine whether or not the individual is disabled.

Proposed 7.00D—How Do We Assess the Effectiveness of Treatment?

In this new section, we set forth our policy on considering the response to, effectiveness of, and adverse consequences of treatment.

Proposed 7.00E—How Do We Evaluate Episodic Hematological Disorders?

In this new section, we propose to revise the requirement in our current listings that events for episodic hematological impairments occur within the 5-month or 12-month period prior to adjudication. Instead of using the date of adjudication, as we do under the current criteria, we propose to require that the events occur within the period we consider in connection with the application or continuing disability review; that is, the period for which we will develop medical evidence through the date we make our determination or decision. Sections 404.1512(d)(2), 404.1593(b), 416.912(d)(2), and 416.993(b) of our regulations discuss the period for which we will develop medical evidence. This period generally begins 12 months prior to either the date of the application or the date the individual signed a report about his or her continuing disability status. This proposed approach is consistent with the way we evaluate episodic impairments in other body systems.

We also indicate that in every listing in which we require more than one event, there must be at least 1 month between the events. We propose this requirement to ensure that we are evaluating separate episodes.

Proposed 7.00F—What Do These Terms in the Listings Mean?

We propose to define the terms ''persistent'' and ''repeated'' or ''repeatedly'' in the hematological disorders listings.

Proposed 7.00G—How Do We Evaluate Specific Hematological Disorders?

We propose to incorporate and clarify current 7.00A, ''Impairment caused by anemia,'' 7.00C, ''Sickle cell disease,'' and 7.00D, ''Coagulation defects,'' and add guidance for evaluating additional hematological disorders. The following is a discussion of the information provided for the disorders in this section.

Proposed 7.00G(1)—Anemia

This paragraph corresponds to current 7.00A, ''Impairment caused by anemia'' and would also replace current listing 7.02B. Current listing 7.02B provides that the effects of chronic anemia should be evaluated under the criteria for the affected body system. In addition to causing residual impairments, chronic anemia can be a marker of severity for an underlying disorder, such as myelofibrosis. Thus, we propose to expand our guidance on chronic anemia to provide that this impairment can be evaluated under the criteria for the underlying disorder or for the affected body system.

Proposed 7.00G(2)—Sickle Cell Disease or One of Its Variants

This paragraph corresponds to the first two paragraphs of current 7.00C. We propose to clarify the policy regarding hematological evidence by adding that, in lieu of a copy of the actual laboratory report, we will accept medical evidence that is persuasive that a positive diagnosis has been confirmed by appropriate laboratory testing at some time prior to evaluation.

We propose to delete the third paragraph of current 7.00C, which defines ''major visceral episodes,'' because the term does not appear in the listings. The term ''major visceral complication'' does appear in the current childhood listing for sickle cell disease, listing 107.05B. Instead of extending the criterion to adults, we propose to delete it from the childhood listing. We explain our reasons for doing so in the discussion of proposed listing 107.02A (the proposed listing that corresponds to current listing 107.05).

Proposed 7.00G(3)—Disorders of Hemostasis

This section corresponds to current 7.00D ''Coagulation defects.'' We are using a more comprehensive term to reflect the criteria in proposed listing 7.03, ''Disorders of hemostasis.'' We would continue to include coagulation defects in the revised section, but as an example rather than as the only disorder covered by the listing.

We would also revise our guidance on how to document these disorders to address all the disorders covered by the proposed listing and to update the medical terminology. We are also adding guidance on how to consider complications of these disorders.

Proposed 7.00G(4)—Hematological Malignancies

The current criteria for evaluating hematological malignancies, such as lymphoma, leukemia, macroglobulinemia or heavy chain disease, and myeloma, are in 7.00. As we indicated above, we propose to move these disorders to 13.00, Malignant Neoplastic Diseases. We are adding this section to reflect that move. We are also adding a reminder that there is a separate listing for lymphoma associated with HIV infection, listing 14.08E.

Proposed 7.00G(5)—Chronic Iron Overload

The medical community is increasingly recognizing complications from this disorder. We propose to add this section to provide guidance on evaluating these complications under the listings.

Proposed 7.00H—How Do We Evaluate non-malignant Hematological Disorders Treated by Allogeneic Bone Marrow or Stem Cell Transplantation?

We provide that non-malignant hematological disorders treated by allogeneic bone marrow or stem cell transplantation must be evaluated under the criteria in proposed listing 7.06, regardless of whether there is another listing that addresses that impairment. We discuss the criteria in proposed listing 7.06. We also discuss some of the factors we consider when we evaluate any residual impairment(s) that results from transplantation.

How Are We Proposing to Change the Criteria in the Listings for Evaluating Hematological Disorders in Adults?

7.01 Category of Impairments, Hematological Disorders

In addition to proposing to move listings 7.11, 7.12, 7.13, 7.14, and 7.16, we propose to delete current listings 7.02, ''Chronic anemia (hematocrit persisting at 30 percent or less due to any cause),'' and 7.07, ''Hereditary telangiectasia.''

Current listing 7.02A requires one or more blood transfusions on an average of at least once every 2 months. The average frequency of blood transfusions is not an accurate measure of severity or duration of the impairment. If an individual had several transfusions performed close together in the past and none thereafter, the average might still satisfy the frequency criterion for the current listing, even though the underlying impairment may not have persisted at this level. Also, some individuals with anemia may be treated with scheduled red cell transfusions in order to maintain the oxygen-carrying capacity of the blood.

As we explained above, we propose to retain the criterion in current listing 7.02B, evaluation of the resulting impairment under the criteria for the affected body system, in proposed 7.00C.

We propose to delete current listing 7.07 because listing-level hereditary telangiectasia is rare and can be evaluated under other criteria, for example, those for other hematological disorders or for the affected body system, such as digestive.

The provisions of proposed 7.00E apply to proposed listings 7.02A, 7.02B, 7.03A2, 7.03B, 7.03C, 7.04B, and 7.05. Because we have already discussed the provisions in proposed 7.00E, they are not included in the following explanation of the proposed listing criteria.

Proposed Listing 7.02—Sickle Cell Disease or One of its Variants

This proposed listing has three separate evaluation criteria. Proposed listing 7.02A, documented painful (vaso-occlusive) crises, corresponds to current listing 7.05A. We propose to include a requirement that the crises require parenteral medication, to clarify the level of severity intended by the listing.

We also propose to lengthen the period of time during which the pain crises must occur from 5 months to 6 months. We believe that pain crises of the type described in proposed listing 7.02A that occur at least 3 times in a 6-month period are indicative of listing-level severity.

Proposed listing 7.02B, hospitalization (for 24 hours or more), is similar to current listing 7.05B. We propose to replace the current requirement of ''beyond emergency care'' with ''for 24 hours or more'' to more clearly define our intent.

Proposed listing 7.02C, chronic anemia, corresponds to current listing 7.05C. We propose to revise the criterion to provide a more accurate measure of severity. The current criterion is a persistent hematocrit of 26 percent or less. A hematocrit at this level does not necessarily correlate to an inability to perform any gainful activity. The hemoglobin level required in the proposed listing is indicative of an impairment that we believe would preclude any gainful activity in individuals with sickle cell disease. Throughout these proposed listings, we are using hemoglobin levels instead of hematocrit values as used in the current listings. Hemoglobin levels are measured directly; hematocrit values must be derived.

We also propose to delete the word ''severe,'' which is used in current listing 7.05C. The use of the word ''severe'' in current listing 7.05C is not intended to be the same as the definition of ''severe'' in §§ 404.1521 and 416.921 of our regulations. We believe the proposed revision is sufficiently clear that we do not need the word. Therefore, we propose to delete it to avoid confusion.

As part of our effort to eliminate reference listings, we propose to delete the criterion in current listing 7.05D, which provides for evaluation of the resulting impairment under the criteria for the affected body system. We have incorporated this criterion in proposed 7.00C(1).

Proposed Listing 7.03—Disorders of Hemostasis

As already noted, we propose to incorporate current listings 7.06, ''Chronic thrombocytopenia,'' and 7.08, ''Coagulation defects,'' under this heading and provide criteria for evaluating hypercoagulable states. The following is a discussion of the criteria in the proposed listing.

Proposed Listing 7.03A—Chronic Thrombocytopenia (Due to Any Cause)

This listing corresponds to current listing 7.06. We propose the following changes:

- In proposed listing 7.03A1, we indicate that chronic thrombocytopenia with platelet counts repeatedly below 10,000/mm^3 despite prescribed therapy is, by itself, an impairment that would preclude an individual from performing any gainful activity.
- In proposed listing 7.03A2, we require platelet counts repeatedly below 20,000/mm^3 instead of the current criterion of 40,000/mm^3. We propose this change because the incidence of spontaneous bleeding episodes increases significantly when the platelet count is below 20,000/mm^3. Some individuals whose platelet counts are 20,000/mm^3 or higher may still be limited or restricted, but many of these individuals will not be precluded from engaging in any gainful activity. Therefore, we will evaluate these individuals on a case-by-case basis.
- In proposed listing 7.03A2, we also propose to clarify the reference to transfusion and change the frequency requirements in current listing 7.06A. We clarify the reference to transfusion by specifying red cell or platelet transfusion. We propose this revision to reflect common medical practice. We also propose to change the frequency requirement from one episode of bleeding within the 5 months prior to adjudication to at least three episodes of bleeding in a consecutive 12-month period. We propose this revision because one episode of bleeding in 5 months is not sufficient to establish that the impairment has lasted or can be expected to last for at least 12 months.
- We propose to replace the criterion in current listing 7.06B, intracranial bleeding within 12 months prior to adjudication, with guidance in 7.00G(3)(c) indicating that intracranial bleeding should be evaluated under listing 11.04. We are proposing this change to be consistent with the criteria in other listings that evaluate intracranial bleeding (for example, listing 4.10D) and to recognize that improved diagnostic techniques can detect very minor bleeds that have no functional impact. We are placing this guidance in the preface, rather than retaining it as a listing criterion, as part of our effort to eliminate reference listings.

Proposed Listing 7.03B—Hemophilia

This listing and proposed listing 7.03C correspond to current listing 7.08, ''Coagulation defects (hemophilia or a similar disorder).'' We propose to separate hemophilia from other hypocoagulable disorders because, unlike those other disorders, current treatment for most individuals with hemophilia includes the use of prophylactic factor replacement. Consistent with this treatment, we propose to replace the requirement for transfusions with a criterion indicating that the bleeding occurs despite prophylactic factor replacement. We would also revise the frequency of bleeding episodes to be consistent with the changes in proposed listing 7.03A2.

Proposed Listing 7.03C—Other Hypocoagulable States (Such as von Willebrand's Disease, or Thrombasthenia)

In this listing, we propose criteria for evaluating hypocoagulable states other than hemophilia. We would change the

frequency of bleeding episodes to be consistent with other proposed listings. We would require hospitalization instead of transfusions to recognize that bleeding in these disorders may often be managed with other forms of treatment. Hospitalization is usually required when the bleeding cannot be easily controlled.

Proposed Listing 7.03D—Hypercoagulable States (Deficiency of Anti-coagulant Proteins Such as C, Protein S, And Anti-thrombin, or the Presence of Abnormal Proteins Such as Factor V Leiden)

We propose to add this listing to recognize that, for individuals with this disorder, thrombotic episodes are comparable to bleeding episodes in individuals who are hypocoagulable.

Proposed Listing 7.04—Aplastic Anemia, Myeloproliferative Disorders (Such as Polycythemia Vera or Myelofibrosis), or Myelodysplastic Syndrome

We propose to combine these disorders because, despite differing etiologies, the functional consequences are similar. This proposed listing incorporates current listings 7.09, ''Polycythemia vera,'' and 7.10, ''Myelofibrosis.''

In proposed listing 7.04A, we would revise the anemia criterion in current listing 7.10A and extend it to the other disorders in the listing. Current listing 7.10A contains a cross-reference to current listing 7.02A which, for the reasons explained above, we are proposing to delete. The proposed anemia criterion is ''repeated hemoglobin of 7.0 gm/dl or less despite prescribed therapy.''

In proposed listing 7.04B, we would revise the infection criterion in current listing 7.10B and extend it to the other disorders in this listing. We propose to require documentation of treatment with parenteral antimicrobial medication, the treatment given for systemic infections, to more clearly define a systemic infection. By using this type of treatment, which is also used to treat other types of systemic infections, such as viral or fungal infections, we are broadening the criterion to acknowledge that other types of systemic infections have the same impact as bacterial infections. We would also revise the frequency of treatment requirement to be consistent with other proposed listings.

As part of our efforts to eliminate reference listings, we propose to delete the criterion in current listing 7.09 that provides for the evaluation of the resulting impairment under the criteria for the affected body system. Instead, we provide general guidance to this effect in 7.00C(1). We also propose to delete the criterion in current listing 7.10C of intractable bone pain with radiologic evidence of osteosclerosis. This complication is very rare, and can be evaluated under the listings 1.00 ff., Musculoskeletal System.

Proposed Listing 7.05—Chronic Granulocytopenia (Due to Any Cause)

This listing corresponds to current listing 7.15. We propose three revisions to the criteria:

- Changing the required neutrophil counts from repeatedly below 1000/mm^3 to repeatedly below 500/mm^3. We propose this change because the incidence of infection increases significantly when the neutrophil count is below 500/mm^3. Some individuals whose neutrophil counts are 500/mm^3 or higher may still be limited or restricted, but many of these individuals will not be precluded from engaging in any gainful activity. Therefore, we will evaluate these individuals on a case-by-case basis.
- Changing the infection criterion in listing 7.05B to be consistent with proposed listing 7.04B.
- Changing the required frequency of treatment in listing 7.05B to be consistent with proposed listing 7.04B.

Proposed Listing 7.06—Non-Malignant Hematological Diseases Treated by Allogeneic Bone Marrow or Stem Cell Transplantation (see 7.00H)

We propose to revise the rule in current listing 7.17, ''Aplastic anemias or hematological malignancies (excluding acute leukemia),'' to recognize the increasing number of diseases treated by allogeneic bone marrow or stem cell transplantation. While the current rule does not specify allogeneic transplantation, it is the type of transplantation that is performed for the disorders evaluated under this body system. We are identifying the type of transplantation in the proposed rule for clarity.

Under this proposed listing, we would consider an individual disabled until at least 12 months from the date of transplantation. As with other proposed listings that use the phrase ''at least,'' there is leeway to establish a longer period when it is justified by the medical evidence. The proposed rule acknowledges the early uncertainty of the outcome, but recognizes that 12 months after the transplant an individual may have improved significantly.

How Are We Proposing to Change the Preface in the Listings for Evaluating Malignant Neoplastic Diseases in Adults?

13.00 Malignant Neoplastic Diseases

We propose to expand and reorganize the preface to these listings to provide additional guidance and reflect the new listings. The following is a detailed explanation of this proposed material.

Proposed 13.00A—What Impairments Do These Listings Cover?

In this new section, we explain that we use these listings to evaluate all malignant neoplasms except carcinoma of the cervix, Kaposi's sarcoma, lymphoma, and squamous cell carcinoma of the anus in individuals with HIV infection. We would continue to evaluate these impairments under listing 14.08E.

Proposed 13.00B—What Do We Consider When We Evaluate Malignant Neoplastic Diseases Under These Listings?

This section corresponds to current 13.00A, ''Introduction.'' For clarity, we propose to use ''origin of the malignancy'' instead of the current prefatory language, ''the site of the lesion, the histogenesis of the tumor.'' We also propose to change the phrase ''apparent adequacy and response to therapy'' in the current section to ''[r]esponse to antineoplastic therapy'' to eliminate any misunderstanding concerning who can make judgments about the appropriateness of the treatment regimen. ''Apparent adequacy'' was intended to mean effectiveness of the therapy. Judgments about its appropriateness must be left entirely to the claimant's treating source. We are adding the word ''antineoplastic'' to be consistent with the language in the listing criteria. We also are specifically identifying the types of antineoplastic therapy referred to in the listings.

Proposed 13.00C—How Do We Apply The Listings?

In this new section, we explain that, except for metastatic carcinoma to the brain or spinal cord (proposed listing 13.13C), we apply the listing criteria to a malignant neoplastic disease originating from the site addressed by the particular listing.

Proposed 13.00D—What Evidence Do We Need?

We propose to expand the guidance in current 13.00B, ''Documentation,'' by:

- Explaining that when the primary site cannot be identified, we will use

documentation of the site(s) of metastasis to evaluate the impairment under proposed listing 13.27.

• Clarifying that we consider biopsies and needle aspirations to be ''operative procedures.''

• Using the more general term ''pathology report'' instead of ''the report of the gross and microscopic examination of the surgical specimen.'' We are making this change to recognize that a report of the gross examination is not always required and to recognize that a microscopic examination of appropriate body fluids may be used as an alternative to the gross and microscopic examination of the surgical specimen.

Proposed 13.00E—When Do We Need Longitudinal Evidence?

We propose to incorporate and expand the guidance in the fourth paragraph of current 13.00C, ''Evaluation.'' We explain when we need longitudinal evidence, and the time period such evidence should cover. We also explain when we may need to defer adjudication.

Proposed 13.00F—How Do We Evaluate Impairments That do not Meet One of the Malignant Neoplastic Diseases Listings?

This paragraph corresponds to the first sentence in the second paragraph of current 13.00D, ''Effects of Therapy.'' We state our basic adjudicative principle that if the individual's impairment(s) does not meet or medically equal the requirements of a listing, we will continue the sequential evaluation process to determine whether or not the individual is disabled.

Proposed 13.00G—How Do We Consider the Effects of Therapy?

We propose to reorganize the guidance in current 13.00D, ''Effects of Therapy.'' We also propose to clarify that we will not delay adjudication to determine whether the therapy has achieved its intended effect if we can make a fully favorable determination or decision based on the evidence in the case record.

Proposed 13.00H—How Long Do We Consider the Individual Disabled?

We propose to incorporate and expand the guidance contained in the third paragraph of current 7.00E, ''Acute leukemia,'' and the fifth paragraph of current 13.00C, ''Evaluation.'' In some of the proposed listings, we specify that the impairment is considered disabling until a particular point in time. If an individual has an impairment(s) that meets or equals a listing in this body system that does not contain such a specification, we provide that we will consider that individual to be under a disability until at least 3 years after onset of complete remission. We also explain what we do when the appropriate time period has passed.

Proposed 13.00I—What Do These Terms in the Listings Mean?

We propose to replace the first two paragraphs and the first sentence of the third paragraph of current 13.00C, ''Evaluation,'' and provide additional definitions. The current section contains an adjudicative definition of ''distant metastases'' and ''metastases beyond the regional lymph nodes.'' We are not retaining this definition because our use of these terms in the proposed listings is consistent with current clinical practice.

In the proposed listings, we also differentiate between the terms ''inoperable'' and ''unresectable.'' With the proposed changes in the listing criteria, we would no longer need to define an unresectable tumor in terms of the nature of the surgery performed.

Proposed 13.00J—Can We Establish the Existence of a Disabling Impairment Prior to the Date of the Evidence That Shows the Malignancy Satisfies the Criteria of a Listing?

This section corresponds to current 13.00E, ''Onset.'' We propose no substantive changes.

Proposed 13.00K—How Do We Evaluate Specific Malignant Neoplastic Diseases?

We incorporate and clarify current 7.00E, ''Acute leukemia,'' the last sentence of the third paragraph in current 13.00C, ''Evaluation,'' and provide guidance for evaluating additional malignant neoplastic disorders. The following is a detailed discussion of the information provided for the disorders in this section.

Proposed 13.00K(1)—Lymphoma

In the first two paragraphs of this new section, we discuss the evaluation of indolent (non-aggressive) lymphomas. We explain that we will defer adjudication for an appropriate period after the initiation of therapy to determine whether the therapy will achieve its intended effect. We do not specify a particular time for this deferral because it will vary from case to case. We also provide a caution that changes in therapy based solely on patient or physician preference are not indicative of a failure to stabilize the disease. We also explain how the disease should be evaluated when stability has been achieved.

We have not retained the last sentence of the third paragraph of current 13.00C, ''Evaluation.'' This sentence states, ''In the evaluation of lymphomas, the tissue type and site of involvement are not necessarily indicators of the degree of impairment.'' We do not believe this guidance provides useful information for applying the criteria in proposed listing 13.05.

In the third paragraph we state that Hodgkin's disease that recurs more than 12 months after completing initial antineoplastic therapy will be evaluated as a new disease rather than as a recurrence.

Proposed 13.00K(2)—Leukemia

In paragraph (a), we expand the guidance in the first paragraph of current 7.00E, ''Acute leukemia,'' to indicate sources of additional diagnostic information. We also clarify the evidence needed to document recurrent disease by requiring one of the three laboratory findings named.

In paragraph (b), we provide guidance on documenting chronic myelogenous leukemia (CML). We have not included in this paragraph the guidance in the second paragraph of current 7.00E, which provides that the acute phase of CML should be considered under the requirements for acute leukemia. Instead, we have incorporated this guidance in proposed listing 13.06B1.

In paragraph (c), we provide guidance for documenting and evaluating chronic lymphocytic leukemia (CLL). Consistent with our effort to eliminate reference listings, this guidance incorporates the cross-references in current listing 7.12 that are appropriate for evaluating CLL.

In paragraph (d), we explain that in cases of chronic leukemia, an elevated white cell count, in itself, is not ordinarily a factor in determining the severity of the impairment.

Proposed 13.00K(3)—Macroglobulinemia or Heavy Chain Disease

This section replaces current listing 7.14, which is a reference listing. We propose no substantive changes in how we evaluate these disorders.

Proposed 13.00K(4)—Bilateral Primary Breast Cancer

We are clarifying the statement in current listing 13.09D, ''bilateral breast carcinoma, synchronous or metachronous is usually primary in each breast'' by removing the suggestion that there are exceptions to this rule.

Proposed 13.00K(5)—Carcinoma-in-situ

In this new section, we explain why this type of carcinoma is not included when ''carcinoma'' is used in these listings.

Proposed 13.00K(6)—Brain Tumors

In this new section, we explain that malignant tumors are evaluated under proposed listing 13.13 and benign tumors are evaluated under proposed listing 11.05. We also explain that we evaluate any complications of malignant brain tumors under the criteria for the affected body system.

Proposed 13.00L—How Do We Evaluate Malignant Neoplastic Diseases Treated by Bone Marrow or Stem Cell Transplantation?

In paragraphs (1) and (2) of this new section, we discuss how long we consider an individual disabled when that individual has leukemia, lymphoma, or multiple myeloma and undergoes bone marrow or stem cell transplantation.

In paragraph (3), we provide that all other malignant neoplastic diseases treated with bone marrow or stem cell transplantation must be evaluated under proposed listing 13.28, regardless of whether there is another listing that addresses that impairment. We explain that under proposed listing 13.28, how long we will consider the individual disabled depends on whether the individual has allogeneic or autologous transplantation. We define ''allogeneic'' and ''autologous,'' and discuss the criteria in proposed listing 13.28.

In paragraph (4), we discuss some of the factors we consider when we evaluate any residual impairment(s) that results from transplantation.

How Are We Proposing to Change the Criteria in the Listings for Evaluating Malignant Neoplastic Diseases in Adults?

13.01 Category of Impairments, Malignant Neoplastic Diseases

We propose to delete current listing 13.15, ''Abdomen,'' because this disorder can be evaluated under other proposed listings. Current listings 13.15A, ''Generalized carcinomatosis,'' and 13.15C, ''Ascites with demonstrated malignant cells,'' represent malignancies that have spread to the abdomen from another site. We would evaluate these conditions under proposed listing 13.27, ''Primary site unknown after appropriate search for primary.'' Current listing 13.15B, ''Retroperitoneal cellular sarcoma not controlled by prescribed therapy,'' would be evaluated under proposed listing 13.04, ''Soft tissue sarcoma.''

In the following proposed listings, we:

- Take into account medical advances in the detection, treatment, control and cure of malignant neoplastic diseases.
- Recognize that in some situations the effects of therapy for these disorders can be disabling.
- Provide for the evaluation of residual impairments.

The following is a detailed explanation of the proposed listing criteria.

Proposed Listing 13.02—Soft Tissue Tumors of the Head and Neck (Except Salivary Glands—13.06—and Thyroid Gland—13.07)

This listing corresponds to current listing 13.02, ''Head and neck.'' We propose to change the listing heading to ensure that only tumors of the soft tissue of the head and neck are considered under this listing. This change would allow us to delete the last two exceptions in the current heading (orbit or temporal fossa), as these are not soft tissue tumors.

Proposed listing 13.02A is substantively the same as current listing 13.02A. We propose to update the terminology to reflect the definitions used in the proposed listings.

In proposed listing 13.02B, which corresponds to current listing 13.02B, we propose to replace ''not controlled by prescribed therapy'' with ''[p]ersistent disease following initial multimodal antineoplastic therapy'' to clarify our intent.

Proposed listing 13.02C corresponds to current listing 13.02C. We propose to replace ''after radical surgery or irradiation'' with ''following initial antineoplastic therapy'' to recognize that other therapeutic modalities may be used. We also propose to exclude local vocal cord recurrences, because these recurrences have a good response to therapy.

Proposed listing 13.02D corresponds to current listing 13.02D. We propose no substantive change.

In proposed listing 13.02E, which corresponds to current listing 13.02E, we propose to delete the current criterion for epidermoid carcinoma in the posterior third of the tongue. Early-stage disease may be successfully treated. Later-stage disease can be assessed under the other criteria in this listing.

We propose to add the criterion in listing 13.02F to recognize the length and debilitating effects of multimodal treatment for head and neck tumors.

Proposed Listing 13.03—Skin

We propose to combine current listing 13.03, ''Sarcoma of skin,'' and current listing 13.05, ''Malignant melanoma,'' so that all malignancies originating in the skin are evaluated under this listing. Accordingly, we propose to revise the heading by removing the reference to sarcoma.

Proposed listing 13.03A corresponds to current listing 13.03A, ''Angiosarcoma with metastases to regional lymph nodes or beyond.'' We propose to expand the provision to include all skin sarcomas and carcinomas because other skin malignancies of the severity described would also be disabling.

Proposed listing 13.03B corresponds to current listing 13.05. We propose to clarify that an additional primary malignancy at a different site is not considered recurrent disease. We are also adding a criterion for palpable nodal metastases.

We propose to move current listing 13.03B, ''Mycosis fungoides'' (a type of lymphoma), to proposed listing 13.05, ''Lymphoma,'' so that all lymphomas will be evaluated under the same listing.

Proposed Listing 13.04—Soft Tissue Sarcoma

This listing proposes to update the heading of current listing 13.04, ''Sarcoma of soft parts,'' to recognize that ''soft tissue'' is a more common term than ''soft parts.'' We propose to add a criterion for regional or distant metastases, proposed listing 13.04A, to be consistent with the criteria for other malignant neoplastic diseases and to recognize the grave prognosis for these conditions. In proposed listing 13.04B, we define the current criterion ''not controlled by prescribed therapy'' similar to the way we defined it in other listings, such as proposed listing 13.02B.

Proposed Listing 13.05—Lymphoma (Including Mycosis Fungoides, but Excluding T-Cell Lymphoblastic Lymphoma—13.06)

This listing corresponds to current listing 13.06. We propose to change the heading from ''Lymph nodes'' to ''Lymphoma'' to more accurately reflect the disease. We provide that we will evaluate T-cell lymphoblastic lymphoma under the listing for acute leukemia. This is because the course, treatment, and outcome of this lymphoma are more similar to acute leukemia than to other lymphomas. We also provide a cross-reference to the explanatory paragraphs in proposed 13.00K(1).

We evaluate both Hodgkin's disease and non-Hodgkin's lymphoma under current listing 13.06A. We propose to separate and clarify the criteria for each of these diseases. Proposed listing 13.05A would provide criteria for evaluating non-Hodgkin's lymphoma; proposed listing 13.05B would provide criteria for Hodgkin's disease. For each of these disorders, we would also clarify the current criteria by replacing the phrase ''progressive disease not controlled by prescribed therapy'' in the current listing with clearer language.

In proposed listing 13.05C, we would provide that a lymphoma treated by bone marrow or stem cell transplantation is considered disabling until at least 12 months from the date of transplantation. After this period, we will evaluate any residual impairment(s) under the criteria for the affected body system.

We propose to delete current listing 13.06B, ''Metastatic carcinoma in a lymph node (except for epidermoid carcinoma in a lymph node in the neck) where the primary site is not determined after adequate search.'' We propose to evaluate this impairment under proposed listing 13.27, ''Primary site unknown after appropriate search for primary.'' We also propose to delete current listing 13.06C. We would evaluate epidermoid carcinoma in a lymph node in the neck under proposed listing 13.02, ''Soft tissue tumors of the head and neck.''

Proposed Listing 13.06—Leukemia

We propose to revise current listing 7.11, ''Acute leukemia,'' and current listing 7.12, ''Chronic leukemia.''

In proposed listing 13.06A, we provide that an individual with acute leukemia (including T-cell lymphoblastic lymphoma) will be considered under a disability until at least 24 months from the date of diagnosis or relapse, or at least 12 months from the date of bone marrow or stem cell transplantation, whichever is later. After the appropriate period, we will evaluate any residual impairment(s) under the criteria for the affected body system.

Under the current listing, we find an individual with acute leukemia disabled for 2½ years from the time of the initial diagnosis. We are proposing to shorten this period to 2 years because of improvement in the treatment of this disorder. However, as with other proposed listings, we provide that we would permit a longer period when the facts warrant it. We would also recognize that a relapse of acute leukemia is as significant as the initial diagnosis.

The criterion we propose for bone marrow or stem cell transplantation in cases of acute leukemia is similar to the proposed transplantation criteria for other diseases. Unlike those diseases, however, we would not reevaluate an individual with acute leukemia who undergoes bone marrow or stem cell transplantation 12 months after transplant if that date is earlier than 24 months after onset or relapse. We provide this option for this disease because of the disease course and the high rate of infection and other complications that occur in individuals with acute leukemia who undergo bone marrow or stem cell transplantation.

Proposed listing 13.06B, ''Chronic myelogenous leukemia,'' would replace current listing 7.12. The current listing is a reference listing. Rather than replace the entire listing with guidance in the preface, we propose to provide separate evaluation criteria for CML. Consistent with our guidance in the second paragraph of current 7.00E, the proposed criteria for the accelerated or blast phase of CML are the same as proposed listing 13.06A.

We propose to retain those references that are appropriate for evaluating chronic lymphocytic leukemia in 13.00K(2)(c).

Proposed Listing 13.07—Multiple Myeloma (Confirmed by Appropriate Serum or Urine Protein Electrophoresis and Bone Marrow Findings)

In this proposed listing, we delete the specific findings in current listing 7.16A–D and substitute the criterion ''[f]ailure to respond or progressive disease following initial antineoplastic therapy.'' Our intent is to clarify that this listing includes all listing-level manifestations of this disease. We also propose that an individual with multiple myeloma who undergoes bone marrow or stem cell transplantation will be considered disabled until at least 12 months from the date of transplantation. After that time, we will evaluate any residual impairment(s) under the criteria for the affected body system.

Proposed Listing 13.08—Salivary Glands

This listing corresponds to current listing 13.07. We propose no substantive changes.

Proposed Listing 13.09—Thyroid Gland

We propose to expand current listing 13.08 to include anaplastic (undifferentiated) carcinoma. This type of carcinoma has a very poor prognosis. We also propose to replace the term ''not controlled by prescribed therapy'' used in the current listing with ''progressive despite radioactive iodine therapy'' to clarify our intent.

Proposed Listing 13.10—Breast

This listing corresponds to current listing 13.09. In listing 13.10A, we propose to revise the criterion in current listing 13.09B, ''Inflammatory carcinoma,'' to include other types of locally advanced carcinoma.

In listing 13.10B, ''Carcinoma with distant metastases,'' we propose to revise current listing 13.09D by deleting the parenthetical statement ''bilateral breast carcinoma, synchronous or metachronous, is usually primary in each breast.'' Instead, we propose to provide guidance about evaluating bilateral breast cancer in proposed 13.00K(4). As indicated in our discussion of that section, we are clarifying this guidance by removing the suggestion that there are exceptions to this rule.

In proposed listing 13.10C, which would replace current listing 13.09C, we propose to replace the term ''controlled by prescribed therapy'' used in the current listing with ''that remits with antineoplastic therapy'' to clarify our intent.

We propose to delete current listing 13.09A, ''inoperable carcinoma,'' to avoid confusion about what this term means for this malignancy. We can evaluate cases in which breast cancer is inoperable under other criteria in the proposed listing. We also propose to delete current listing 13.09E, ''Sarcoma with metastases anywhere.'' We would evaluate this impairment under proposed listing 13.04, ''Soft tissue sarcoma.''

Proposed Listing 13.11—Skeletal System

This listing would replace current listing 13.10. We propose to expand the listing to include tumors of the mandible that are currently evaluated under listing 13.11. In proposed listings 13.11A, 13.11B, and 13.11C, we would revise current listing 13.10A to clarify when these tumors are of listing-level severity. In listing 13.11D, we propose to provide that we will consider all other malignant tumors originating in bone with multimodal antineoplastic therapy disabling until 12 months from the date of diagnosis. Consistent with the changes we have proposed for other listings, after that period, any residual impairment(s) would be evaluated under the criteria for the affected body system. With this criterion, we recognize the length and debilitating effects of multimodal treatment for these tumors.

Proposed Listing 13.12 Maxilla, Orbit, or Infratemporal Fossa

This listing corresponds to current listing 13.11. As noted above, we propose to evaluate tumors of the mandible under proposed listing 13.11. Proposed listings 13.12A and 13.12B correspond to current listings 13.11A and 13.11B and are substantively unchanged.

In proposed listing 13.12C, we consolidate the disease sites in current listings 13.11C, 13.11D, 13.11E, and 13.11F.

Proposed Listing 13.13—Nervous System

This listing incorporates the criteria for malignant brain tumors in current listing 11.05, ''Brain tumors,'' in the neurological body system, and replaces current listing 13.12, ''Brain or spinal cord.'' We propose to expand the listings to include tumors of the spinal cord, spinal nerve roots, and the peripheral nervous system. We also propose to include tumors of the central nervous system that are not specifically named.

Under listing 13.13A, we propose to evaluate central nervous system malignant neoplasms; that is, those affecting the brain or spinal cord. In proposed listing 13.13A1, we list and revise the criteria for the impairments named in current listing 11.05A. We propose to revise the reference to medulloblastoma to include other primitive neuroectodermal tumors (PNETs) and to require documented metastases for this type of tumor. Advances in treatment have significantly improved the overall prognosis of this disease, so that in the absence of metastases many individuals do well. We can evaluate medulloblastomas or other PNETs that have not metastasized, as well as the malignant brain tumors listed in current listing 11.05B, under proposed listing 13.13A2.

We also propose to add diffuse intrinsic brain stem gliomas in proposed listing 13.13A1. We are proposing to require that the impairment be ''diffuse'' and ''intrinsic'' because progress in medical diagnostic tools has now allowed for effective treatment of individuals with localized brain stem tumors.

In proposed listing 13.13B, we provide criteria for evaluating malignant tumors of peripheral nerves and spinal roots.

Proposed listing 13.13C, for metastatic carcinoma to the brain or spinal cord, is substantively the same as current listing 13.12A. We propose to clarify that this listing includes ''epidural metastases.''

We propose to delete current listing 13.12B, which provides cross-references to listings 11.05 and 11.08, as we have incorporated this guidance in the other sections of this proposed listing and 13.00K(6).

Proposed Listing 13.14—Lungs

This listing corresponds to current listing 13.13. In proposed listing 13.14A, we consolidate current listings 13.13A, 13.13B, 13.13D, and 13.13E. This change is consistent with current medical terminology, which no longer distinguishes between the types of non-small-cell carcinoma. We also propose to remove metastases to the hilar nodes from the listing criteria as metastases to the hilum can often be surgically excised.

We are redesignating current listing 13.13C as proposed listing 13.14B. We propose no substantive changes.

Proposed Listing 13.15—Pleura or Mediastinum

This listing corresponds to current listing 13.14. Proposed listing 13.15A is the same as current listing 13.14A. In proposed listing 13.15B, which corresponds to current listing 13.14C, we provide new language that would clarify the phrase ''not controlled by prescribed therapy'' used in the current listing.

We propose to delete current listing 13.14B, ''Malignant tumors, metastatic to pleura.'' This malignancy would be evaluated under proposed listing 13.27, ''Primary site unknown.''

Proposed Listing 13.16—Esophagus or Stomach

This listing corresponds to current listing 13.16. Proposed listing 13.16A is the same as current listing 13.16A. In proposed listing 13.16B, we would consolidate current listings 13.16B through 13.16E to clarify that all of those criteria relate to carcinoma or sarcoma of the stomach. We would also provide new language to clarify the phrase ''not controlled by prescribed therapy'' used in current listing 13.16C.

Proposed Listing 13.17—Small Intestine

This listing corresponds to current listing 13.17. In proposed listing 13.17A, we expand the criterion in current listing 13.17B, for recurrent malignancies, to indicate that inoperable and unresectable malignancies are also of listing-level severity. We would also provide new language to clarify the phrase ''not controlled by prescribed therapy'' used in current listing 13.17C. Proposed listing 13.17B corresponds to current listing 13.17A, and is substantively unchanged.

Proposed Listing 13.18—Large Intestine (From Ileocecal Valve to and Including Anal Canal)

This listing corresponds to current listing 13.18. We propose to delete the phrase ''carcinoma or sarcoma'' from the heading of this listing because sarcomas of the large intestine are extremely rare. In proposed listing 13.18A, we consolidate current listings 13.18A and 13.18C and clarify that these criteria apply to adenocarcinoma. In proposed listing 13.18B, we provide that squamous cell carcinoma of the anus will not be found to meet the listing unless it is recurrent after surgery. Advances in treatment have made chemotherapy and radiation the treatment of choice for this disorder. However, good results can be achieved through surgery if the preferred treatment is not effective. Proposed listing 13.18C is the same as current listing 13.18B.

Proposed Listing 13.19—Liver or Gallbladder

This listing corresponds to current listing 13.19. We propose to clarify that the listing applies only to malignancies that originate in the liver, gallbladder, or bile ducts. We will evaluate metastases to the liver from other sites under the criteria for the site of origin or under the criteria of proposed listing 13.27, when the primary site is unknown.

Proposed Listing 13.20—Pancreas

This listing corresponds to current listing 13.20. We are not proposing any changes, other than adding ''inoperable'' conditions to the second listing criterion. We would make this change to reflect the revised definitions used in these listings.

Proposed Listing 13.21—Kidneys, Adrenal Glands, or Ureters

This listing corresponds to current listing 13.21. In proposed listing 13.21A, we would expand the criteria to include inoperable and recurrent tumors. Proposed listing 13.21B consolidates current listings 13.21B and 13.21C. We propose to eliminate the modifier ''hematogenous'' used in current listing 13.21B because metastases by lymphatic spread or by direct extension carry the same poor prognosis.

Proposed Listing 13.22—Urinary Bladder

This listing corresponds to current listing 13.22. We propose to delete current listing 13.22E, which provides

for the evaluation of renal impairment following total cystectomy under the criteria in listing 6.02, because it is a reference listing.

Proposed Listing 13.23—Cancers of the Female Genital Tract

In this listing, we propose to incorporate and revise current listings 13.25, ''Uterus,'' 13.26, ''Ovaries,'' 13.28, ''Uterine (Fallopian) tubes, and 13.30, ''Vulva.''

In proposed listings 13.23A, ''Uterus (corpus),'' and 13.23B ''Uterine cervix,'' we would replace the current criteria in listings 13.25B, ''Recurrent after total hysterectomy,'' and 13.25C, ''Total pelvic exenteration,'' with ''Persistent or recurrent following initial antineoplastic therapy.'' With this revision, we recognize changes in treatment for these disorders. In proposed 13.23C, ''Vulva,'' we provide criteria in addition to the criteria for distant metastases used in the current listing.

In proposed 13.23D1, '' Extending to the serosa or beyond,'' we replace the criteria in current listings 13.28A, ''Unresectable,'' and 13.28B, ''Metastases to regional lymph nodes.'' Tumors extending to the serosa are considered to be unresectable for the purposes of this listing; tumors extending beyond the serosa equate to tumors that have metastasized to the regional lymph nodes. We also propose adding criteria to evaluate fallopian tube tumors when the initial antineoplastic therapy has not achieved the desired effect.

In proposed 13.23E, ''Ovaries,'' we propose to separate germ cell and non-germ cell tumors. In proposed 13.23E1, which provides the criteria for evaluating non-germ cell tumors, we would expand the criteria in current listing 13.26 to reflect advances in diagnostic techniques and treatment. We provide criteria for evaluating germ cell tumors in proposed listing 13.23E2.

Proposed Listing 13.24—Prostate Gland

In this listing, which corresponds to current listing 13.23, we propose to provide new language to clarify the phrase ''not controlled by prescribed therapy'' used in the current listing.

Proposed Listing 13.25—Testicles

This listing corresponds to current listing 13.24. We propose to delete current listing 13.24A, for choriocarcinoma, in recognition of advances in the treatment of this disease.

Proposed Listing 13.26—Penis

This listing corresponds to current listing 13.29. We have clarified the listing to explicitly include metastases to or beyond the regional lymph nodes.

Proposed Listing 13.27—Primary Site Unknown After Appropriate Search for Primary

We propose to provide for the evaluation of the occasional case in which metastases have been appropriately verified but the site of the primary malignancy cannot be determined. The proposed listing specifically excludes solitary squamous cell carcinoma in the neck, as this type of metastasis is often amenable to treatment.

Proposed Listing 13.28—Malignant Neoplastic Diseases Treated by Bone Marrow or Stem Cell Transplantation

In this listing, we propose to indicate how long we consider individuals who undergo bone marrow or stem cell transplantation disabled. The criterion for allogeneic transplantation, proposed listing 13.28A, is consistent with the criterion in proposed listing 7.06. This criterion states that we consider the individual disabled until at least 12 months from the date of transplantation. For autologous transplantation, we would consider the individual to be under a disability until at least 12 months from the date of the first treatment under the treatment plan that includes transplantation. We use an earlier date to begin the 12-month period for autologous transplantation because the recovery period after this type of transplantation is generally shorter than for allogeneic transplantation. In both cases, we will evaluate any residual impairment(s) after the applicable period under the criteria for the affected body system.

How Are We Proposing to Change the Preface in the Listings for Evaluating Hematological Disorders in Children?

107.00 Hematological Disorders

As in proposed 7.00 in the adult rules, we propose to change the name of this body system to ''Hematological Disorders'' and to move the guidance contained in current 107.00C, ''Acute leukemia,'' to proposed 113.00K(2)(a).

Except for minor changes to refer to children, we have repeated much of the preface of proposed 7.00 in the preface to proposed 107.00. This is because the same basic rules for establishing and evaluating the existence and severity of hematological impairments in adults also apply to children. Because we have already described these provisions under the explanation of proposed 7.00, the following discussions describe only those provisions that are unique to the childhood rules or that require further explanation.

Proposed 107.00C—How Do We Evaluate Impairments That Do Not Meet One of the Hematological Disorders Listings?

In this section, we use the definition of disability for children who claim SSI payments.

Proposed 107.00G—How Do We Evaluate Specific Hematological Disorders?

In this section, we incorporate and revise the guidance in current 107.00A, ''Sickle cell disease,'' and 107.00B, ''Coagulation defects,'' and provide guidance for evaluating additional hematological disorders in children. Proposed 107.00G(1), ''Anemia,'' 107.00G(3), ''Disorders of hemostasis,'' and 107.00G(4), ''Hematological malignancies,'' contain the same information as the adult sections that address these disorders.

Proposed 107.00G(2)—Hemolytic Anemias

Proposed 107.00G(2)(a)—Sickle Cell Disease or One of Its Variants

In proposed 107.00G(2)(a)(i), which is the same as proposed 7.00G(2), we incorporate and expand the guidance from the first two paragraphs of current 107.00A.

In proposed 107.00G(2)(a)(iv), we explain that, to meet the criterion in proposed listing 107.02A2, hospitalizations must be due to complications of sickle cell disease and that the most common complications requiring hospitalization are shown in the listing. However, we also provide that hospitalizations for complications other than the ones listed can be determined to be of equal clinical significance and thus be medically equal to the ones listed.

We propose to delete the guidance in the third and fourth paragraphs of current 107.00A. The third paragraph summarizes the listing criteria but provides no additional information on how to evaluate the disorder. The fourth paragraph lists examples of major visceral episodes, a criterion of current listing 107.05B, the current childhood listing for sickle cell disease. We propose to delete this criterion. We explain the reasons for this proposed deletion under the explanation of proposed listing 107.02A, the listing that corresponds to current listing 107.05B.

Proposed 107.00G(2)(b)—Thalassemia

In this new section, we propose to provide guidance on how to document this disorder. We discuss some of the residual impairments that result from this disorder and indicate that we evaluate these, or any other, residual impairments resulting from this disorder under the criteria for the affected body system.

Proposed 107.00G(2)(c)—Prophylactic Transfusion Programs

In this new section, we propose to explain why, for children on prophylactic transfusion programs, we will not use pre-transfusion hemoglobin values to determine if the child's sickle cell disease or thalessmia major meet the requirements of proposed listings 107.02A or 107.02B.

Proposed 107.00G(2)(d)—Chronic Iron Overload

In this section, which is similar to proposed 7.00G(5), we propose to provide that residuals from chronic iron overload due to chronic transfusion programs will be evaluated under the criteria for the affected body system. In proposed 7.00G(5), we include guidance on evaluating residuals from chronic iron overload due to hereditary hemochromatosis as well as chronic transfusion programs. We have not repeated the guidance on hereditary hemochromatosis in the childhood rules because residuals from this disorder are very rare in children. As the proposed childhood guidance addresses only residuals from chronic iron overload due to chronic transfusion programs, we believe it is appropriate to place this guidance in the same section as the guidance on prophlylactic transfusion programs, rather than in a separate section.

How Are We Proposing To Change the Criteria in the Listings for Evaluating Hematological Disorders in Children?

107.01 Category of Impairments, Hematological Disorders

We propose to move current listing 107.11, ''Acute leukemia,'' to the malignant neoplastic diseases body system (proposed listing 113.06). We also propose to add new listings 107.05, ''Chronic granulocytopenia (due to any cause),'' and 107.06, ''Non-malignant hematological diseases treated by allogeneic bone marrow or stem cell transplantation,'' because they are applicable to children as well as adults. We are not explaining these new listings here as they are identical to, and explained in, the corresponding adult listings. We also propose to renumber these listings to be consistent with the adult listings. Because of this, the numbers of the proposed childhood listings are not consecutive.

Proposed Listing 107.02—Anemia

In proposed listings 107.02A and 107.02B, we incorporate current listings 107.05, ''Sickle cell disease,'' and 107.03, ''Hemolytic anemia (due to any cause).'' In proposed listing 107.02C, we add criteria to evaluate aplastic anemia. We discuss the provisions of proposed listing 107.02 below.

Proposed Listing 107.02A—Sickle Cell Disease or One of Its Variants

Proposed listing 107.02A1, for documented painful vaso-occlusive crises, would replace current listing 107.05A. The proposed criteria provide more specificity and clarity than the criterion ''Recent, recurrent, severe'' used in the current listing. We also propose to delete the parenthetical list of examples of vaso-occlusive crises to avoid any confusion about the types of crises that can be considered.

Proposed listing 107.02A2 would replace current listing 107.05C and partially replace current listing 107.05B. Many children with sickle cell disease are hospitalized on a precautionary basis. To ensure that the hospitalizations considered under the listing are due to complications of the disease, and are not precautionary, we list the most common complications that result in hospitalizations. We provide, in proposed 107.00G(2)(a)(iv), that hospitalizations for other complications can be used to determine whether a complication medically equals the listings.

We propose to delete the criterion for a ''major visceral complication'' from current listing 107.05B and, as indicated above, to delete the fourth paragraph of current 107.00A which provides examples of ''major visceral episodes.'' If a major visceral episode results in hospitalization, we will consider it under proposed listing 107.02A2. If an episode results in another impairment(s), we will evaluate the residual impairment(s) under the criteria for the affected body system(s). However, the kinds of complications described in the fourth paragraph of current 107.00A, as well as those in current listing 107.05C, may be acute and resolve completely with treatment. The fact that a child has had one episode is not sufficient to establish that the child has been, or will be, disabled for a continuous period of at least 12 months.

Proposed listing 107.02A3, requiring chronic anemia, would revise the criterion in current listing 107.05D to reflect a more accurate measure of severity. The current criterion is a persistent hematocrit of 26 percent or less. A hematocrit at this level does not necessarily correlate with an impairment of listing-level severity.

Consistent with our changes in the adult rules, we would not retain the word ''severe'' used in current listing 107.05D in our proposed criterion for sickle cell disease with chronic anemia. We explain our reasons for deleting this word in our discussion of proposed listing 7.02.

Proposed Listing 107.02B—Other Hemolytic Anemias

In this listing, we propose to revise the criteria in current listing 107.03 to provide a more accurate measure of severity. Children whose hematocrit persists at 26 percent or less despite prescribed therapy will not necessarily have marked and severe functional limitations. Additionally, we propose to delete the requirement for reticulocyte counts since a reticulocyte count is not needed to determine whether the impairment is of listing-level severity and such counts may not be included in the laboratory findings.

Proposed Listing 107.02C—Aplastic Anemia

This listing contains the same criteria as proposed listing 7.04.

Proposed listing 107.03—Disorders of Hemostasis

For this listing, we use the same criteria as proposed listing 7.03. The following is a discussion of how these proposed criteria relate to the current criteria.

Proposed listing 107.03A, ''Chronic thrombocytopenia (due to any cause),'' replaces current listing 107.06, ''Chronic idiopathic thrombocytopenic purpura of childhood.'' The proposed criteria are more accurate measures of severity. The current criterion requires platelet counts of 40,000/mm^3 or less despite therapy or recurrent upon withdrawal of treatment, but platelet counts at this level will not necessarily result in marked and severe functional limitations. We would also delete the specification of thrombocytopenic purpura, broadening the listing to address chronic thrombocytopenia due to any cause.

Proposed listings 107.03B, ''Hemophilia,'' and 107.03C, ''Other hypocoagulable states (such as von Willebrand's disease or thrombasthenia),'' would replace current listing 107.08, ''Inherited coagulation disorder.'' The proposed criteria provide more specificity and

clarity than the criterion in current listing 107.08A, ''repeated spontaneous or inappropriate bleeding.'' We propose to move the criterion in current listing 107.08B, for hemarthrosis with joint deformity, to proposed 107.00G(3)(c). The current listing does not specify the level of joint deformity required. We propose to make it clear that only serious joint deformity resulting in listing-level functional deficit will constitute an impairment of listing-level severity. To do this, we propose that this complication be evaluated under current listing 101.02. Because this guidance would result in a reference listing, we are placing it in the preface.

How Are We Proposing To Change the Preface in the Listings for Evaluating Malignant Neoplastic Diseases in Children?

113.00 Malignant Neoplastic Diseases

We propose to delete the discussion in current 113.00C, ''Malignant solid tumors,'' for the following reasons:

- We are proposing to delete current listing 113.03, the general listing for malignant solid tumors. We provide the reason for this deletion in the discussion of 113.01.
- We are proposing to incorporate the guidance about the evaluation of thyroid tumors in the second sentence of current 113.00C in proposed listing 113.09.
- We are proposing to move the criteria for evaluating malignant brain tumors to this body system. Therefore, we would no longer need the reference to current listing 111.05.

As we explained in the discussion of 107.00, we have, with the exception of minor changes to refer to children, repeated much of the preface of proposed 13.00 in the preface to proposed 113.00. Because we have already described these provisions under the explanation of proposed 13.00, the following discussions describe only those provisions that are unique to the childhood rules or that require further explanation.

Proposed 113.00B—What Do We Consider When We Evaluate Malignant Neoplastic Diseases Under These Listings?

In this section, which is the same as proposed 13.00B, we replace the guidance in current 113.00A1.

Proposed 113.00D—What Evidence Do We Need?

In this section, we replace and expand current 113.00B. This section is the same as proposed 13.00D, except that we have deleted the guidance about what we need when the primary site cannot be identified. We are not proposing a childhood listing to correspond to proposed listing 13.27, primary site unknown, because the inability to determine the primary site is an extremely rare occurrence in childhood malignancies. In these rare situations, we would use proposed listing 13.27.

Proposed 113.00E—When Do We Need Longitudinal Evidence?

This section is similar to proposed 13.00E. We are adding a general description of most malignant childhood tumors.

Proposed 113.00F—How Do We Evaluate Impairments That Do Not Meet One of the Malignant Neoplastic Diseases Listings?

In this section, we repeat the guidance in proposed 13.00F but use the definition of disability for children who claim SSI payments.

Proposed 113.00G—How Do We Consider the Effects of Therapy?

This section would replace current 113.00A2 and the last paragraph of 113.00A. We repeat the guidance in proposed 13.00G but use the definition of disability for children who claim SSI payments.

Proposed 113.00H—How Long Do We Consider the Child Disabled?

This section would replace current 113.00D, ''Duration of disability,'' which refers to the periods of disability included in current listings 113.02 and 113.03. Although we do not cite specific listings in the proposed rule, we indicate that some listings specify that the impairment should be considered disabling until a particular point in time. In proposed 113.00H(2) we also state that when the listing does not contain such a specification, we will find a child whose impairment meets or medically equals the listings in this body system to be under a disability until at least 3 years after onset of complete remission. We propose this to ensure consistency between the adult and childhood rules.

Proposed 113.00K—How Do We Evaluate Specific Malignant Neoplastic Diseases?

In this section, we incorporate the discussion in current 107.00C, ''Acute leukemia,'' and provide guidance for other childhood malignancies. Except for minor changes to refer to children, proposed 113.00K(3), ''Brain Tumors,'' is the same as the proposed 13.00K(6). The following discussions of lymphoma and leukemia reflect criteria we are proposing specifically for the evaluation of these malignancies in children.

Proposed 113.00K(1)—Lymphoma

In this section we indicate that proposed listing 113.05 should not be used for evaluating low grade or indolent lymphomas because they are rare in children. We would evaluate these lymphomas under proposed listing 13.05. We also provide a reminder to consider the duration and effects of long-term protocols used to treat lymphoma.

Proposed 113.00K(2)—Leukemia

Proposed 113.00K(2)(a), ''Acute leukemia,'' is the same as proposed 13.00K(2)(a).

Proposed 113.00K(2)(b), ''Chronic myelogenous leukemia (CML),'' is the same as proposed 13.00K(2)(b).

In proposed 113.00K(2)(c), we provide a description of juvenile CML (JCML).

Proposed 113.00K(2)(d) is similar to proposed 13.00K(2)(d). We did not repeat the reference to chronic lymphocytic leukemia in proposed 13.00K(2)(c) because the disorder is extremely rare in children.

Proposed 113.00L—How Do We Evaluate Malignant Neoplastic Diseases Treated by Bone Marrow or Stem Cell Transplantation?

In this section, we provide the same guidance as in proposed 13.00L, but we do not refer to multiple myeloma because this impairment is not included in the proposed childhood listings.

How Are We Proposing To Change the Criteria in the Listings for Evaluating Malignant Neoplastic Diseases in Children?

113.01 Category of Impairments, Malignant Neoplastic Diseases

We propose to delete current listing 113.03, ''Malignant solid tumors.'' Instead, we propose to provide separate listings for specific types of malignant solid tumors, such as soft tissue sarcoma (proposed listing 113.04), osteogenic sarcoma (proposed listing 113.11), and Wilms' tumor (proposed listing 113.21B). Due to advances in treatment, all malignant solid tumors in children do not necessarily result in listing-level severity. We would evaluate any malignant solid tumor not listed in these proposed rules on a case-by-case basis.

We propose to renumber the childhood listings to maintain consistency with the adult rules for those malignancies that are addressed in both the adult and childhood rules. Because of this, the numbers of the

proposed childhood listings are not consecutive.

Proposed Listing 113.04—Soft Tissue Sarcoma (Including Ewing's Sarcoma, Primitive Neuroectodermal Tumor (PNET)

In proposed listing 113.04A, we provide for a finding of disability for at least 12 months from the date of diagnosis for any localized tumor with or without metastases. With this provision, we would recognize the duration and debilitating effects of the treatment for this malignancy in children. In proposed listing 113.04B, we provide for a finding of disability when treatment has not been effective.

Proposed Listing 113.05—Lymphoma (Excluding T-cell Lymphoblastic Lymphoma—113.06)

This listing corresponds to current listing 113.02, ''Lymphoreticular malignant neoplasms.'' We propose to revise the listing to make it more consistent with proposed listing 13.05. In the discussion of the proposed adult listing above, we explain why we evaluate T-cell lymphocytic lymphoma under the criteria for leukemia.

Proposed listing 113.05A would replace the criteria for Non-Hodgkin's lymphoma in current listing 113.02B. Currently, there are several treatment regimens for this disease, and they vary in the amount of time needed to complete them. Many are of sufficiently short duration that the period of time the child has an impairment of listing-level severity is usually less than 12 months. Due to these advances in treatment, it is no longer appropriate to presume that the impairment will meet the statutory duration requirement. Instead, we propose to find a child disabled when treatment has not been effective.

Proposed listing 113.05B would replace the criteria for Hodgkin's disease in current listing 113.02A. With the proposed criterion, we clarify what we mean by ''progressive disease not controlled by prescribed therapy'' in the current listing.

In proposed listing 113.05C, we would add a criterion for bone marrow or stem cell transplantation.

Proposed 113.06—Leukemia

This listing would replace current listing 107.11, ''Acute leukemia.'' In proposed listing 113.06A, ''Acute leukemia,'' we also include T-cell lymphoblastic lymphoma and JCML. JCML is an aggressive leukemia that responds poorly to therapy and is, therefore, more appropriately evaluated like an acute leukemia. The criteria in this listing are the same as in proposed listing 13.06A, and are explained in the discussion of that listing.

In proposed listing 113.06B, which is the same as proposed listing 13.06B, we would add criteria for evaluating CML, other than JCML.

Proposed Listing 113.09—Thyroid Gland

This listing is the same as proposed adult listing 13.09 and would incorporate the guidance contained in current 113.00C. The listing criteria define when the malignancy is not controlled by prescribed therapy.

Proposed Listing 113.10—Retinoblastoma

This proposed listing would revise current listing 113.05. We propose to delete current listing 113.05A, for bilateral involvement, because with advances in treatment this condition is often treated successfully. If treatment is not successful, we will evaluate the impairment under the other criteria in the proposed listing.

Proposed listing 113.10A corresponds to current listing 113.05C. We propose no substantive changes.

Proposed listing 113.10B corresponds to current listing 113.10D. We propose to revise the criteria to recognize that persistence after treatment, as well as recurrence, indicates a poor prognosis.

Proposed listing 113.10C corresponds to current listing 113.05B. We propose to revise the description to make it clear that any metastatic disease is included under the listing.

Proposed 113.11—Osteogenic Sarcoma

This listing is the same as proposed listing 13.11 except that we propose to limit the listing to ''osteogenic sarcoma'' instead of the broader category used in proposed listing 13.11 because other bone tumors are extremely rare in children.

Proposed 113.13—Nervous System

This listing would revise the criteria for malignant brain tumors in current listing 111.05, ''Brain tumors.'' We propose to use the same criteria as proposed listing 13.13.

Proposed Listing 113.21—Kidneys and Adrenal Glands

Proposed listing 113.21A would revise current listing 113.04, ''Neuroblastoma,'' to reflect the present evaluation and treatment of this condition.

Proposed listing 113.21B adds criteria for evaluating Wilms' tumor.

Proposed Listing 113.25—Testicles

This listing is the same as proposed listing 13.25.

Proposed Listing 113.26—Germ Cell Tumors

In this listing, we provide criteria for evaluating these malignancies.

Proposed Listing 113.28—Malignant Neoplastic Diseases Treated by Bone Marrow or Stem Cell Transplantation

This listing is the same as proposed listing 13.28.

What Other Revisions Are We Proposing?

Consistent with the proposed changes explained above, we also propose to:

- Revise current 11.00B to indicate that malignant brain tumors should be evaluated under the criteria in listing 13.13.
- Add 111.00E to provide the same guidance as proposed 11.00B.
- Revise current listings 11.05 and 111.05 by removing the criteria for malignant brain tumors.
- Revise the cross-references in current listings 14.08G and 114.08G to reflect the numbers in the proposed hematological disorders listings.

Clarity of These Proposed Rules

Executive Order 12866 and the President's memorandum of June 1, 1998 (63 FR 31885) require each agency to write all rules in plain language. In addition to your substantive comments on these proposed rules, we invite your comments on how to make these proposed rules easier to understand.

For example:

- Have we organized the material to suit your needs?
- Are the requirements in the rules clearly stated?
- Do the rules contain technical language or jargon that isn't clear?
- Would a different format (grouping and order of sections, use of headings, paragraphing) make the rules easier to understand?
- Would more (but shorter) sections be better?
- Could we improve clarity by adding tables, lists, or diagrams?
- What else could we do to make the rules easier to understand?

Regulatory Procedures

Executive Order 12866

The Office of Management and Budget (OMB) has reviewed these proposed rules in accordance with Executive Order 12866.

Regulatory Flexibility Act

We certify that these proposed rules would not have a significant economic impact on a substantial number of small entities because they would affect only individuals. Thus, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

Paperwork Reduction Act

These proposed rules contain reporting requirements at 7.00A, 7.00B, 7.00D, 7.00E, 7.00G, 7.02, 7.03, 7.04, 7.05, 13.00B, 13.00D, 13.00E, 13.00G, 13.00K, 107.00A, 107.00B, 107.00D, 107.00E, 107.00G, 107.02, 107.03, 107.05, 113.00B, 113.00D, 113.00E, 113.00G, and 113.00K. The public reporting burden is accounted for in the Information Collection Requests for the various forms that the public uses to submit the information to SSA. Consequently, a 1-hour placeholder burden is being assigned to the specific reporting requirement(s) contained in these rules. We are seeking clearance of the burdens referenced in these rules because they were not considered during the clearance of the forms. An Information Collection Request has been submitted to OMB. We are soliciting comments on the burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility and clarity; and on ways to minimize the burden on respondents, including the use of automated collection techniques or other forms of information technology. Comments should be submitted to the Social Security Administration at the following address:

Social Security Administration, Attn: SSA Reports Clearance Officer, Rm. 1–A–20, Operations Building, 6401 Security Boulevard, Baltimore, MD 21235–6401

Comments can be received for between 30 and 60 days after publication of this notice and will be most useful if received by SSA within 30 days of publication.

(Catalog of Federal Domestic Program Nos. 96.001, Social Security-Disability Insurance; 96.002, Social Security-Retirement Insurance; 96.004, Social Security-Survivors Insurance; and 96.006, Supplemental Security Income)

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-Age, Survivors, and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

Dated: November 8, 2001.

Larry G. Massanari,

Acting Commissioner of Social Security.

For the reasons set forth in the preamble, we propose to amend chapter III of title 20 of the Code of Federal Regulations as set forth below:

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950–)

1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205(a), (b), and (d)–(h), 216(i), 221(a) and (i), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a), (b), and (d)–(h), 416(i), 421(a) and (i), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189.

Appendix 1 to Subpart P of Part 404—[Amended]

2. Appendix 1 to subpart P of part 404 is amended as follows:

a. Items 8 and 14 of the introductory text before part A are revised.

b. The Table of Contents for part A is amended by revising the body system names for sections 7.00 and 13.00.

c. Section 7.00 of part A is revised.

d. Paragraph B of the introductory text of section 11.00, Neurological, of part A is revised.

e. Listing 11.05 of part A is revised.

f. Section 13.00 of part A is revised.

g. Listing 14.08G of part A is revised.

h. The Table of Contents for part B is amended by revising the body system names for sections 107.00 and 113.00.

i. Section 107.00 of part B is revised.

j. Section 111.00E is added to part B.

k. Listing 111.05 of part B is revised.

l. Section 113.00 of part B is revised.

m. Listing 114.08G of part B is revised.

The revised text is set forth as follows:

Appendix 1 to Subpart P of Part 404–Listing of Impairments

* * * * *

8. Hematological disorders (7.00 and 107.00): (*insert date 5 years from the effective date of the final rules*).

* * * * *

14. Malignant Neoplastic Diseases (13.00 and 113.00): (*insert date 5 years from the effective date of the final rules*).

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Part A

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7.00 Hematological Disorders

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13.00 Malignant Neoplastic Diseases

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7.00 Hematological Disorders

A. What do we Consider when we Evaluate Hematological Disorders Under These Listings?

We consider factors such as the:

(1) Type of disorder.

(2) Response to therapy.

(3) Side effects of therapy.

(4) Effects of any post-therapeutic residuals.

(5) Degree of limitation the disorder imposes on the individual.

(6) Expected duration.

B. What Documentation do we Need?

(1) We generally need a longitudinal clinical record covering a period of at least 3 months of observations and treatment, unless we can make a fully favorable determination or decision without it. The record should include laboratory findings, such as hemoglobin values or platelet counts, obtained on more than one examination over the 3-month period.

(2) Any longitudinal clinical record should also include a description of the therapy prescribed by the treating source and the individual's response to treatment, because medical management may improve functional status. The longitudinal record should provide information regarding functional recovery, if any.

(3) Even when an individual does not receive ongoing treatment or have an ongoing relationship with a medical source, it is important to obtain evidence from relevant sources over a sufficient period. Such evidence may provide information about the:

(a) Ongoing medical severity of the impairment.

(b) Frequency, severity, and duration of symptoms.

(c) Level of the individual's functioning.

C. How Do We Evaluate Impairments That Do Not Meet one of the Hematological Disorders Listings?

(1) These listings are only examples of common hematological disorders that we consider severe enough to prevent an individual from doing any gainful activity. If the individual's impairment(s) does not meet the criteria of any of these listings, we must also consider whether the individual has an impairment(s) that satisfies the criteria of a listing in another body system.

(2) If an individual has a medically determinable impairment(s) that does not meet a listing, we will determine whether the impairment(s) medically equals the listings. (See §§ 404.1526 and 416.926.) An individual who has an impairment(s) that does not meet or medically equal the listings may or may not have the residual functional capacity to engage in substantial gainful activity. For such an individual, we proceed to the fourth, and if necessary, the fifth steps of the sequential evaluation process in §§ 404.1520 and 416.920. When we decide whether an adult continues to be disabled, we use the rules in §§ 404.1594 and 416.994.

D. How Do We Assess the Effectiveness of Treatment?

(1) We assess the effectiveness of treatment by seeing if there is improvement in the

signs, symptoms, and laboratory findings of the disorder, and if there are side effects that may result in functional limitations in the individual. Because the response to treatment and adverse consequences of treatment may vary widely, we consider each case on an individual basis.

(2) We will request a specific description of the:

(a) Drugs or treatment given.

(b) Dosage, method, and frequency of administration.

(3) We will also request a description of the complications or adverse effects of treatment, such as the following:

(a) Continuing gastrointestinal symptoms.

(b) Persistent weakness.

(c) Neurological complications.

(d) Cardiovascular complications.

(e) Reactive mental disorders.

(4) Because the effects of treatment may be temporary, enough time must pass to allow us to evaluate the impact of treatment.

E. How Do We Evaluate Episodic Hematological Disorders?

Some hematological disorders listings are met when a specified number of events have occurred within a specified time period, such as 3 events within a consecutive 12-month period. Events include pain crises, hospitalizations, treatment with parenteral antimicrobial medication, bleeding episodes, and thromboses. When we use such criteria, the period specified in the listing (either 6 months or 12 months) must occur within the period we are considering in connection with an application or continuing disability review. In every listing in which we require more than one event, there must be at least 1 month between the events, in order to ensure that we are evaluating separate episodes.

F. What Do These Terms in the Listings Mean?

(1) *Persistent:* The longitudinal clinical record shows that, with few exceptions, the hemoglobin level has been at or below, or is expected to be at or below, the level specified in the listing for a continuous period of at least 12 months.

(2) *Repeated, repeatedly:* The longitudinal clinical record shows that the platelet count, neutrophil count, or hemoglobin level, as appropriate, satisfies the criteria in the listing most of the time, and that pattern has lasted or is expected to last for a continuous period of at least 12 months.

G. How Do We Evaluate Specific Hematological Disorders?

(1) *Anemia.* Anemia refers to decreased oxygen-carrying capacity of the blood and is usually measured as a decrease in hemoglobin concentration. A gradual reduction in hemoglobin, even to very low levels, is often well tolerated in individuals with normal cardiovascular and pulmonary systems. We generally evaluate the effects of chronic anemia under the criteria for the underlying disorder or for the affected body system. However, we include listings for sickle cell disease or one of its variants and aplastic anemia because of their specific manifestations.

(2) *Sickle cell disease or one of its variants.* (a) Sickle cell disease is a chronic hemolytic anemia in which the abnormal sickle cell hemoglobin may be either homozygous or in combination with thalassemia or with another abnormal hemoglobin. The diagnosis of sickle cell disease or one of its variants should be based on appropriate hematological evidence, such as hemoglobin electrophoresis. We accept medical evidence that is persuasive that a positive diagnosis of sickle cell disease or one of its variants has been confirmed by appropriate laboratory testing at some time prior to evaluation in lieu of a copy of the actual laboratory report.

(b) We will document the intensity, frequency, duration, and response to treatment of vaso-occlusive or aplastic episodes.

(c) Parenteral medication as required under 7.02A does not include hydration.

(3) *Disorders of hemostasis.* (a) ''Disorders of hemostasis'' refers to abnormalities in the ability of the blood to clot. These disorders must be documented by appropriate laboratory evidence, including platelet counts and evaluation of plasma clotting factors such as Factor VIII or Factor V Leiden.

(b) We will document the frequency, severity, and treatment of bleeding episodes or thromboses. Prophylactic therapy, such as factor concentrates or antithrombotic agents, does not, by itself, indicate any specific degree of severity.

(c) We must consider complications such as development of inhibitors against clotting factors, intrusiveness of treatment, and limitation of function. We must also consider effects on other body systems. For example, we will evaluate hemarthrosis with joint deformity under 1.02, and intracranial bleeding under 11.04.

(4) *Hematological malignancies.* With the exception of lymphoma associated with human immunodeficiency virus (HIV) infection, we use the guidance in 13.00K(3) (Macroglobulinemia or heavy chain disease) or the criteria in 13.05 (Lymphoma), 13.06 (Leukemia), 13.07 (Multiple myeloma), or 13.28 (Malignant neoplastic diseases treated by bone marrow or stem cell transplantation) to evaluate hematological malignancies. We evaluate lymphoma associated with HIV infection under the criteria in 14.08E.

(5) *Chronic iron overload.* Chronic iron overload resulting from hereditary hemochromatosis, a genetic disorder of excessive absorption of dietary iron, is usually treated by iron removal through repeated phlebotomy. Chronic iron overload resulting from repeated red blood cell transfusion (transfusion hemosiderosis) is generally treated with iron chelation therapy. We evaluate residuals of this impairment under the criteria for the affected body system, such as cardiovascular or digestive.

H. How Do We Evaluate Non-Malignant Hematological Disorders Treated by Allogeneic Bone Marrow or Stem Cell Transplantation?

Allogeneic bone marrow or stem cell transplantation (transplantation from an unrelated donor or a related donor other than an identical twin) is performed for a variety of non-malignant hematological diseases, such as sickle cell disease and aplastic anemia. We will evaluate any non-malignant hematological disorder that is treated with allogeneic bone marrow or stem cell transplantation under 7.06, regardless of whether there is another listing that addresses that impairment. Under 7.06, we consider an individual disabled until at least 12 months from the date of transplantation. Thereafter, for purposes of evaluating disability, we consider any residual impairment(s), such as complications arising from:

(1) Graft-versus-host (GVH) disease.

(2) Immunosuppressive therapy, such as frequent infections.

(3) Significant deterioration of other organ systems.

7.01 Category of Impairments, Hematological Disorders

7.02 *Sickle cell disease or one of its variants,* with one of the following:

A. Documented painful (vaso-occlusive) crises requiring parenteral medication, occurring at least 3 times in a consecutive 6-month period (see 7.00E).

OR

B. Hospitalization (for 24 hours or more) for sickle cell related diseases, occurring at least 3 times in a consecutive 12-month period (see 7.00E).

OR

C. Chronic anemia manifested by persistent hemoglobin of 7.0 gm/dl or less despite prescribed therapy (see 7.00F).

7.03 *Disorders of hemostasis.*

A. Chronic thrombocytopenia (due to any cause), with either 1 or 2:

1. Platelet counts repeatedly below 10,000/mm3 despite prescribed therapy (see 7.00F).

2. Platelet counts repeatedly below 20,000/mm3 and spontaneous bleeding despite prescribed therapy, requiring red cell or platelet transfusion at least 3 times in a consecutive 12-month period (see 7.00E, 7.00F). Consider under a disability for 12 months from the date of the last transfusion. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

OR

B. Hemophilia with spontaneous bleeding despite prophylactic factor replacement, occurring at least 3 times in a consecutive 12-month period (see 7.00E).

OR

C. Other hypocoagulable states (such as von Willebrand's disease or thrombasthenia) with spontaneous bleeding requiring hospitalization (for 24 hours or more), occurring at least 3 times in a consecutive 12-month period (see 7.00E).

OR

D. Hypercoagulable states (deficiency of anti-coagulant proteins such as protein C, protein S, and antithrombin, or the presence of abnormal proteins such as Factor V Leiden) with documented thromboses occurring at least 3 times in a consecutive 12-month period (see 7.00E).

7.04 *Aplastic anemia, myeloproliferative disorders (such as polycythemia vera or myelofibrosis), or myelodysplastic syndrome* with:

A. Chronic anemia manifested by repeated hemoglobin of 7.0 gm/dl or less despite prescribed therapy (see 7.00F).

OR

B. Documented treatment with parenteral antimicrobial medication occurring at least 3 times in a consecutive 12-month period (see 7.00E).

7.05 *Chronic granulocytopenia* (due to any cause), with both A and B:

A. Absolute neutrophil counts repeatedly below 500/mm3 (see 7.00F).

AND

B. Documented treatment with parenteral antimicrobial medication occurring at least 3 times in a consecutive 12-month period (see 7.00E).

7.06 *Non-malignant hematological diseases treated by allogeneic bone marrow or stem cell transplantation (see 7.00H).* Consider under a disability until at least 12 months from the date of transplantation. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

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11.00 NEUROLOGICAL

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B. *Brain tumors.* We evaluate malignant brain tumors under the criteria in 13.13. For benign brain tumors, we determine the severity and duration of the impairment on the basis of symptoms, signs, and laboratory findings (11.05).

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11.05 *Benign brain tumors.* Evaluate under 11.02, 11.03, 11.04A or B, or 12.02.

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13.00 MALIGNANT NEOPLASTIC DISEASES

A. *What impairments do these listings cover?* We use these listings to evaluate all malignant neoplasms except certain neoplasms associated wih human immunodeficiency virus (HIV) infection. We use the criteria in 14.08E to evaluate carcinoma of the cervix, Kaposi's sarcoma, lymphoma, and squamous cell carcinoma of the anus in individuals with HIV infection.

B. *What do we consider when we evaluate malignant neoplastic diseases under these listings?* We consider factors such as the:

(1) Origin of the malignancy.

(2) Extent of involvement.

(3) Duration, frequency, and response to antineoplastic therapy. Antineoplastic therapy means surgery, irradiation, chemotherapy, hormones, immunotherapy, or bone marrow or stem cell transplantation. When we refer to surgery as an antineoplastic treatment, we mean surgical excision for treatment, not for diagnostic purposes.

(4) Effects of any post-therapeutic residuals.

C. *How do we apply these listings?* Except for metastatic carcinoma to the brain or spinal cord (13.13C), we apply the criteria in a specific listing to a malignancy originating from that specific site.

D. *What evidence do we need?* (1) We need medical evidence that specifies the type, extent, and site of the primary, recurrent, or metastatic lesion. When the primary site cannot be identified, we will use evidence documenting the site(s) of metastasis to evaluate the impairment under 13.27.

(2) For operative procedures, including a biopsy or a needle aspiration, we need a copy of both the:

(a) Operative note.

(b) Pathology report.

(3) When we cannot get these documents, we will accept the summary of hospitalization(s) or other medical reports. This evidence should include details of the findings at surgery and, whenever appropriate, the pathological findings.

(4) In some situations we may also need evidence about recurrence, persistence, or progression of the malignancy, the response to therapy, and any significant residuals. (See 13.00G.)

E. *When do we need longitudinal evidence?* (1) *Tumors with distant metastases.* We generally do not need longitudinal evidence for tumors that have metastasized beyond the regional lymph nodes because these tumors usually meet the requirements of a listing. Exceptions are for tumors with distant metastases that are expected to respond to antineoplastic therapy. For these exceptions, we usually need a longitudinal record of 3 months after therapy starts to determine whether the intended effect of therapy has been achieved and is likely to persist.

(2) *Other malignancies.* When there are no distant metastases, many of the listings require that we consider the individual's response to initial antineoplastic therapy; that is, the initial planned treatment regimen. This therapy may consist of a single modality or a combination of modalities (multimodal) given in close proximity as a unified whole, and is usually planned before any treatment(s) is initiated. Examples of multimodal therapy include:

(a) Surgery followed by chemotherapy or radiation.

(b) Chemotherapy followed by surgery.

(c) Chemotherapy and concurrent radiation.

(3) *Types of treatment.* Whenever the initial planned therapy is a single modality, enough time must pass to allow a determination about whether the therapy will achieve its intended effect. If the treatment fails, it will often happen within 6 months after it starts, and there will often be a change in the treatment regimen. Whenever the initial planned therapy is multimodal, a determination about the effectiveness of the therapy usually cannot be made until the effects of all the planned modalities can be determined. In some cases, we may need to defer adjudication until the effectiveness of therapy can be assessed. However, we do not need to defer adjudication to determine whether the therapy will achieve its intended effect if we can make a fully favorable determination or decision based on the length and effects of therapy, or the residuals of the malignancy or therapy (see 13.00G).

F. *How do we evaluate impairments that do not meet one of the Malignant Neoplastic Diseases listings?*

(1) These listings are only examples of malignant neoplastic diseases that we consider severe enough to prevent an individual from engaging in any gainful activity. If the individual's impairment(s) does not meet the criteria of any of these listings, we must also consider whether the individual has an impairment(s) that satisfies the criteria of a listing in another body system.

(2) If an individual has a medically determinable impairment(s) that does not meet a listing, we will determine whether the impairment(s) medically equals the listings. (See §§ 404.1526 and 416.926.) An individual who has an impairment(s) that does not meet or medically equal the listings may or may not have the residual functional capacity to engage in substantial gainful activity. For such an individual, we proceed to the fourth, and if necessary, the fifth steps of the sequential evaluation process in §§ 404.1520 and 416.920. When we decide whether an adult continues to be disabled, we use the rules in §§ 404.1594 and 416.994.

G. *How do we consider the effects of therapy?* (1) *How we consider the effects of therapy under the listings.* In many cases, malignancies meet listing criteria only if the therapy does not achieve the intended effect: the malignancy persists, progresses, or recurs despite treatment. However, as explained in the following paragraphs, we will not delay adjudication if we can make a fully favorable determination or decision based on the evidence in the case record.

(2) *Effects can vary widely.* (a) Because the therapy and its toxicity may vary widely, we consider each case on an individual basis. We will request a specific description of the therapy, including these items:

(i) Drugs given.

(ii) Dosage.

(iii) Frequency of drug administration.

(iv) Plans for continued drug administration.

(v) Extent of surgery.

(vi) Schedule and fields of radiation therapy.

(b) We will also request a description of the complications or adverse effects of therapy, such as the following:

(i) Continuing gastrointestinal symptoms.

(ii) Persistent weakness.

(iii) Neurological complications.

(iv) Cardiovascular complications.

(v) Reactive mental disorders.

(3) *Effects of therapy may change.* Because the severity of the adverse effects of antineoplastic therapy may change during treatment, enough time must pass to allow us to evaluate the therapy's effect. The residual effects of treatment are temporary in most instances. But, on occasion, the effects may be disabling for a consecutive period of at least 12 months.

(4) *When the initial antineoplastic therapy is effective.* We evaluate any post-therapeutic residual impairment(s) not included in the Malignant Neoplastic Diseases listings under the criteria for the affected body system. We must consider any complications of therapy. When the residual impairment(s) does not meet or medically equal the listings, we must consider its affect on the individual's ability to do substantial gainful activity.

H. *How long do we consider the individual disabled?*

(1) In some listings, we specify that the impairment will be considered disabling until a particular point in time (for example, at least 18 months from the date of diagnosis). We may consider the impairment

to be disabling beyond this point when justified by the medical and other evidence.

(2) When a listing does not contain such a specification, we will find an individual whose impairment(s) meets or medically equals a listing in this body system to be under a disability until at least 3 years after onset of complete remission. When the original tumor and any metastases have not been evident for at least 3 years after complete remission, the impairment(s) no longer meets or equals the criteria under this body system.

(3) Following the appropriate period, we will consider any residual impairment(s), including residuals of the malignancy or therapy (see 13.00G), in determining whether the individual is disabled.

I. *What do these terms in the listings mean?* (1) *Inoperable:* Surgery was thought to be of no therapeutic value or the surgery could not be performed. Examples of when surgery cannot be performed include a tumor that is too large or that invades crucial structures, or an intolerance of anesthesia or surgery due to other medical conditions. This term does not include situations in which the tumor could have been surgically removed but another method of treatment was chosen; for example, an attempt at organ preservation. Determining whether a tumor is inoperable usually occurs before attempts to shrink the tumor with chemotherapy or radiation.

(2) *Unresectable:* The operation was performed, but the malignant tumor was not removed. This term includes situations in which a tumor is incompletely resected or the surgical margins are positive.

(3) *Persistent:* Failure to achieve a complete remission.

(4) *Progressive:* The malignancy became more extensive after treatment.

(5) *Recurrent:* A malignancy that had been in complete remission or entirely removed by surgery has returned.

J. *Can we establish the existence of a disabling impairment prior to the date of the evidence that shows the malignancy satisfies the criteria of a listing?* Yes. We will consider factors such as:

(1) The type of malignancy and its location.

(2) The extent of involvement when the malignancy was first demonstrated.

(3) Medically reported symptoms.

K. *How do we evaluate specific malignant neoplastic diseases?* (1) *Lymphoma.* (a) Many indolent (non-aggressive) lymphomas, although they may produce intermittent symptoms and signs, are often controlled by well-tolerated treatment modalities. Therefore, we will defer adjudication of these cases for an appropriate period after initiation of therapy to determine whether the therapy will achieve its intended effect. (See 13.00E(3).) For an indolent lymphoma, the intended effect of therapy is usually stability of the disease process. When stability has been achieved, severity should be assessed on the basis of the extent of involvement of other organ systems and residuals from therapy.

(b) A change in therapy is usually an indicator that the therapy is not achieving its intended effect. However, it is not an indicator if the change is based on the individual's (or the physician's) choice rather than a failure to achieve stability. If the therapy is changed due solely to choice, the requirements of listing 13.05A.2.a are not met.

(c) We consider Hodgkin's disease that recurs more than 12 months after completing initial antineoplastic therapy to be a new disease rather than a recurrence.

(2) *Leukemia.* (a) *Acute leukemia.* The initial diagnosis of acute leukemia, including the accelerated or blast phase of chronic myelogenous (granulocytic) leukemia, is based upon definitive bone marrow examination. Additional diagnostic information is based on chromosomal analysis, cytochemical and surface marker studies on the abnormal cells, or other methods consistent with the prevailing state of medical knowledge and clinical practice. Recurrent disease must be documented by peripheral blood, bone marrow, or cerebrospinal fluid examination. The initial and follow-up pathology reports should be included.

(b) *Chronic myelogenous leukemia (CML).* The diagnosis of CML should be based upon documented granulocytosis, including immature forms such as differentiated or undifferentiated myelocytes and myeloblasts, and a chromosomal analysis that demonstrates the Philadelphia chromosome. In the absence of a chromosomal analysis, or if the Philadelphia chromosome is not present, the diagnosis may be made by other methods consistent with the prevailing state of medical knowledge and clinical practice.

(c) *Chronic lymphocytic leukemia.* (i) The diagnosis of chronic lymphocytic leukemia (CLL) must be documented by evidence of a chronic lymphocytosis of at least 10,000/mm^3 for 3 months or longer, or other acceptable diagnostic techniques consistent with the prevailing state of medical knowledge and clinical practice.

(ii) We will evaluate the complications and residual impairments from CLL under the appropriate listing, such as 13.05A2, 7.03A, and 7.05.

(d) *Elevated white cell counts.* In cases of chronic leukemia (either myelogenous or lymphocytic), an elevated white cell count, in itself, is not ordinarily a factor in determining the severity of the impairment.

(3) *Macroglobulinemia or heavy chain disease.* The diagnosis of these diseases must be confirmed by protein electrophoresis or immunoelectrophoresis. We evaluate the resulting impairment(s) under the criteria of 7.03 or 7.04, or of any other affected body system.

(4) *Bilateral primary breast cancer.* We evaluate bilateral primary breast cancer (synchronous or metachronous) under 13.10A, which covers local primary disease, and not as a primary disease that has metastasized.

(5) *Carcinoma-in-situ.* Carcinoma-in-situ, or preinvasive carcinoma, usually responds to treatment. When we use the term ''carcinoma'' in these listings, it does not include carcinoma-in-situ.

(6) *Brain tumors.* We use the criteria in 13.13 to evaluate malignant brain tumors. We will evaluate any complications of malignant brain tumors, such as resultant neurological or psychological impairments, under the criteria for the affected body system. We evaluate benign brain tumors under 11.05.

L. *How do we evaluate malignant neoplastic diseases treated by bone marrow or stem cell transplantation?* Bone marrow or stem cell transplantation is performed for a variety of malignant neoplastic diseases.

(1) *Acute leukemia (including T-cell lymphoblastic lymphoma) or accelerated or blast phase of CML.* We consider an individual who undergoes bone marrow or stem cell transplantation for any of these disorders disabled until at least 24 months from the date of diagnosis or relapse, or at least 12 months from the date of transplantation, whichever is later.

(2) *Lymphoma, multiple myeloma, or chronic phase of CML.* We consider an individual who undergoes bone marrow or stem cell transplantation for any of these disorders disabled until at least 12 months from the date of transplantation.

(3) *Other malignancies.* We will evaluate any other malignant neoplastic disease treated with bone marrow or stem cell transplantation under 13.28, regardless of whether there is another listing that addresses that impairment. The length of time we consider an individual whose impairment is evaluated under 13.28 to be disabled depends on whether the individual undergoes allogeneic or autologous transplantation.

(a) *Allogeneic bone marrow or stem cell transplantation.* We will consider an individual who undergoes allogeneic transplantation (transplantation from an unrelated donor or a related donor other than an identical twin) disabled until at least 12 months from the date of transplantation.

(b) *Autologous bone marrow or stem cell transplantation.* We will consider an individual who undergoes autologous transplantation (transplantation of the individual's own cells or cells from an identical twin (syngeneic transplantation)) disabled until at least 12 months from the date of the first treatment under the treatment plan that includes transplantation. The first treatment usually refers to the initial therapy given to prepare the individual for transplantation.

(4) *Evaluating disability after the appropriate time period has elapsed.* We consider any residual impairment(s), such as complications arising from:

(a) Graft-versus-host (GVH) disease.

(b) Immunosuppressant therapy, such as frequent infections.

(c) Significant deterioration of other organ systems.

13.01 Category of Impairments, Malignant Neoplastic Diseases

13.02 *Soft tissue tumors of the head and neck (except salivary glands—13.06—and thyroid gland—13.07).*

A. Inoperable or unresectable.

OR

B. Persistent disease following initial multimodal antineoplastic therapy.

OR

C. Recurrent disease following initial antineoplastic therapy, except local vocal cord recurrence.

OR

D. With metastases beyond the regional lymph nodes.

OR

E. Epidermoid carcinoma occurring in the pyriform sinus.

OR

F. Soft tissue tumors of the head and neck not addressed in A–E, with multimodal antineoplastic therapy. Consider under a disability until at least 18 months from the date of diagnosis. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

13.03 *Skin.*

A. Sarcoma or carcinoma with metastases to or beyond the regional lymph nodes.

OR

B. Melanoma, with either 1 or 2:

1. Recurrence after wide excision (except an additional primary melanoma at a different site, which is not considered to be recurrent disease).

2. Palpable nodal metastases or metastases to adjacent skin (satellite lesions) or elsewhere.

13.04 *Soft tissue sarcoma.*

A. With regional or distant metastases.

OR

B. Persistent or recurrent following initial antineoplastic therapy.

13.05 *Lymphoma (including mycosis fungoides, but excluding T-cell lymphoblastic lymphoma—13.06).* (See 13.00K(1).)

A. Non-Hodgkin's lymphoma, as described in 1 or 2:

1. Intermediate or high-grade lymphoma persistent or recurrent following initial antineoplastic therapy.

2. Low-grade or indolent lymphoma requiring initiation of more than 1 antineoplastic treatment regimen within a consecutive 12-month period. Consider under a disability from the date of initiation of the treatment regimen that failed within 12 months.

OR

B. Hodgkin's disease with failure to achieve clinically complete remission, or recurrent disease within 12 months of completing initial antineoplastic therapy.

OR

C. With bone marrow or stem cell transplantation. Consider under a disability until at least 12 months from the date of transplantation. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

13.06 *Leukemia.* (See 13.00K(2).)

A. Acute leukemia (including T-cell lymphoblastic lymphoma). Consider under a disability until at least 24 months from the date of diagnosis or relapse, or at least 12 months from the date of bone marrow or stem cell transplantation, whichever is later. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

OR

B. Chronic myelogenous leukemia, as described in 1 or 2:

1. Accelerated or blast phase. Consider under a disability until at least 24 months from the date of diagnosis or relapse, or at least 12 months from the date of bone marrow or stem cell transplantation, whichever is later. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

2. Chronic phase, as described in a or b:

a. Consider under a disability until at least 12 months from the date of bone marrow or stem cell transplantation. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

b. Progressive disease following initial antineoplastic therapy.

13.07 *Multiple myeloma (confirmed by appropriate serum or urine protein electrophoresis and bone marrow findings),* with 1 or 2:

1. Failure to respond or progressive disease following initial antineoplastic therapy.

2. Bone marrow or stem cell transplantation. Consider under a disability until at least 12 months from the date of transplantation. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

13.08 *Salivary glands*—carcinoma or sarcoma with metastases beyond the regional nodes.

13.09 *Thyroid gland.*

A. Anaplastic (undifferentiated) carcinoma.

OR

B. Carcinoma with metastases beyond the regional lymph nodes progressive despite radioactive iodine therapy.

13.10 *Breast (except sarcoma—13.04).* (See 13.00K(4).)

A. Locally advanced carcinoma (inflammatory carcinoma, tumor of any size with direct extension to the chest wall or skin, tumor of any size with metastases to the ipsilateral internal mammary nodes).

OR

B. Carcinoma with distant metastases.

OR

C. Recurrent carcinoma, except local recurrence that remits with antineoplastic therapy.

13.11 *Skeletal system*—carcinoma or sarcoma.

A. Inoperable or unresectable.

OR

B. Recurrent tumor (except local recurrence) after initial antineoplastic therapy.

OR

C. With distant metastases.

OR

D. All other tumors originating in bone with multimodal antineoplastic therapy. Consider under a disability for 12 months from the date of diagnosis. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

13.12 *Maxilla, orbit, or infratemporal fossa.*

A. Sarcoma or carcinoma of any type with regional or distant metastases.

OR

B. Carcinoma of the antrum with extension into the orbit or ethmoid or sphenoid sinus, or with regional or distant metastases.

OR

C. Tumors with extension to the base of the skull, orbit, meninges, or sinuses.

13.13 *Nervous system.* (See 13.00K(6).)

A. Central nervous system neoplasms (brain and spinal cord), including:

1. Highly malignant tumors, such as Grades III and IV astrocytoma, glioblastoma multiforme, ependymoblastoma, medulloblastoma or other primitive neuroectodermal tumors (PNETs) with documented metastases, diffuse intrinsic brain stem gliomas, or primary sarcomas.

2. Any central nervous system neoplasm progressive or recurrent following initial antineoplastic therapy.

OR

B. Peripheral nerve or spinal root neoplasm, as described in 1 or 2:

1. Metastatic.

2. Progressive or recurrent following initial antineoplastic therapy.

OR

C. Metastatic carcinoma to brain or spinal cord (includes epidural metastases).

13.14 *Lungs.*

A. Non-small-cell carcinoma—inoperable, unresectable, recurrent, or metastatic disease to or beyond the mediastinal or subcarinal lymph nodes.

OR

B. Small-cell (oat cell) carcinoma.

13.15 *Pleura or mediastinum.*

A. Malignant mesothelioma of pleura.

OR

B. Tumors of the mediastinum, as described in 1 or 2:

1. Metastatic.

2. Persistent or recurrent following initial antineoplastic therapy.

13.16 *Esophagus or stomach.*

A. Carcinoma or sarcoma of the esophagus.

OR

B. Carcinoma or sarcoma of the stomach, as described in 1 or 2:

1. Inoperable, unresectable, extending to surrounding structures, or recurrent.

2. With metastases to or beyond the regional lymph nodes.

13.17 *Small intestine*—carcinoma, sarcoma, or carcinoid.

A. Inoperable, unresectable, or recurrent.

OR

B. With metastases beyond the regional lymph nodes.

13.18 *Large intestine (from ileocecal valve to and including anal canal).*

A. Adenocarcinoma that is inoperable, unresectable, or recurrent.

OR

B. Squamous cell carcinoma of the anus, recurrent after surgery.

OR

C. With metastases beyond the regional lymph nodes.

13.19 *Liver or gallbladder*—tumors of the liver, gallbladder, or bile ducts.

13.20 *Pancreas.*

A. Carcinoma (except islet cell carcinoma).

OR

B. Islet cell carcinoma that is inoperable or unresectable and physiologically active.

13.21 *Kidneys, adrenal glands, or ureters*—carcinoma.

A. Inoperable, unresectable, or recurrent.

OR

B. With metastases to the regional lymph nodes or beyond.

13.22 *Urinary bladder*—carcinoma, with:

A. Infiltration beyond the bladder wall.

OR

B. Recurrent after total cystectomy.

OR

C. Inoperable or unresectable.

OR

D. Metastases to or beyond the regional lymph nodes.

13.23 *Cancers of the female genital tract*—carcinoma or sarcoma.

A. Uterus (corpus), as described in 1, 2, or 3:

1. Invading adjoining organs.

2. With metastases to or beyond the regional lymph nodes.

3. Persistent or recurrent following initial antineoplastic therapy.

OR

B. Uterine cervix, as described in 1 or 2:

1. Extending to the pelvic wall, lower portion of the vagina, or adjacent or distant organs.

2. Persistent or recurrent following initial antineoplastic therapy.

OR

C. Vulva, as described in 1, 2, or 3:

1. Invading adjoining organs.

2. With metastases to or beyond the regional lymph nodes.

3. Persistent or recurrent following initial antineoplastic therapy.

OR

D. Fallopian tube, as described in 1 or 2:

1. Extending to the serosa or beyond.

2. Persistent or recurrent following initial antineoplastic therapy.

OR

E. Ovaries, as described in 1 or 2:

1. All tumors except germ cell tumors, with at least one of the following:

a. Tumor extension beyond the pelvis; for example, tumor implants on peritoneal, omental, or bowel surfaces.

b. Metastases to or beyond the regional lymph nodes.

c. Ruptured ovarian capsule, tumor on the serosal surface of the ovary, ascites with malignant cells, or positive peritoneal washings.

d. Recurrence following initial antineoplastic therapy.

2. Germ cell tumors—progressive or recurrent following initial antineoplastic therapy.

13.24 *Prostate gland*—carcinoma.

A. Progressive or recurrent despite initial hormonal intervention.

OR

B. With visceral metastases.

13.25 *Testicles*—tumor with metastatic disease progressive or recurrent following initial chemotherapy.

13.26 *Penis*—carcinoma with metastases to or beyond the regional lymph nodes.

13.27 *Primary site unknown after appropriate search for primary*—metastatic carcinoma or sarcoma, except for solitary squamous cell carcinoma in the neck.

13.28 *Malignant neoplastic diseases treated by bone marrow or stem cell transplantation.* (See 13.00L.)

A. Allogeneic transplantation. Consider under a disability until at least 12 months from the date of transplantation. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

OR

B. Autologous transplantation. Consider under a disability until at least 12 months from the date of the first treatment under the treatment plan that includes transplantation. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

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14.08 Human Immunodeficiency Virus (HIV) Infection

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G. Hematologic abnormalities:

1. Anemia, as described under the criteria in 7.02C; or

2. Granulocytopenia, as described under the criteria in 7.05; or

3. Thromobocytopenia, as described under the criteria in 7.03A.

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Part B

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107.00 Hematological Disorders

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113.00 Malignant Neoplastic Diseases

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107.00 Hematological Disorders

A. *What do we consider when we evaluate hematological disorders under these listings?* We consider factors such as the:

(1) Type of disorder.

(2) Response to therapy.

(3) Side effects of therapy.

(4) Effects of any post-therapeutic residuals.

(5) Degree of limitation the disorder imposes on the child.

(6) Expected duration.

B. *What documentation do we need?*

(1) We generally need a longitudinal clinical record covering a period of at least 3 months of observations and treatment, unless we can make a fully favorable determination or decision without it. The record should include laboratory findings, such as hemoglobin values or platelet counts, obtained on more than one examination over the 3-month period.

(2) Any longitudinal clinical record should also include a description of the therapy prescribed by the treating source and the child's response to treatment, because medical management may improve functional status. The longitudinal record should provide information regarding functional recovery, if any.

(3) Even when a child does not receive ongoing treatment or have an ongoing relationship with a medical source, it is important to obtain evidence from relevant sources over a sufficient period. Such evidence may provide information about the:

(a) Ongoing medical severity of the impairment.

(b) Frequency, severity, and duration of symptoms.

(c) Level of the child's functioning.

C. *How do we evaluate impairments that do not meet one of the Hematological Disorders listings?*

(1) These listings are only examples of common hematological disorders that we consider severe enough to result in marked and severe functional limitations. If the child's impairment(s) does not meet the criteria of any of these listings, we must also consider whether the child has an impairment(s) that satisfies the criteria of a listing in another body system.

(2) If a child has a medically determinable impairment(s) that does not meet a listing, we will determine whether the impairment(s) medically equals the listings, or, in the case of a claim for SSI payments, functionally equals the listings. (See §§ 404.1526, 416.926, and 416.926a.) When we decide whether a child receiving SSI payments continues to be disabled, we use the rules in § 416.994a.

D. *How do we assess the effectiveness of treatment?* (1) We assess the effectiveness of treatment by seeing if there is improvement in the signs, symptoms, and laboratory findings of the disorder, and if there are side effects that may result in functional limitations in the child. Because the response to treatment and adverse consequences of treatment may vary widely, we consider each case on an individual basis.

(2) We will request a specific description of the:

(a) Drugs or treatment given.

(b) Dosage, method, and frequency of administration.

(3) We will also request a description of the complications or adverse effects of treatment, such as the following:

(a) Continuing gastrointestinal symptoms.

(b) Persistent weakness.

(c) Neurological complications.

(d) Cardiovascular complications.

(e) Reactive mental disorders.

(4) Because the effects of treatment may be temporary, enough time must pass to allow us to evaluate the impact of treatment.

E. *How do we evaluate episodic hematological disorders?* Some hematological disorders listings are met when a specified number of events have occurred within a specified time period, such as 3 events within a consecutive 12-month period. Events include pain crises, hospitalizations, treatment with parenteral antimicrobial medication, bleeding episodes, and thromboses. When we use such criteria, the period specified in the listing (either 6 months or 12 months) must occur within the period we are considering in connection with an application or continuing disability review. In every listing in which we require more than one event, there must be at least 1 month between the events, in order to ensure that we are evaluating separate episodes.

F. *What do these terms in the listings mean?* (1) *Persistent:* The longitudinal clinical record shows that, with few exceptions, the hemoglobin level has been at or below, or is expected to be at or below, the level specified in the listing for a continuous period of at least 12 months.

(2) *Repeated, repeatedly:* The longitudinal clinical record shows that the platelet count, neutrophil count, or hemoglobin level, as appropriate, satisfies the criteria in the listing most of the time, and that pattern has lasted or is expected to last for a continuous period of at least 12 months.

G. *How do we evaluate specific hematological disorders?* (1) *Anemia.* Anemia refers to decreased oxygen-carrying capacity of the blood and is usually measured as a decrease in hemoglobin

concentration. A gradual reduction in hemoglobin, even to very low levels, is often well tolerated in infants and children with normal cardiovascular and pulmonary systems. We generally evaluate the effects of chronic anemia under the criteria for the underlying disorder or for the affected body system. However, we include listings for hemolytic anemias and aplastic anemia because of their specific manifestations.

(2) *Hemolytic anemias.* (a) *Sickle cell disease or one of its variants.* (i) Sickle cell disease is a chronic hemolytic anemia in which the abnormal sickle cell hemoglobin may be either homozygous or in combination with thalassemia or with another abnormal hemoglobin. The diagnosis of sickle cell disease or one of its variants should be based on appropriate hematological evidence, such as hemoglobin electrophoresis. Frequently, this information is a part of the newborn screening data. We accept medical evidence that is persuasive that a positive diagnosis of sickle cell disease or one of its variants has been confirmed by appropriate laboratory testing at some time prior to evaluation in lieu of a copy of the actual laboratory report.

(ii) We will document the intensity, frequency, duration, and response to treatment of vaso-occlusive or aplastic episodes.

(iii) Parenteral medication as required under 107.02A1 does not include hydration.

(iv) To satisfy the criterion in 107.02A2, hospitalizations for children with sickle cell disease must be due to complications of the disease. We list the most common complications of sickle cell disease requiring hospitalization in the listing. Other complications of sickle cell disease requiring hospitalization may be of equal clinical significance to, and thus be medically equal to the ones listed. When we make a determination whether a complication is of equal clinical significance, we will make reasonable efforts to ensure that a qualified pediatrician or other individual who specializes in childhood hematological disorders evaluates the case.

(b) *Thalassemia.* Thalassemia is a type of hemolytic disorder in which the rate of erythropoeisis (red cell formation in the bone marrow) is inappropriate for the degree of anemia. Documentation of the disorder requires analysis of levels of hemoglobin types together with measurement of red cell size. Compensatory intra-medullary hematopoiesis, which results in bone marrow expansion, can lead to pathologic fractures and marked hepatosplenomegaly, especially in children with thalassemia major (the homozygous form) or those in whom the thalassemic state is combined with hemoglobin E (E thalassemia). We evaluate these, or any other, residual impairments resulting from this disorder under the criteria for the affected body system.

(c) *Prophylactic transfusion programs.* Many children with sickle cell disease or thalassemia major are on prophylactic transfusion programs. Even though these children may have pre-transfusion hemoglobin values of less than 7.0 gm/dl, they are usually asymptomatic. Therefore, we will not use pre-transfusion hemoglobin values to determine if sickle cell disease or thalessemia major meet the requirements of 107.02A or 107.02B. We may use pre-transfusion hemoglobin values to evaluate these disorders in children who are not on prophylactic transfusion programs, or to evaluate other hematological disorders.

(d) *Chronic iron overload.* Chronic iron overload (transfusion hemosiderosis) is a serious consequence of chronic transfusion programs. It is generally treated with iron chelation therapy. We will evaluate residuals of this impairment under the criteria for the affected body system, such as cardiovascular or digestive.

(3) *Disorders of hemostasis.* (a) ''Disorders of hemostasis'' refers to abnormalities in the ability of the blood to clot. These disorders must be documented by appropriate laboratory evidence, including platelet counts and evaluation of plasma clotting factors such as Factor VIII or Factor V Leiden.

(b) We will document the frequency, severity, and treatment of bleeding episodes or thromboses. Prophylactic therapy, such as factor concentrates or antithrombotic agents, does not, by itself, indicate any specific degree of severity.

(c) We must consider complications such as development of inhibitors against clotting factors, intrusiveness of treatment, and limitation of function. We must also consider effects on other body systems. For example, we will evaluate hemarthrosis with joint deformity under 101.02, and intracranial bleeding under 111.06 or 111.09.

(4) *Hematological malignancies.* With the exception of lymphoma associated with human immunodeficiency virus (HIV) infection, we use the criteria in 113.05 (Lymphoma), 113.06 (Leukemia), and 113.28 (Malignant neoplastic diseases treated by bone marrow or stem cell transplantation) to evaluate hematological malignancies. We evaluate lymphoma associated with HIV infection under the criteria in 114.08E.

H. *How do we evaluate non-malignant hematological disorders treated by allogeneic bone marrow or stem cell transplantation?* Allogeneic bone marrow or stem cell transplantation is performed for a variety of non-malignant hematological diseases, such as sickle cell disease and aplastic anemia. We will evaluate any non-malignant hematological disorder that is treated with allogeneic bone marrow or stem cell transplantation under 107.06, regardless of whether there is another listing that addresses that impairment. Under 107.06, we consider a child disabled until at least 12 months from the date of transplantation. Thereafter, for purposes of evaluating disability, we consider any residual impairment(s), such as complications arising from:

(1) Graft-versus-host (GVH) disease.

(2) Immunosuppressive therapy, such as frequent infections.

(3) Significant deterioration of other organ systems.

107.01 Category of Impairments, Hematological Disorders

107.02 Anemia

A. Sickle cell disease or one of its variants, with either 1, 2, or 3:

1. Documented painful (vaso-occlusive) crises requiring parenteral medication, occurring at least 3 times in a consecutive 6-month period (see 107.00E).

2. Hospitalization (for 24 hours or more) occurring at least 3 times in a consecutive 12-month period (see 107.00E), due to any of the following complications of sickle cell disease:

a. Hand/foot syndrome.

b. Chest syndrome.

c. Sequestration crisis.

d. Hyperhemolytic crisis.

e. Aplastic crisis.

f. Stroke.

g. Fever requiring treatment with parenteral antimicrobial medication.

3. Chronic anemia manifested by persistent hemoglobin of 7.0 gm/dl or less despite prescribed therapy (see 107.00F).

OR

B. Other hemolytic anemias (such as thalassemia) with chronic anemia manifested by persistent hemoglobin of 7.0 gm/dl or less despite prescribed therapy (see 107.00F).

OR

C. Aplastic anemia, with either 1 or 2:

1. Chronic anemia manifested by repeated hemoglobin of 7.0 gm/dl or less despite prescribed therapy (see 107.00F).

2. Documented treatment with parenteral antimicrobial medication occurring at least 3 times in a consecutive 12-month period (see 107.00E).

107.03 Disorders of Hemostasis

A. Chronic thrombocytopenia (due to any cause), with either 1 or 2:

1. Platelet counts repeatedly below 10,000/mm^3 despite prescribed therapy (see 107.00F).

2. Platelet counts repeatedly below 20,000/mm^3 and spontaneous bleeding despite prescribed therapy requiring red cell or platelet transfusions at least 3 times in a consecutive 12-month period (see 107.00E, 107.00F). Consider under a disability for 12 months from the date of the last transfusion. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

OR

B. Hemophilia with spontaneous bleeding despite prophylactic factor replacement, occurring at least 3 times in a consecutive 12-month period (see 107.00E).

OR

C. Other hypocoagulable states (such as von Willebrand's disease or thrombasthenia) with spontaneous bleeding requiring hospitalization (for 24 hours or more), occurring at least 3 times in a consecutive 12-month period (see 107.00E).

OR

D. Hypercoagulable states (deficiency of anti-coagulant proteins such as protein C, protein S, and antithrombin, or the presence of abnormal proteins such as Factor V Leiden) with documented thromboses occurring at least 3 times in a consecutive 12-month period (see 107.00E).

107.05 Chronic Granulocytopenia (Due to Any Cause), With Both A and B

A. Absolute neutrophil counts repeatedly below 500/mm^3 (see 107.00F).

AND

B. Documented treatment with parenteral antimicrobial medication occurring at least 3

times in a consecutive 12-month period (see 107.00E).

107.06 Non-malignant hematological diseases treated by allogeneic bone marrow or stem cell transplantation (see 107.00H)

Consider under a disability until at least 12 months from the date of transplantation. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

* * * * *

111.00 Neurological

* * * * *

E. *Brain tumors.* We evaluate malignant brain tumors under the criteria in 113.13. For benign brain tumors, we determine the severity and duration of the impairment on the basis of symptoms, signs, and laboratory findings (111.05).

* * * * *

111.05 Benign Brain Tumors

Evaluate under the criteria for the resulting neurological impairment.

* * * * *

113.00 Malignant Neoplastic Diseases

A. *What impairments do these listings cover?* We use these listings to evaluate all malignant neoplasms except certain neoplasms associated with human immunodeficiency virus (HIV) infection. We use the criteria in listing 114.08E to evaluate carcinoma of the cervix, Kaposi's sarcoma, lymphoma, and squamous cell carcinoma of the anus in children with HIV infection.

B. *What do we consider when we evaluate malignant neoplastic diseases under these listings?* We consider factors such as the:

(1) Origin of the malignancy.

(2) Extent of involvement.

(3) Duration, frequency, and response to antineoplastic therapy. Antineoplastic therapy means surgery, irradiation, chemotherapy, hormones, immunotherapy, or bone marrow or stem cell transplantation. When we refer to surgery as an antineoplastic treatment, we mean surgical excision for treatment, not for diagnostic purposes.

(4) Effects of any post-therapeutic residuals.

C. *How do we apply these listings?* Except for metastatic carcinoma to the brain or spinal cord (113.13C), we apply the criteria in a specific listing to a malignancy originating from that specific site.

D. *What evidence do we need?* (1) We need medical evidence that specifies the type, extent, and site of the primary, recurrent, or metastatic lesion.

(2) For operative procedures, including a biopsy or a needle aspiration, we need a copy of both the:

(a) Operative note.

(b) Pathology report.

(3) When we cannot get these documents, we will accept the summary of hospitalization(s) or other medical reports. This evidence should include details of the findings at surgery and, whenever appropriate, the pathological findings.

(4) In some situations we may also need evidence about recurrence, persistence, or progression of the malignancy, the response to therapy, and any significant residuals. (See 113.00G.)

E. *When do we need longitudinal evidence?* (1) *Tumors with distant metastases.* Most malignant tumors of childhood consist of a local lesion with metastases to regional lymph nodes and, less often, distant metastases. We generally do not need longitudinal evidence for tumors that have metastasized beyond the regional lymph nodes because these tumors usually meet the requirements of a listing. Exceptions are for tumors with distant metastases that are expected to respond to antineoplastic therapy. For these exceptions, we usually need a longitudinal record of 3 months after therapy starts to determine whether the intended effect of therapy has been achieved and is likely to persist.

(2) *Other malignancies.* When there are no distant metastases, many of the listings require that we consider the child's response to initial antineoplastic therapy; that is, the initial planned treatment regimen. This therapy may consist of a single modality or a combination of modalities (multimodal) given in close proximity as a unified whole, and is usually planned before any treatment(s) is initiated. Examples of multimodal therapy include:

(a) Surgery followed by chemotherapy or radiation.

(b) Chemotherapy followed by surgery.

(c) Chemotherapy and concurrent radiation.

(3) *Types of treatment.* Whenever the initial planned therapy is a single modality, enough time must pass to allow a determination about whether the therapy will achieve its intended effect. If the treatment fails, it will often happen within 6 months after it starts, and there will often be a change in the treatment regimen. Whenever the initial planned therapy is multimodal, a determination about the effectiveness of the therapy usually cannot be made until the effects of all the planned modalities can be determined. In some cases, we may need to defer adjudication until the effectiveness of therapy can be assessed. However, we do not need to defer adjudication to determine whether the therapy will achieve its intended effect if we can make a fully favorable determination or decision based on the length and effects of therapy, or the residuals of the malignancy or therapy (see 113.00G).

F. *How do we evaluate impairments that do not meet one of the Malignant Neoplastic Diseases listings?*

(1) These listings are only examples of malignant neoplastic diseases that we consider severe enough to result in marked and severe functional limitations. If the child's impairment(s) does not meet the criteria of any of these listings, we must also consider whether the child has an impairment(s) that satisfies the criteria of a listing in another body system.

(2) If a child has a medically determinable impairment(s) that does not meet a listing, we will determine whether the impairment(s) medically equals or, in the case of a claim for SSI payments, functionally equals the listings. (See §§ 404.1526, 416.926, and 416.926a.) When we decide whether a child receiving SSI payments continues to be disabled, we use the rules in § 416.994a.

G. *How do we consider the effects of therapy?*

(1) *How we consider the effects of therapy under the listings.* In many cases, malignancies meet listing criteria only if the therapy does not achieve the intended effect: the malignancy persists, progresses, or recurs despite treatment. However, as explained in the following paragraphs, we will not delay adjudication if we can make a fully favorable determination or decision based on the evidence in the case record.

(2) *Effects can vary widely.* (a) Because the therapy and its toxicity may vary widely, we consider each case on an individual basis. We will request a specific description of the therapy, including these items:

(i) Drugs given.

(ii) Dosage.

(iii) Frequency of drug administration.

(iv) Plans for continued drug administration.

(v) Extent of surgery.

(vi) Schedule and fields of radiation therapy.

(b) We will also request a description of the complications or adverse effects of therapy, such as the following:

(i) Continuing gastrointestinal symptoms.

(ii) Persistent weakness.

(iii) Neurological complications.

(iv) Cardiovascular complications.

(v) Reactive mental disorders.

(3) *Effects of therapy may change.* Because the severity of the adverse effects of antineoplastic therapy may change during treatment, enough time must pass to allow us to evaluate the therapy's effect. The residual effects of treatment are temporary in most instances. But, on occasion, the effects may be disabling for a consecutive period of at least 12 months.

(4) *When the initial antineoplastic therapy is effective.* We evaluate any post-therapeutic residual impairment(s) not included in the Malignant Neoplastic Diseases listings under the criteria for the affected body system. We must consider any complications of therapy. When the residual impairment(s) does not meet a listed impairment, we must consider whether it medically equals the listings, or, as appropriate, functionally equals the listings.

H. *How long do we consider the child disabled?* (1) In some listings, we specify that the impairment will be considered disabling until a particular point in time (for example, at least 12 months from the date of diagnosis). We may consider the impairment to be disabling beyond this point when justified by the medical and other evidence.

(2) When a listing does not contain such a specification, we will find a child whose impairment(s) meets or medically equals a listing in this body system to be under a disability until at least 3 years after onset of complete remission. When the original tumor and any metastases have not been evident for at least 3 years after complete remission, the impairment(s) no longer meets or equals the criteria under this body system.

(3) Following the appropriate period, we will consider any residual impairment(s), including residuals of the malignancy or therapy (see 113.00G), in determining whether the child is disabled.

I. *What do these terms in the listings mean?*

(1) *Inoperable:* Surgery was thought to be of no therapeutic value or the surgery could not be performed. Examples of when surgery cannot be performed include a tumor that is too large or invades crucial structures or an intolerance of anesthesia or surgery due to other medical conditions. This term does not include situations in which the tumor could have been surgically removed but another method of treatment was chosen; for example, an attempt at organ preservation. Determining whether a tumor is inoperable usually occurs before attempts to shrink the tumor with chemotherapy or radiation.

(2) *Unresectable:* The operation was performed, but the malignant tumor was not removed. This term includes situations in which a tumor is incompletely resected or the surgical margins are positive.

(3) *Persistent:* Failure to achieve a complete remission.

(4) *Progressive:* The malignancy became more extensive after treatment.

(5) *Recurrent:* A malignancy that had been in complete remission or entirely removed by surgery has returned.

J. *Can we establish the existence of a disabling impairment prior to the date of the evidence that shows the malignancy satisfies the criteria of a listing?* Yes. We will consider factors such as:

(1) The type of malignancy and its location.

(2) The extent of involvement when the malignancy was first demonstrated.

(3) Medically reported symptoms.

K. *How do we evaluate specific malignant neoplastic diseases?*

(1) *Lymphoma.* (a) Listing 113.05 provides criteria for evaluating intermediate or high-grade lymphomas that have not responded to antineoplastic therapy. Low grade or indolent lymphomas are rare in children. We will evaluate these impairments under 13.05 in part A.

(b) We consider Hodgkin's disease that recurs more than 12 months after completing initial antineoplastic therapy to be a new disease rather than a recurrence.

(c) Many children with lymphoma are treated according to a long-term protocol that can result in significant adverse medical, social, and emotional consequences. We will consider the duration and effects of treatment when we determine disability (see 113.00G).

(2) *Leukemia.* (a) *Acute leukemia.* The initial diagnosis of acute leukemia, including the accelerated or blast phase of chronic myelogenous (granulocytic) leukemia, is based upon definitive bone marrow examination. Additional diagnostic information is based on chromosomal analysis, cytochemical and surface marker studies on the abnormal cells, or other methods consistent with the prevailing state of medical knowledge and clinical practice. Recurrent disease must be documented by peripheral blood, bone marrow, or cerebrospinal fluid examination. The initial and follow-up pathology reports should be included.

(b) *Chronic myelogenous leukemia (CML).* The diagnosis of CML should be based upon documented granulocytosis, including immature forms such as differentiated or undifferentiated myelocytes and myeloblasts, and a chromosomal analysis that demonstrates the Philadelphia chromosome. In the absence of a chromosomal analysis, or if the Philadelphia chromosome is not present, the diagnosis may be made by other methods consistent with the prevailing state of medical knowledge and clinical practice.

(c) *Juvenile chronic myelogenous leukemia (JCML).* JCML is a rare, Philadelphia-chromosome-negative childhood leukemia which is aggressive and clinically similar to acute myelogenous leukemia. We evaluate JCML under 113.06A.

(d) *Elevated white cell counts.* In cases of chronic leukemia, an elevated white cell count, in itself, is not ordinarily a factor in determining the severity of the impairment.

(3) *Brain tumors.* We use the criteria in 113.13 to evaluate malignant brain tumors. We will evaluate any complications of malignant brain tumors, such as resultant neurological or psychological impairments, under the criteria for the affected body system. We evaluate benign brain tumors under 111.05.

L. *How do we evaluate malignant neoplastic diseases treated by bone marrow or stem cell transplantation?* Bone marrow or stem cell transplantation is performed for a variety of malignant neoplastic diseases.

(1) *Acute leukemia (including T-cell lymphoblastic lymphoma and JCML), or accelerated or blast phase of CML.* We consider a child who undergoes bone marrow or stem cell transplantation for any of these disorders disabled until at least 24 months from the date of diagnosis or relapse, or at least 12 months from the date of transplantation, whichever is later.

(2) *Lymphoma or chronic phase of CML.* We consider a child who undergoes bone marrow or stem cell transplantation for either of these disorders disabled until at least 12 months from the date of transplantation.

(3) *Other malignancies.* We will evaluate any other malignant neoplastic disease treated with bone marrow or stem cell transplantation under 113.28, regardless of whether there is another listing that addresses that impairment. The length of time we consider a child whose impairment is evaluated under 113.28 to be disabled depends on whether the child undergoes allogeneic or autologous transplantation.

(a) *Allogeneic bone marrow or stem cell transplantation.* We will consider a child who undergoes allogeneic transplantation (transplantation from an unrelated donor or a related donor other than an identical twin) disabled until at least 12 months from the date of transplantation.

(b) *Autologous bone marrow or stem cell transplantation.* We consider a child who undergoes autologous transplantation (transplantation of the child's own cells or cells from an identical twin (syngeneic transplantation)) disabled until at least 12 months from the date of the first treatment under the treatment plan that includes transplantation. The first treatment usually refers to the initial therapy given to prepare the child for transplantation.

(4) *Evaluating disability after the appropriate time period has elapsed.* We consider any residual impairment(s), such as complications arising from:

(a) Graft-versus-host (GVH) disease.

(b) Immunosuppressant therapy, such as frequent infections.

(c) Significant deterioration of other organ systems.

113.01 Category of Impairments, Malignant Neoplastic Diseases.

113.04 Soft Tissue Sarcoma (Including Ewing's Sarcoma, Primitive Neuroectodermal Tumor (PNET))

A. Localized tumor with or without metastases. Consider under a disability until at least 12 months from the date of diagnosis. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

OR

B. Persistent or recurrent following initial antineoplastic therapy.

113.05 Lymphoma (Excluding T-Cell Lymphoblastic Lymphoma—113.06) (See 113.00K(1))

A. Non-Hodgkins lymphoma, including Burkitt's and anaplastic large cell. Persistent or recurrent following initial antineoplastic therapy.

OR

B. Hodgkin's disease with failure to achieve clinical complete remission, or recurrent disease within 12 months of completing initial antineoplastic therapy.

OR

C. With bone marrow or stem cell transplantation. Consider under a disability until at least 12 months from the date of transplantation. Thereafter, evaluate any residual impairment(s) under the criteria of the affected body system.

113.06 Leukemia (See 113.00K(2))

A. Acute leukemia (including T-cell lymphoblastic lymphoma and juvenile chronic myelogenous leukemia (JCML)). Consider under a disability until at least 24 months from the date of diagnosis or relapse, or at least 12 months from the date of bone marrow or stem cell transplantation, whichever is later. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

OR

B. Chronic myelogenous leukemia (except JCML), as described in 1 or 2:

1. Accelerated or blast phase. Consider under a disability until at least 24 months from the date of diagnosis or relapse, or at least 12 months from the date of bone marrow or stem cell transplantation, whichever is later. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

2. Chronic phase, as described in a or b:

a. Consider under a disability until at least 12 months from the date of bone marrow or stem cell transplantation. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

b. Progressive disease following initial antineoplastic therapy.

113.09 Thyroid Gland

A. Anaplastic (undifferentiated) carcinoma.

OR

B. Carcinoma with metastases beyond the regional lymph nodes progressive despite radioactive iodine therapy.

113.10 Retinoblastoma

A. With extension beyond the orbit.

OR

B. Persistent or recurrent following initial antineoplastic therapy.

OR

C. With regional or distant metastases.

113.11 Osteogenic Sarcoma

A. Inoperable or unresectable.

OR

B. Recurrent tumor (except local recurrence) after initial antineoplastic therapy.

OR

C. With distant metastases.

OR

D. All other osteogenic sarcoma. Consider under a disability for 12 months from the date of diagnosis. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

113.13 Nervous System (See 113.00K(3))

A. Central nervous system neoplasms (brain and spinal cord), including:

1. Highly malignant tumors such as Grades III and IV astrocytomas, glioblastoma multiforme, ependymoblastoma, medulloblastoma or other primitive neuroectodermal tumors (PNETs) with documented metastases, diffuse intrinsic brain stem gliomas, or primary sarcoma.

2. Any central nervous system neoplasm progressive or recurrent following initial antineoplastic therapy.

OR

B. Peripheral nerve and spinal root neoplasm, as described in 1 or 2:

1. Metastatic.

2. Progressive or recurrent following initial antineoplastic therapy.

OR

C. Metastatic carcinoma to brain or spinal cord (includes epidural metastases).

113.21 Kidneys and Adrenal Glands

A. Neuroblastoma, as described in 1 or 2:

1. With DNA index less than or equal to 1, amplified N-*myc* or unfavorable Shimada histology. Consider under a disability for 12 months from the date of diagnosis. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

2. For children age 1 or older with tumor crossing the midline, unilateral tumor with bilateral lymph node involvement, or disseminated tumor excluding disease confined to the skin, liver or bone marrow. Consider under a disability for 12 months from the date of diagnosis. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

OR

B. Wilms' tumor persistent or recurrent following initial antineoplastic therapy.

113.25 Testicles—Tumor With Metastatic Disease Progressive or Recurrent Following Initial Chemotherapy

113.26 Germ Cell Tumors—Gonadal or Extragonadal

Persistent or recurrent following initial antineoplastic therapy.

113.28 Malignant Neoplastic Diseases Treated by Bone Marrow or Stem Cell Transplantation (See 113.00L.)

A. Allogeneic transplantation. Consider under a disability until at least 12 months from the date of transplantation. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system;

OR

B. Autologous transplantation. Consider under a disability until at least 12 months from the date of the first treatment under the treatment plan that includes the transplantation. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

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114.08 Human Immunodeficiency Virus (HIV) Infection

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G. Hematologic abnormalities:

1. Anemia, as described under the criteria in 107.02A.3; or

2. Granulocytopenia, as described under the criteria in 107.05; or

3. Thromobocytopenia, as described under the criteria in 107.03A.

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November 27, 2001

Part III

United States Sentencing Commission

Sentencing Guidelines for United States Courts; Notice

UNITED STATES SENTENCING COMMISSION

Sentencing Guidelines for United States Courts

AGENCY: United States Sentencing Commission.

ACTION: Notice of proposed amendments to sentencing guidelines, policy statements, and commentary. Request for public comment.

SUMMARY: Pursuant to section 994(a), (o), and (p) of title 28, United States Code, the Commission is considering promulgating certain amendments to the sentencing guidelines, policy statements, and commentary. This notice sets forth the proposed amendments and, for each proposed amendment, a synopsis of the issues addressed by that amendment. Additionally, issues for comment follow proposed amendments 1, 2, and 4.

The specific amendments proposed in this notice are summarized as follows: (1) Proposed amendment to provide a new guideline, § 2B1.5, to cover a variety of offenses involving the theft of, damage to, destruction of, or illicit trafficking in cultural heritage resources, including national memorials, archaeological resources, national parks, and national historic landmarks; (2) proposed amendment to change statutory references in Appendix A (Statutory Index) to the Foreign Corrupt Practices Act, 15 U.S.C. §§ 78dd–1 through 78dd–3, from § 2B4.1 (Bribery in Procurement of Bank Loan and Other Commercial Bribery) to § 2C1.1 (Offering, Giving, Soliciting, or Receiving a Bribe; Extortion Under Color of Official Right); (3) proposed amendment to provide special rules in § 4B1.1 (Career Offender) for determining and imposing a guideline sentence in the case of a defendant who is convicted of an offense under 18 U.S.C. § 924(c) or § 929(a) and, as a result of that conviction, is determined to be a career offender under §§ 4B1.1 and 4B1.2 (Definitions of Terms Used in Section 4B1.1); (4) proposed amendment to expand the persons who may qualify as an official victim for purposes of the enhancement in § 3A1.2 (Official Victim); (5) proposed amendment to (A) eliminate the additional one-level reduction in § 3E1.1(b)(1) that applies if the defendant timely provides complete information to the government concerning the defendant's own involvement in the offense; and (B) resolve a circuit conflict regarding whether the court may deny a reduction for acceptance of responsibility under § 3E1.1 if the defendant commits a new offense unrelated to the offense of conviction; and (6) proposed amendment to make technical and conforming amendments to various guideline provisions.

DATES: Written public comment should be received by the Commission not later than February 4, 2002.

ADDRESSES: Public comment should be sent to: United States Sentencing Commission, One Columbus Circle, NE., Suite 2–500, Washington, DC 20002–8002, Attention: Public Information.

FOR FURTHER INFORMATION CONTACT: Michael Courlander, Public Affairs Officer, Telephone: (202) 502–4590.

SUPPLEMENTARY INFORMATION: The United States Sentencing Commission is an independent agency in the judicial branch of the United States Government. The Commission promulgates sentencing guidelines and policy statements for federal sentencing courts pursuant to 28 U.S.C. § 994(a). The Commission also periodically reviews and revises previously promulgated guidelines pursuant to 28 U.S.C. § 994(o) and submits guideline amendments to the Congress not later than the first day of May each year pursuant to 28 U.S.C. § 994(p).

The proposed amendments are presented in this notice in one of two formats. First, some of the amendments are proposed as specific revisions to a guideline or commentary. Bracketed text within a proposed amendment indicates a heightened interest on the Commission's part for comment and suggestions for alternative policy choices; for example, a proposed enhancement of [2] levels indicates that the Commission is considering, and invites comment on, alternative policy choices regarding the appropriate level of enhancement. Similarly, bracketed text within a specific offense characteristic or application note means that the Commission specifically invites comment on whether the proposed provision is appropriate. Second, the Commission has highlighted certain issues for comment and invites suggestions for how the Commission should respond to those issues.

Authority: 28 U.S.C. § 994(a), (o), (p), (x); USSC Rules of Practice and Procedure 4.3, 4.4.

Diana E. Murphy,
Chair.

1. Synopsis of Proposed Amendment

This amendment proposes to add to Chapter Two, Part B, a new guideline, § 2B1.5, to cover a variety of offenses involving the theft of, damage to, destruction of, or illicit trafficking in cultural heritage resources, including national memorials, archaeological resources, national parks, and national historic landmarks. The proposal was developed in response to concerns raised by the Departments of Justice and the Interior, among others, that the guidelines inadequately address such offenses.

Cultural heritage resource crimes are fundamentally different than general property crimes because, unlike other property crimes where the primary harm is pecuniary, the effect of cultural heritage resource crimes is in great part non-pecuniary in nature. Punishment of these crimes should reflect these intrinsic differences.

The effect of cultural heritage resource crimes transcends monetary considerations. Individuals, communities, and nations identify themselves through intellectual, emotional, and spiritual connections to places and objects. For much of this cultural heritage in the United States, the federal government has a perpetual duty to act either as a trustee for the public, generally, or as a fiduciary on behalf of American Indians, Alaska Natives and Native Hawaiian Organizations. The current guidelines, however, do not specifically address the importance of cultural identity and fiduciary obligation when crimes are committed against cultural heritage resources. Therefore, a separate guideline amendment is proposed that takes into account the transcendent and irreplaceable, *e.g.*, the non-pecuniary value of cultural heritage resources, and punishes in a proportionate way the particular offense characteristics associated with the range of cultural heritage resource crimes.

First, the amendment proposes a base offense level of level 8, which is two levels higher than the base offense level for general property destruction. The higher base offense level represents the intangible and non-pecuniary harm caused by the theft of, damage to, or destruction of, essentially irreplaceable cultural heritage resources.

Second, the amendment proposes an enhancement, tied to the loss table at § 2B1.1, that assesses the monetary value of the damage caused. Use of the standard economic crime concept of ''loss'' is not used, however, because it implies a fungible and compensatory system of value which is inappropriate for measuring the harm caused by cultural heritage resources offenses. Instead, the calculation is based on either commercial value or archaeological value, as appropriate to the particular resource, which may be

necessary to preserve or otherwise care for the resource, together with the cost of restoration and repair of the resource. These values already exist in federal law and are codified in federal regulations.

Third, the amendment proposes a two-level enhancement if the offense involved commercial advantage or private financial gain, in order to distinguish between offenders who are motivated by financial gain or commercial purposes from offenders who merely are motivated by their interest in the past and personal desire to possess cultural heritage resources, and is consistent with similar provisions elsewhere in the guidelines. See, *e.g.*, §§ 2Q2.1(b)(1) and 2B5.3(b)(3). A two-level enhancement is also proposed if the offense involved a pattern of similar violations, which is defined as ''two or more civil or administrative adjudications for misconduct similar to the instant offense, in violation of any Federal, state, or local provision, rule, regulation, ordinance, or permit.''

Fourth, the amendment proposes two-level enhancements that increase the offense level if the offense involves specially protected resources from specially protected places. A two-level enhancement will attach if the offense involves a resource from one of seven locations particularly designated by Congress as dedicated solely to the preservation of the resource and further education of the public. An additional two-level increase attaches to four specific types of cultural heritage resources that have merited special treatment in federal law.

Fifth, the amendment proposes a two-level enhancement and a minimum offense level of level 14 if a firearm was possessed or a dangerous weapon (including a firearm) was brandished. This enhancement reflects the harm caused by the increased danger of violence and risk to law enforcement officers and innocent passers-by in vast expanses of land, and is consistent with similar provisions elsewhere in the guidelines. See, *e.g.*, § 2B1.1(b)(11)(B).

Sixth, an upward departure provision is proposed when the offense level substantially understates the seriousness of the offense. For example, if an upward departure may be warranted in addition to cultural heritage resources, the offense involved theft of, damage to, or destruction of other items such as administrative property. In such a case, the extent of the upward departure should not exceed the number of levels from the table in § 2B1.1 corresponding to the dollar amount of the non-cultural heritage resources.

Seventh, the proposed guideline for cultural heritage resources contains three issues for comment. The first issue requests comment on the extent of the proposed enhancement in subsection (b)(4)(B) regarding ''pattern of similar violations'' and the proposed definition in Application Note 5. The second issue requests comment on proposed Application Note 7 regarding the nature of a structured upward departure for cases involving offense conduct that damages or destroys both cultural heritage resources and non-cultural heritage resources, specifically, is it appropriate to use the applicable numbers of levels from the loss table or the loss commentary in § 2B1.1 for the determination of the non-cultural heritage resource harm caused. The second issue also requests comment on whether an upward departure should be provided if the value of the cultural heritage resource, as determined under proposed subsection (b)(1) and Application Note 2, underestimates its actual value. The third issue requests comment regarding whether the proposed guideline should include an enhancement for the use of explosives.

Finally, the Statutory Index (Appendix) is updated to reference a variety of offenses to the new guideline.

Chapter Two, Part B, Subpart 1 is amended by adding at the end the following:

''§ 2B1.5. Theft of, Damage to, or Destruction of, Cultural Heritage Resources; Unlawful Sale, Purchase, Exchange, Transportation, or Receipt of Cultural Heritage Resources

(a) Base Offense Level: [8]

(b) Specific Offense Characteristics

(1) If the value of the cultural heritage resources (A) exceeded $2,000 but did not exceed $5,000, increase by 1 level; or (B) exceeded $5,000, increase by the number of levels from the table in § 2B1.1 (Theft, Property Destruction, and Fraud) corresponding to that amount.

(2) If the offense involved a cultural heritage resource from, or located, prior to the offense, on or in (A) the national park system; (B) a National Historic Landmark; (C) a national monument or national memorial; (D) a national marine sanctuary; (E) a national cemetery; (F) a museum; or (G) the World Heritage List, increase by 2 levels.

(3) If the offense involved a cultural heritage resource constituting (A) human remains; (B) a funerary object; (C) designated archeological or ethnological material; or (D) a pre-Columbian monumental or architectural sculpture or mural, increase by 2 levels.

(4) If the offense (A) was committed for pecuniary gain or otherwise involved a commercial purpose; or (B) involved a pattern of similar violations, increase by 2 levels.

(5) If (A) a dangerous weapon (including a firearm) was brandished; or (B) a firearm was possessed in connection with the offense, increase by 2 levels. If the resulting offense level is less than level 14, increase to level 14.

Commentary

Statutory Provisions: 16 U.S.C. § 470ee; 18 U.S.C. §§ 541–546, 641, 661, 666, 668, 1152–1153, 1163, 1170, 1361, 2314–2315. For additional statutory provisions, see Appendix A (Statutory Index).

Application Notes

1. Meaning of 'Cultural Heritage Resource'—For purposes of this guideline, 'cultural heritage resource' means any of the following:

(A) A historic property, as defined in 16 U.S.C. § 470w(5).

(B) A historic resource, as defined in 16 U.S.C. § 470w(5).

(C) An archaeological resource, as defined in 16 U.S.C. § 470bb(1) (see also section 3(a) of 43 CFR part 7, 36 CFR part 296, 32 CFR part 299, and 18 CFR part 1312).

(D) A cultural item, as defined in section 2(3) of the Native American Graves Protection and Repatriation Act, 25 U.S.C. § 3001(3)(see also 43 CFR 10.2(d)).

(E) A commemorative work. 'Commemorative work' (A) has the meaning given that term in section 2(c) of Public Law 99–652 (40 U.S.C. § 1002(c)); and (B) includes any national monument or national memorial.

(F) An object of cultural heritage, as defined in 18 U.S.C. § 668(a).

2. Value of the Cultural Heritage Resources.—This note applies to the determination of the value of the cultural heritage resources for purposes of subsection (b)(1).

(A) In General.—Except as provided in subdivision (B), the value of a cultural heritage resource is its commercial value, and the cost of restoration and repair.

(B) Archaeological Resources.—The value of an archaeological resource is (i) the greater of its commercial value or its archaeological value; and (ii) the cost of restoration and repair.

(C) Definitions.—For purposes of this application note:

(i) 'Archaeological value' of an archaeological resource means the cost of the retrieval of the scientific information which would have been obtainable prior to the offense,

including the cost of preparing a research design, conducting field work, conducting laboratory analysis, and preparing reports as would be necessary to realize the information potential. (See 43 CFR § 7.14(a); 36 CFR § 296.14(a); 32 CFR § 229.14(a); 18 CFR § 1312.14(a).)

(ii) 'Commercial value' of a cultural heritage resource, including an archeological resource, means the fair market value of the cultural heritage resource. In the case of a cultural heritage resource that has been damaged as a result of the offense, the fair market value shall be determined using the condition of the cultural heritage resource prior to commission of the offense, if the prior condition can be determined. (See 43 CFR § 7.14(b); 36 CFR § 296.14(b); 32 CFR § 229.14(b); 18 CFR § 1312.14(b).)

(iii) 'Cost of restoration and repair' includes all actual and projected costs of curation, disposition, and appropriate reburial of, and consultation with respect to, the cultural heritage resource; and any other actual and projected costs to complete restoration and repair of the cultural heritage resource, including (I) its reconstruction and stabilization; (II) reconstruction and stabilization of ground contour and surface; (III) research necessary to conduct reconstruction and stabilization; (IV) the construction of physical barriers and other protective devices; (V) examination and analysis of the cultural heritage resource as part of efforts to salvage remaining information about the resource; and (VI) preparation of reports. (See 43 CFR § 7.14(c); 36 CFR § 296.14(c); 32 CFR § 229.14(c); 18 CFR § 1312.14(c).)

(D) Determination of Value in Cases Involving A Variety of Cultural Heritage Resources.—In a case involving a variety of cultural heritage resources, the value of the cultural heritage resources is the sum of all calculations made for those resources under this note.

3. Enhancement in Subsection (b)(2).—For purposes of subsection (b)(2):

(A) 'Museum' has the meaning given that term in 18 U.S.C. § 668(1).

(B) ''National cemetery'' has the meaning given that term in Application Note 1 of § 2B1.1 (Theft, Property Destruction, and Fraud).

(C) 'National Historic Landmark' has the meaning given that term in 16 U.S.C. § 470(a)(1)(B).

(D) 'National marine sanctuary' means a national marine sanctuary designated as such by the Secretary of Commerce pursuant to 16 U.S.C. § 1433.

(E) 'National monument or national memorial' means any national monument or national memorial established as such by Act of Congress or by proclamation pursuant to the Antiquities Act of 1906 (16 U.S.C. § 431).

(F) 'National park system' has the meaning given that term in 16 U.S.C. § 1c(a).

(G) 'World Heritage List' means the World Heritage List maintained by the World Heritage Committee of the United Nations Educational, Scientific, and Cultural Organization in accordance with the Convention Concerning the Protection of the World Cultural and Natural Heritage.

4. Enhancement in Subsection (b)(3).—For purposes of subsection (b)(3):

(A) 'Designated archaeological or ethnological material' has the meaning given that term in 19 U.S.C. § 2601(7).

(B) 'Funerary object' means an object that, as a part of the death rite or ceremony of a culture, was placed intentionally, at the time of death or later, with or near human remains.

(C) 'Human remains' (A) means the physical remains of the body of a human; and (B) does not include remains that reasonably may be determined to have been freely disposed of or naturally shed by the human from whose body the remains were obtained, such as hair made into ropes or nets.

(D) 'Pre-Columbian monumental or architectural sculpture or mural' has the meaning given that term in 19 U.S.C. § 2095(3).

5. Enhancements in Subsection (b)(4).—

(A) Pecuniary Gain.—For purposes of subsection (b)(4)(A), 'for pecuniary gain' means for receipt of, or in anticipation of receipt of, anything of value, whether monetary or in goods or services. Therefore, offenses committed for pecuniary gain include both monetary and barter transactions, as well as activities designed to increase gross revenue.

(B) Pattern of Similar Violations.—For purposes of subsection (b)(4)(B), 'pattern of similar violations' means two or more civil or administrative adjudications of misconduct similar to the instant offense, in violation of any Federal, state, or local provision, rule, regulation, ordinance, or permit.

6. Dangerous Weapons Enhancement.—For purposes of subsection (b)(6), 'brandished', 'dangerous weapon', and 'firearm' have the meaning given those terms in the Commentary to § 1B1.1 (Application Instructions).

7. Upward Departure Provision.—There may be cases in which the offense level determined under this guideline substantially understates the seriousness of the offense. In such cases, an upward departure may be warranted. For example, an upward departure may be warranted if, in addition to cultural heritage resources, the offense involved theft of, damage to, or destruction of, items that are not cultural heritage resources (such as an offense involving the theft from a national cemetery of lawnmowers and other administrative property in addition to historic gravemarkers or other cultural heritage resources). In such a case, the extent of the upward departure should not exceed the number of levels from the table in § 2B1.1 (Theft, Property Destruction, and Fraud) corresponding to the dollar amount involved in the theft of, damage to, or destruction of, the items that are not cultural heritage items.

Section 2B1.1(c) is amended by adding at the end the following new subdivision:

''(4) If the offense involved a cultural heritage resource, apply § 2B1.5 (Theft of, Damage to, or Destruction of, Cultural Heritage Resources).''.

The Commentary to § 2B1.1 captioned 'Application Notes' is amended by redesignating Notes 12 through 15 as Notes 13 through 16; and by inserting after Note 11 the following:

''12. Cross Reference in Subsection (c)(4).—For purposes of subsection (c)(4) 'cultural heritage resource' has the meaning given that term in Application Note 1 of § 2B1.5 (Theft of, Damage to, or Destructive of, Cultural Heritage Resources).''.

Section 2Q2.1 is amended by adding after subsection (b) the following:

''(c) Cross Reference

(1) If the offense involved a cultural heritage resource, apply § 2B1.5 (Theft of, Damage to, or Destruction of, Cultural Heritage Resources).''.

The Commentary to § 2Q2.1 captioned ''Application Notes'' is amended by adding at the end the following:

''6. For purposes of subsection (c)(1), 'cultural heritage resource' has the meaning given that term in Application Note 1 of § 2B1.5 (Theft of, Damage to, or Destruction of, Cultural Heritage Resources).''.

Section 3D1.2 is amended in subsection (d) by inserting ''2B1.5,'' after ''2B1.4,''.

Appendix A (Statutory Index) is amended by striking the line referenced to ''16 U.S.C. § 433'' and inserting the following new line:

''16 U.S.C. § 470ee 2B1.5'';

in the line referenced to 16 U.S.C. § 668(a) by inserting ''2B1.5,'' before ''2Q2.1'';

in the line referenced to 16 U.S.C. § 707(b) by inserting ''2B1.5,'' before ''2Q2.1'';
in the line referenced to 18 U.S.C. § 541 by inserting ''2B1.5,'' before ''2T3.1'';
in the line referenced to 18 U.S.C. § 542 by inserting ''2B1.5,'' before ''2T3.1'';
in the line referenced to 18 U.S.C. § 543 by inserting ''2B1.5,'' before ''2T3.1'';
in the line referenced to 18 U.S.C. § 544 by inserting ''2B1.5,'' before ''2T3.1'';
in the line referenced to 18 U.S.C. § 545 by inserting ''2B1.5,'' before ''2Q2.1'';
by inserting after the line referenced to ''18 U.S.C. § 545'' the following new line:
''18 U.S.C. § 546 2B1.5'';
in the line referenced to 18 U.S.C. § 641 by inserting '', 2B1.5'' after ''2B1.1'';
in the line referenced to 18 U.S.C. § 661 by inserting '', 2B1.5'' after ''2B1.1'';
in the line referenced to 18 U.S.C. § 662 by inserting '', 2B1.5'' after ''2B1.1'';
in the line referenced to 18 U.S.C. § 666(a)(1)(A) by inserting '', 2B1.5'' after ''2B1.1'';
in the line referenced to 18 U.S.C. § 668 by striking ''2B1.1'' and inserting ''2B1.5'';
by inserting after the line referenced to ''18 U.S.C. § 1121'' the following new line:
''18 U.S.C. § 1152 2B1.5'';
in the line referenced to ''18 U.S.C. § 1153'' by inserting ''2B1.5,'' after ''2B1.1'';
in the line referenced to ''18 U.S.C. § 1163'' by inserting '', 2B1.5'' after ''2B1.1'';
by inserting after the line referenced to ''18 U.S.C. § 1168'' the following new line:
''18 U.S.C. § 1170 2B1.5'';
in the line referenced to ''18 U.S.C. § 1361'' by inserting '', 2B1.5'' after ''2B1.1'';
in the line referenced to 18 U.S.C. § 2232 by inserting '' 2B1.5,'' before ''2J1.2'';
in the line referenced to 18 U.S.C. § 2314 by inserting '', 2B1.5'' after ''2B1.1''; and
in the line referenced to 18 U.S.C. § 2315 by inserting '', 2B1.5'' after ''2B1.1''.

Issues for Comment: (1) The proposed amendment provides an enhancement in subsection (b)(4)(B) for a ''pattern of similar violations'', which proposed Application Note 5 defines as ''two or more civil or administrative adjudications of misconduct similar to the instant offense, in violation of any Federal, state, or local provision, rule, regulation, ordinance, or permit''. The Commission requests comment on the extent of this enhancement. For example, in addition to civil or administrative adjudications, should the enhancement cover prior convictions for similar misconduct as well? Should the enhancement cover similar misconduct for which there has not been a civil or administrative adjudicate?

(2) Proposed Application Note 7 provides, as an example of an upward departure that might be warranted, a structured upward departure for cases in which the offense also involved theft of, damage to, or destruction of, items that are not cultural heritage items. Instead of a structured upward departure, should the Commission provide an enhancement if the offense involved theft of, damage to, or destruction of, items that are not cultural heritage items? If so, should the extent of the enhancement correspond to the applicable number of levels from the loss table in § 2B1.1 (Theft, Property Destruction, and Fraud), and should the loss commentary from § 2B1.1 be used to determine the dollar amount of the theft, damage, or destruction? Generally, should proposed Application Note 7 provide an upward departure if the value of a cultural heritage resource, as determined under subsection (b)(1) and Application Note 2, underestimates its actual value?

(3) Should the proposed amendment include an enhancement if the offense involved the use of destructive devices?

2. Synopsis of Proposed Amendment

This amendment changes the Statutory Index reference for violations of the Foreign Corrupt Practices Act, 15 U.S.C. §§ 78dd–1 through 78dd–3, from § 2B4.1 (Bribery in Procurement of Bank Loan and Other Commercial Bribery) to § 2C1.1 (Offering, Giving, Soliciting, or Receiving a Bribe; Extortion Under Color of Official Right). This change is proposed because many such violations involve public corruption of foreign officials and therefore are more like public corruption cases than commercial bribery cases. In addition, such a change arguably would better implement the Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, which requires the United States, as a signatory, to impose comparable sentences for foreign bribery cases as for domestic bribery cases.

Although this proposal references all offenses under the Foreign Corrupt Practice Act to § 2C1.1, an issue for comment is included regarding whether some of the offenses under that Act should continue to be referenced to § 2B4.1. Although offenses under 15 U.S.C. §§ 78dd–1(a)(1), 78dd–2(a)(1), and 78dd–3(a)(1) involve bribery of foreign officials, some of the offenses under that Act involve bribery of foreign candidates for political office (see 15 U.S.C. §§ 78dd–1(a)(2), 78dd–2(a)(2), and 78dd–3(a)(2)). Other offenses involve bribery of persons who are neither public officials nor candidates for political office, but the defendant knows that some portion of the funds might be used directly or indirectly to influence public officials or political candidates (see 15 U.S.C. §§ 78dd–1(a)(3), 78dd–2(a)(3), and 78dd–3(a)(3)). Similar offenses involving United States Presidential and Vice Presidential candidates currently are referenced to § 2B4.1. Section 2B4.1 may continue to be the appropriate guideline for offenses which do not directly involve a foreign governmental official.

The Commentary to § 2B4.1 captioned ''Statutory Provisions'' is amended by striking ''15 U.S.C. §§ 78dd–1, 78dd–2;''.

The Commentary to § 2B4.1 captioned ''Application Notes'' is amended in Note 1 by inserting '', foreign governments, or public international organizations'' after ''local government''; and by striking ''governmental'' and inserting ''any such''.

The Commentary to § 2B4.1 captioned ''Background'' is amended in the sixth paragraph by striking ''to violations of the Foreign Corrupt Practices Act, 15 U.S.C. §§ 78dd–1 and 78dd–2, and''.

The Commentary to § 2C1.1 captioned ''Statutory Provisions'' is amended by inserting ''15 U.S.C. §§ 78dd–1, 78dd–2, 78dd–3;'' before ''18 U.S.C. §§ 201''.

Appendix A (Statutory Index) is amended in the line referenced to ''15 U.S.C. § 78dd–1'' by striking ''2B4.1'' and inserting ''2C1.1'';
in the line referenced to ''15 U.S.C. § 78dd–2'' by striking ''2B4.1'' and inserting ''2C1.1;
by inserting after the line referenced to ''15 U.S.C. § 78dd–2'' the following new line:
''15 U.S.C. § 78dd–3 2C1.1'';
and in the line referenced to ''15 U.S.C. § 78ff'' by striking ''2B4.1'' and inserting ''2C1.1''.

Issue for Comment: Although this proposed amendment references all offenses under the Foreign Corrupt Practice Act to § 2C1.1 (Offering, Giving, Soliciting, or Receiving a Bribe; Extortion Under Color of Official Right), the Commission requests comment regarding whether some of the offenses under that Act should continue to be referenced to § 2B4.1. Although offenses under 15 U.S.C. §§ 78dd–1(a)(1), 78dd–2(a)(1), and 78dd–3(a)(1) involve bribery of foreign officials, some of the offenses under that Act involve bribery of foreign candidates for political office (see 15 U.S.C. §§ 78dd–1(a)(2), 78dd–2(a)(2), and 78dd–3(a)(2)). Other offenses

involve bribery of persons who are neither public officials nor candidates for political office, but the defendant knows that some portion of the funds might be used directly or indirectly to influence public officials or political candidates (see 15 U.S.C. §§ 78dd–1(a)(3), 78dd–2(a)(3), and 78dd–3(a)(3)). Similar offenses involving United States Presidential and Vice Presidential candidates under 26 U.S.C. §§ 9012(e) and 9042(d) currently are referenced to § 2B4.1. Is § 2B4.1 the appropriate guideline for offenses which do not directly involve a foreign governmental official? Alternatively, should offenses under 26 U.S.C. §§ 9012(e) and 9042(d) be referenced to § 2C1.1 instead of § 2B4.1, inasmuch as those offenses are more akin to public bribery than to commercial bribery?

3. Synopsis of Proposed Amendment

This proposed amendment provides special rules in § 4B1.1 for determining and imposing a guideline sentence when the defendant is convicted of an offense under 18 U.S.C. § 924(c) or § 929(a) and, as a result of that conviction, is determined to be a Career Offender under § 4B1.1 and § 4B1.2. The amendment reverses the decision made by the Commission in Amendment 600 (effective November 1, 2000), that such offenses do not qualify as a crime of violence or controlled substance offense for Career Offender purposes, except as a prior conviction. Some have expressed doubt about whether that decision complies with the statutory command in 28 U.S.C. § 994(h), as construed by the United States Supreme Court in *United States v. Labonte*, 520 U.S. 751 (1997).

Operationally, this amendment achieves the goals of (1) permitting such offenses, whether as the instant or prior offense of conviction, to qualify for Career Offender purposes, and (2) ensuring that, when such an instant offense establishes the defendant as a Career Offender, the resulting guideline sentence is determined under § 4B1.1 using a count of conviction that has a statutory maximum of life imprisonment. The resulting consecutive sentence to be imposed on the 18 U.S.C. § 924(c) or 18 U.S.C. § 929(a) count is at least the minimum required by statute, and may be longer to the extent necessary to achieve the total Career Offender punishment. This amendment does not change the current guideline rules forbidding application of guideline weapon enhancements when the defendant is convicted of a 18 U.S.C. § 924(c) or 18 U.S.C. § 929(a) offense. Furthermore, under this amendment, when the defendant is convicted of a 18 U.S.C. § 924(c) or 18 U.S.C. § 929(a) offense but that offense, together with any prior convictions, does not establish the defendant as a Career Offender, the current guideline rules for sentencing on that 18 U.S.C. § 924(c) or 18 U.S.C. § 929(a) count continue to apply. Accordingly, under § 2K2.4, the guideline sentence on that count is the statutory minimum, and that sentence is imposed independently and consecutively to the sentence on other counts. No adjustments in Chapters Three or Four apply to adjust the guideline sentence for that 18 U.S.C. § 924(c) or 18 U.S.C. § 929(a) count.

However, under this amendment, when the 18 U.S.C. § 924(c) or 18 U.S.C. § 929(a) count establishes the defendant as a Career Offender, which the court will determine under §§ 4B1.1 and 4B1.2, new special rules/instructions will apply. To determine the guideline sentence on the 18 U.S.C. § 924(c) or 18 U.S.C. § 929(a) count, the court moves directly from § 2K2.4 to § 4B1.1 and applies the new Special Instruction therein, including the instructions regarding multiple counts of conviction.

Section 2K2.4 is amended by redesignating subsection (b) as subsection (d); by striking subsection (a) and inserting the following:

''(a) If the defendant, whether or not convicted of another crime, was convicted of violating section 844(h) of title 18, United States Code, the guideline sentence is the term of imprisonment required by statute. Chapters Three and Four shall not apply to that count of conviction.

(b) Except as provided in subsection (c), if the defendant, whether or not convicted of another crime, was convicted of violating section 924(c) or section 929(a) of title 18, United States Code, the guideline sentence is the minimum term of imprisonment required by statute. Chapters Three and Four shall not apply to that count of conviction.

(c) If the defendant (i) was convicted of violating section 924(c) or section 929(a) of title 18, United States Code; and (ii) as a result of that conviction (alone or in addition to another offense of conviction), is determined to be a career offender under § 4B1.1(Career Offender), the guideline sentence shall be determined under § 4B1.1(c). Except for §§ 3E1.1 (Acceptance of Responsibility), 4B1.1, and 4B1.2 (Definitions of Terms Used in Section 4B1.1), Chapters Three and Four shall not apply to that count of conviction.''.

The Commentary to § 2K2.4 captioned ''Application Notes'' is amended by striking the text of Note 1 and inserting the following:

''(A) Application of Subsection (a).—Section 844(h) of title 18, United State Code, provides a mandatory term of imprisonment of 10 years (or 20 years for the second or subsequent offense). Accordingly, the guideline sentence for a defendant convicted under 18 U.S.C. § 844(h) is the term required by the statute. Section 844(h) of title 18, United States Code, also requires a term of imprisonment imposed under that section to run consecutively to any other term of imprisonment.

(B) Application of Subsection (b).—Sections 924(c) and 929(a) of title 18, United States Code, provide mandatory minimum terms of imprisonment (*e.g.,* not less than five years). Except as provided in subsection (c), in a case in which the defendant is convicted under 18 U.S.C. § 924(c) or § 929(a), the guideline sentence is the minimum term required by the relevant statute. Each of 18 U.S.C. §§ 924(c) and 929(a) also requires that a term of imprisonment imposed under this section shall run consecutively to any other term of imprisonment.

In a case in which the guideline sentence is determined under subsection (b), a sentence above the minimum term required by 18 U.S.C. § 924(c) or § 929(a) is an upward departure from the guideline sentence. A departure may be warranted, for example, to reflect the seriousness of the defendant's criminal history in a case in which the defendant is convicted of an 18 U.S.C. § 924(c) or § 929(a) offense but is not determined to be a Career Offender under § 4B1.1. See Application Note 3.

(C) Application of Subsection (c).—In a case in which the defendant (i) was convicted of violating 18 U.S.C. § 924(c) or 18 U.S.C. § 929(a) and (ii) as a result of that conviction (alone or in addition to another offense of conviction), is determined to be a career offender under § 4B1.1(Career Offender), the guideline sentence shall be determined under § 4B1.1(c). The amount of the mandatory term of imprisonment that is imposed to run consecutively in such a case also is determined under § 4B1.1(c).''.

The Commentary to § 2K2.4 captioned ''Application Notes'' is amended in Note 2 in the first sentence of the first paragraph by inserting ''Weapon Enhancement—'' before ''If a sentence''; and by striking the third paragraph (beginning ''In a few cases,'') in its entirety.

The Commentary to § 2K2.4 captioned ''Application Notes'' is amended by striking the text of Note 3 and inserting the following:

''Chapters Three and Four.—Except for those cases covered by subsection (c), do not apply Chapter Three (Adjustments) and Chapter Four (Criminal History and Criminal Livelihood) to any offense sentenced under this guideline. Such offenses are excluded from application of these chapters because the guideline sentence for each offense is determined only by the relevant statute. See §§ 3D1.1 (Procedure for Determining Offense Level on Multiple Counts) and 5G1.2 (Sentencing on Multiple Counts of Conviction). For those cases covered by subsection (c), the adjustment in § 3E1.1 (Acceptance of Responsibility) may apply, as provided in § 4B1.1(c). No other adjustments in Chapter Three and no provisions of Chapter Four (Criminal History and Criminal Livelihood), other than §§ 4B1.1 and 4B1.2, shall apply in determining the guideline sentence on a conviction under 18 U.S.C. § 924(c) or § 929(a).''.

The Commentary to § 2K2.4 captioned ''Application Notes'' is amended in Note 4 by inserting ''Terms of Supervised Release.—'' before ''Imposition''.

The Commentary to § 2K2.4 captioned ''Application Notes'' is amended in Note 5 by inserting ''Fines.—'' before ''Subsection (b)''.

Section 4B1.1 is amended by striking ''A defendant is a career offender'' and all that follows through ''corresponding to that adjustment.'' and inserting the following:

''(a) A defendant is a career offender if (1) the defendant was at least eighteen years old at the time the defendant committed the instant offense of conviction, (2) the instant offense of conviction is a felony that is either a crime of violence or a controlled substance offense, and (3) the defendant has at least two prior felony convictions of either a crime of violence or a controlled substance offense.

(b) Except as provided in subsection (c), if the offense level for a career offender from the table below is greater than the offense level otherwise applicable, the offense level from the table below shall apply. A career offender's criminal history category in every case under this subsection shall be Category VI.

Offense statutory maximum	Offense level *
(1) Life	37
(2) 25 years or more	34
(3) 20 years or more, but less than 25 years	32
(4) 15 years or more, but less than 20 years	29
(5) 10 years or more, but less than 15 years	24
(6) 5 years or more, but less than 10 years	17
(7) More than 1 year, but less than 5 years	12

* If an adjustment from § 3E1.1 (Acceptance of Responsibility) applies, decrease the offense level by the number of levels corresponding to that adjustment.

(c) If the defendant (1) was convicted of violating 18 U.S.C. § 924(c) or § 929(a); and (2) as a result of that conviction (alone or in addition to another offense of conviction), is determined to be a career offender under subsection (a):

(A) The offense level shall be—

(i) in the case of a conviction only of an offense under 18 U.S.C. § 924(c) or § 929(a): level 37, decreased by the number of levels corresponding to any adjustment under § 3E1.1 (Acceptance of Responsibility) that applies; or

(ii) in the case of multiple counts of conviction: the greater of (I) the offense level applicable to the counts of conviction other than the 18 U.S.C. § 924(c) or § 929(a) count, or (II) level 37, decreased by the number of levels corresponding to any adjustment under § 3E1.1 that applies.

(B) The criminal history category shall be Category VI.

(C) The amount of the mandatory term of imprisonment that is imposed to run consecutively shall be determined as follows:

(i) A consecutive sentence of imprisonment shall be imposed on any count of conviction under 18 U.S.C. § 924(c) or § 929(a). The length of such consecutive sentence shall be at least the minimum term required by law.

(ii) After taking into account the required statutory minimum consecutive sentence under subdivision (i), the balance of the total punishment shall be allocated and imposed, to the extent possible, on the counts of conviction, other than 18 U.S.C. §§ 924(c) and 929(a), in accordance with the rules in § 5G1.2 (Sentencing on Multiple Counts of Conviction), as applicable.

(iii) If the statutory minimum sentence on the count of conviction under 18 U.S.C. § 924(c) or § 929(a) together with the sentence imposed on the remaining counts is less than the total punishment, then the minimum sentence on the count of conviction under 18 U.S.C. § 924(c) or § 929(a) shall be increased to the extent necessary to achieve the total punishment.''.

The Commentary to § 4B1.2 captioned ''Application Notes'' is amended by striking in the first paragraph of Note 1 ''For purposes of this guideline—'' and inserting ''Definitions.—For purposes of this guideline:''; and by striking ''A prior conviction for violating'' and all that follows through ''Criminal History)).'' and inserting the following:

''A violation of 18 U.S.C. § 924(c) or § 929(a) is a ''crime of violence'' or a ''controlled substance offense'' if the offense of conviction established that the underlying offense was a ''crime of violence'' or a ''controlled substance offense''. (Note that in the case of a prior 18 U.S.C. § 924(c) or § 929(a) conviction, if the defendant also was convicted of the underlying offense, the two prior convictions will be treated as related cases under § 4A1.2 (Definitions and Instruction for Computing Criminal History)).''.

The Commentary to § 4B1.2 captioned ''Application Notes'' is amended by striking the text of Note 2 in its entirety and inserting the following:

''Application of § 4B1.1(c).—

(A) In General.—Section 4B1.1(c) applies in any case in which the defendant (i) was convicted of violating 18 U.S.C. § 924(c) or § 929(a); and (ii) as a result of that conviction (alone or in addition to another offense of conviction), is determined to be a career offender under § 4B1.1(a).

(B) Imposition of Consecutive Term of Imprisonment.—The amount of the mandatory term of imprisonment that is imposed to run consecutively in such a case also is determined under § 4B1.1(c). The sentence imposed for a conviction under 18 U.S.C. § 924(c) or § 929(a) must, under that statute, consist of a minimum term of imprisonment imposed to run consecutively to the sentence on any other count. In the case of a career offender to whom § 4B1.1(c) applies, typically the court will determine the applicable statutory minimum sentence, subtract that minimum from the total punishment determined for all counts considered together, impose that minimum consecutive sentence on the 18 U.S.C. § 924(c) or § 929(a) count, and then impose the balance of the total punishment on the other counts in accordance with the rules provided in § 5G1.2 (Sentencing on Multiple Counts of Convictions). In some cases covered by § 4B1.1(c), a consecutive term of imprisonment longer than the minimum required by the 18 U.S.C. § 924(c) or § 929(a) statute will be necessary in order both to achieve the required total punishment determined by the court and also comply with the applicable statutory requirements. Note that a

consecutive sentence longer than the statutory minimum under 18 U.S.C. § 924(c) or § 929(a) will be necessary when the total guideline punishment determined by the court exceeds the aggregate statutory maximum term(s) of imprisonment on any counts other than 18 U.S.C. §§ 924(c) and 929(a) by more than the aggregate statutory minimum terms on the 18 U.S.C. §§ 924(c) and 929(a) counts.

(C) Examples.—The following examples illustrate the application of § 4B1.1(c) in a variety of multiple count situations in which the 18 U.S.C. § 924(c) count establishes the defendant as Career Offender:

(i) The defendant is convicted of one count of violating 18 U.S.C. § 924(c) for possessing a firearm in furtherance of a drug trafficking crime (15 year mandatory minimum), and one count of violating 21 U.S.C. § 841(b)(1)(C) (assume the statutory maximum of 20 years applies). Applying § 4B1.1(c), the court determines a combined offense level of 34 (assuming a 3-level reduction under § 3E1.1), and determines that a total punishment of 300 months is appropriate. The court then imposes a minimum sentence of 60 months, as statutorily required under 18 U.S.C. § 924(c), and also as required by 18 U.S.C. § 924(c), imposes that sentence to run consecutively to a sentence of 240 months (300 − 60 = 240) imposed on the 21 U.S.C. § 841 count. Alternatively, had the court determined that a sentence of 327 months (top of the guideline range) was appropriate, it necessarily would have increased the consecutive sentence on the 18 U.S.C. § 924(c) count to 87 months.

(ii) The defendant is convicted of one count of 18 U.S.C. § 924(c) (firearm possession in furtherance of drug trafficking), one count of drug trafficking under 21 U.S.C. § 841(b)(1)(C) (assume the statutory maximum sentence of 30 years applies), and one count of violating 21 U.S.C. § 843(b) (statutory maximum of 4 years). Applying § 4B1.1(c), the court determines a combined offense level of 36 and selects a total punishment of 324 months. Sentence is imposed as follows: (I) a minimum sentence of 60 months on the 18 U.S.C. § 924(c) count imposed to run consecutively to all other counts; (II) a sentence of 264 months on the 21 U.S.C. § 841 count (324 − 60 = 264 months balance of total punishment to be allocated and imposed on the non-924(c) counts); and (III) a sentence of 48 months on the 21 U.S.C. § 843(b) count, imposed to run concurrently with the 21 U.S.C. § 841 count. Alternatively, if the court had determined that a sentence of 405 months (top of the guideline range) was appropriate, the sentence on the 21 U.S.C. § 841 count would have been increased to 345 months (405 − 60 = 345).

(iii)The defendant is convicted of two counts of 18 U.S.C. § 924(c) (for possessing a firearm in two separate drug trafficking offenses), and one count of conspiracy under 21 U.S.C. § 846 (assume a statutory maximum of life and minimum of ten years is applied). The court determines, under § 4B1.1(c), that the combined offense level is 42 and that a total punishment of 480 months is appropriate. As required by statute, a minimum consecutive sentence of 60 months is imposed on the first 18 U.S.C. § 924(c) count, and a minimum consecutive sentence of 300 months is imposed on the second 18 U.S.C. § 924(c) count. The balance of the total punishment, 120 months (480 − (60 + 300) = 120), is imposed on the 21 U.S.C. § 846 count.''.

Section 5G1.2(a) is amended by inserting a comma after ''other term of imprisonment''; and by inserting '', except as provided in § 4B1.1 (Career Offender)'' after ''independently''.

The Commentary to § 5G1.2 is amended by striking the first paragraph and inserting the following:

''Application Notes:

1. In General.—This section specifies the procedure for determining the specific sentence to be formally imposed on each count in a multiple-count case. The combined length of the sentences (''total punishment'') is determined by the court after determining the adjusted combined offense level and the Criminal History Category. Except as otherwise required by law or by § 4B1.1(c), the total punishment is to be imposed on each count, and the sentences on all counts are imposed to run concurrently to the extent allowed by the statutory maximum sentence of imprisonment for each count of conviction.''; and by striking the last paragraph and inserting the following:

''2. Mandatory Minimum and Mandatory Consecutive Terms of Imprisonment (Not Covered by Special Instruction).—Subsection (a) applies if a statute (A) specifies a term of imprisonment to be imposed; and (B) requires that such term of imprisonment be imposed to run consecutively to any other term of imprisonment. See, *e.g.,* 18 U.S.C. § 924(c) (requiring mandatory minimum terms of imprisonment, based on the conduct involved, and also requiring the sentence imposed to run consecutively to any other term of imprisonment). Except for certain Career Offender situations in which subsection (c) of § 4B1.1 (Career Offender) applies, the term of years to be imposed consecutively is the minimum required by the statute of conviction, and is independent of the guideline sentence on any other count. See, *e.g.,* Commentary to §§ 2K2.4 (Use of Firearm, Armor-Piercing Ammunition, or Explosive During or in Relation to Certain Crimes) and 3D1.1 (Procedure for Determining Offense Level on Multiple Counts) regarding determination of the offense levels for related counts when a conviction under 18 U.S.C. § 924(c) is involved. Note, however, that even in the case of a consecutive term of imprisonment imposed under subsection (a), any term of supervised release imposed is to run concurrently with any other term of supervised release imposed. See 18 U.S.C. § 3624(e). Subsection (a) also applies in certain other instances in which an independently determined and consecutive sentence is required. See, *e.g.,* Application Note 3 of the Commentary to § 2J1.6 (Failure to Appear by Defendant), relating to failure to appear for service of sentence.''.

4. Synopsis of Proposed Amendment

This amendment proposes to expand the persons who may qualify as an official victim for purposes of the enhancement in § 3A1.2 (Official Victim). Specifically, this proposed amendment responds to *United States* v. *Walker,* 202 F.3d 181 (3d Cir. 1999), which held that the enhancement under § 3A1.2(b) was not applicable in the case of a defendant prison inmate who attacked his supervisor, a food service department employee at the prison. *Walker* held that the work supervisor was not a corrections officer within the meaning of § 3A1.2. The proposed amendment amends § 3A1.2(b) to apply to assaults of any prison employee or other person retained or designated by the prison to perform duties within the prison. The amendment also limits application of the enhancement, in the case of assaults on corrections officers and prison employees, to offenses that occurred while the defendant was in the custody or control of the correctional facility or prison.

A general request for comment follows regarding the appropriate scope of coverage under the enhancement (*i.e.,* who should be considered an official victim for purposes of proposed subsection (b)(2)).

Section 3A1.2 is amended by striking the text of subsection (b) and inserting the following:

''during the course of the offense or immediate flight therefrom, the defendant or a person for whose conduct the defendant is otherwise

accountable, knowing or having reasonable cause to believe that a person was—

(1) a law enforcement officer, or

(2) a corrections officer or prison employee, in the case of an offense that occurred while the defendant (or a person for whose conduct the defendant is otherwise accountable) was in the custody or control of a prison or other correctional facility,

assaulted such officer or employee in a manner creating a substantial risk of serious bodily injury,

increase by 3 levels.''.

The Commentary to § 3A1.2 captioned ''Application Notes'' is amended by striking the text of Note 5 and inserting the following:

''Subdivision (b) applies in circumstances tantamount to aggravated assault against a law enforcement officer, corrections officer, or prison employee, committed in the course of, or in immediate flight following, another offense. While this subdivision may apply in connection with a variety of offenses that are not by nature targeted against official victims (such as a bank robbery), its applicability is limited to assaultive conduct against law enforcement officers, corrections officers, or prison employees that is sufficiently serious to create at least a ''substantial risk of serious bodily injury'' and that is proximate in time to the commission of the offense.

''Prison employee'', for purposes of subsection (b)(2), includes any individual retained or designated by a prison or other correctional facility to perform any duty or function within the prison or other correctional facility, regardless of whether the individual is compensated for the performance of the duty or function and whether the individual technically is an employee of the prison or other correctional facility. For example, the term ''prison employee'' includes an individual employed by the prison as a kitchen supervisor, as well as a nurse who, under contract, provides medical services to prisoners in the prison health facility.''.

Issue for Comment: The Commission requests comment on the appropriate scope of the enhancement provided in § 3A1.2(b)(2). Are there particular individuals or groups of individuals against whom assaults by the defendant in a correctional or prison setting should subject the defendant to enhanced punishment? For example, should the enhancement be expanded, further than that proposed in the amendment, to include individuals who assist law enforcement officers in the performance of official duties? Should the enhancement cover individuals who perform functions within a prison (as an employee, under contract, or otherwise) but who do not have regular contact with, or exercise any supervision of, prisoners (*e.g.,* an electrician under contract who repairs wiring in a building typically off-limits to prisoners)? Should the enhancement cover, for example, a minister or attorney who is assaulted while providing volunteer services to inmates?

5. Synopsis of Amendment

This proposal amends § 3E1.1 (Acceptance of Responsibility) by (1) deleting subsection (b)(1) which provides an additional one-level reduction if the defendant timely provides complete information to the government concerning his own involvement in the offense; and (2) resolving a circuit conflict regarding whether the court may deny an acceptance of responsibility reduction when the defendant commits a new offense unrelated to the offense of conviction.

Section 3E1.1(b) provides alternative reductions for either (1) timely providing complete information to the government concerning the defendant's own involvement in the offense; or (2) timely notifying authorities of the defendant's intention to enter a plea of guilty. Subsection (b)(2) specifically addresses the goal of permitting the government to avoid preparing for trial and permitting the court to allocate its resources efficiently. However, it has been argued that subsection (b)(1) undermines the incentive to plead guilty in subsection (b)(2), because the defendant can receive the reduction even if the defendant has caused the government and the court to devote substantial resources to preparing the case for trial. Under this proposal, a defendant who accepts responsibility for the offense would receive a two-level reduction under subsection (a), and an additional one-level reduction only if the defendant timely notifies authorities of his intent to plead guilty. This proposal is intended to save both judicial and governmental resources by providing defendants a stronger incentive to timely plead guilty.

This amendment also resolves a circuit conflict regarding whether the court may deny an acceptance of responsibility reduction when the defendant commits a new offense unrelated to the offense of conviction. The majority of circuits have held that the sentencing court may consider new criminal conduct (*i.e.,* conduct occurring after the defendant has been charged for the instant offense), such as subsequent drug use or the commission of the new offense, when determining whether an adjustment for acceptance of responsibility is warranted. The Sixth Circuit, the sole minority circuit, has held that the court may not look at post-indictment conduct unrelated to the offense of conviction when assessing the defendant's acceptance of responsibility for the underlying offense (see United States v. Morrison, 983 F.2d 730 (6th Cir. 1993)). This amendment adopts the majority view by making clear that a defendant who commits another offense while pending trial or sentencing on the instant offense ordinarily is not entitled to a reduction under this guideline.

Section 3E1.1(b) is amended by striking ''has assisted authorities'' and all that follows through ''notifying'' and inserting ''notified''.

The Commentary to § 3E1.1 captioned ''Application Notes'' is amended in Note 1 by inserting ''Appropriate Considerations in Determining Applicability of Acceptance of Responsibility.—'' before ''In determining''.

The Commentary to § 3E1.1 captioned ''Application Notes'' is amended in Note 2 by inserting ''Convictions by Trial.—'' before ''This adjustment''.

The Commentary to § 3E1.1 captioned ''Application Notes'' is amended in Note 3 by inserting ''Application of Subsection (a).—'' before ''Entry of a plea''.

The Commentary to § 3E1.1 captioned ''Application Notes'' is amended by striking the text of Note 4 in its entirety and inserting the following:

''Inapplicability of Adjustment.—A defendant who (A) receives an enhancement under § 3C1.1 (Obstructing or Impeding the Administration of Justice); or (B) commits another offense while pending trial or sentencing on the instant offense, ordinarily is not entitled to a reduction under this guideline. [There may, however, be extraordinary cases in which an adjustment under this guideline is warranted even though the defendant received an enhancement under § 3C1.1, or committed another such offense, or both.]''.

The Commentary to § 3E1.1 captioned ''Application Notes'' is amended in Note 5 by inserting ''Deference on Review.—'' before ''The sentencing judge''.

The Commentary to § 3E1.1 captioned ''Application Notes'' is amended by striking the first sentence of Note 6 and inserting ''Application of Subsection (b).—''; and by striking ''has assisted authorities in the investigation or prosecution of his own misconduct by

taking one or both of the steps set forth in subsection (b)'' and inserting ''timely notified authorities of the defendant's intention to enter a guilty plea''.

The Commentary to § 3E1.1 captioned ''Background'' is amended in the second sentence of the first paragraph by striking ''by taking, in a timely fashion, one or more of the actions listed above (or some equivalent action)''; and in the second paragraph by striking ''has assisted authorities in the investigation or prosecution of his own misconduct by taking one or more of the steps specified in subsection (b)'' and inserting ''timely notified authorities of the defendant's intention to enter a guilty plea''.

6. Synopsis of Proposed Amendment

This proposed amendment makes technical and conforming changes to various guideline provisions. The proposed amendment accomplishes the following:

(1) Clarifies that language in § 5D1.2(c) (recommending the maximum term of supervised release for sex offenders) is a policy statement;

(2) Conforms the language in § 2B4.1(b)(2) concerning offenses that ''affect a financial institution'' with subsection (b)(12) of § 2B1.1 (Larceny, Embezzlement, and other forms of Theft; Offenses Involving Stolen Property; Property Damage or Destruction; Fraud and Deceit).

(3) Inserts a missing ''or'' in §§ 2C1.7(b)(1)(A) and 2Q1.6(a)(3).

(4) (A) Updates statutory references in §§ 2D1.9 (Placing or Maintaining Dangerous Devices on Federal Property to Protect the Unlawful Production of Controlled Substances; Attempt and Conspiracy), 2D1.11 (Unlawfully Distributing, Importing, Exporting or Possessing a Listed Chemical; Attempt or Conspiracy), and 2D1.13 (Structuring Chemical Transactions or Creating a Chemical Mixture to Evade Reporting or Recordkeeping Requirements) and Appendix A (Statutory Index) to correspond to statutory redesignations made by the Hillory J. Farias and Samantha Reid Date Rape Prevention Act; and (B) corrects references to the new chemical quantity tables in § 2D1.11.

(5) Corrects a change to the commentary of § 2N2.1(b)(1) that was inadvertently made as part of the conforming package of amendments in the Economic Crime Package.

(6) Corrects a grammatical error in Note (D) of § 2T1.1(c)(1) by replacing ''subdivisions (A), (B), or (C)'' with ''subdivision (A), (B), or (C)''.

(7) Adds a mandatory condition to §§ 5B1.3 (Conditions of Probation) and 5D1.3 (Conditions of Supervised Release) that the defendant provide DNA if the defendant is required to do so by the DNA Analysis Backlog Elimination Act of 2000. Pursuant to section 3 of this Act, a defendant is required to provide a DNA sample if the defendant is convicted of certain offenses (*e.g.,* murder, kidnapping).

(8) Deletes from Application Note 5 of § 5E1.1 (Fines for Individual Defendants) an incorrect statement concerning the Clean Air Act.

(9) Inserts a missing ''Background'' title in § 5F1.7 (Shock Incarceration).

(10) Conforms Part A of Chapter Seven and § 7B1.3 (Revocation of Supervised Release) to current statutory law and provides an explanatory note concerning the condition of intermittent confinement as a condition of supervised release.

(11) Updates statutory references in § 5F1.5 (Occupational Restrictions).

(12) Refers 18 U.S.C. § 2245 (sexual abuse resulting in death) to § 2A1.1 (First Degree Murder) in Appendix A (Statutory Index).

(13) Repromulgates amendment 568, effective November 1, 1997, to correct an inadvertent omission of a conforming amendment to § 4B1.4 (Armed Career Criminal) from amendment 568.

(14) Responds to new legislation as follows:

(A) Updates, in § 2B1.1, a statutory reference in the definition of ''means of identification'' to correspond to a redesignation made by the Internet False Identification Prevention Act of 2000, Pub. L. 106–578, Dec. 28, 2000, 114 Stat. 305.

(B) References in Appendix A two new offenses created by the American Homeownership and Economic Opportunity Act of 2000, Pub. L. 106–569, Dec. 27, 2000, _ Stat. _. Section 5410(b) of title 42, which provides that knowing and willful violations of a state's installation program standards shall be punishable as a Class A misdemeanor, is referenced to § 2N2.1. Section 14905 of title 42, which provides a criminal penalty of a $250,000 fine and five years' imprisonment for equity skimming, is referenced to § 2B1.1.

(C) References 16 U.S.C. § 1437(c) to § 2A2.4 (Obstructing or Impeding Officers). Section 1437, as amended by the National Marine Sanctuaries Act of 2000, Pub. L. 106–513, Nov. 13, 2000, 114 Stat. 2387, prohibits the interference with the enforcement of conservation activities authorized in title 16, United States Code, including refusing to permit any officer authorized to enforce such title to board a vessel for purposes of conducting a search or inspection in connection with the enforcement of title 16. The Act provides a statutory maximum of six months, or if the offense involved the use of a dangerous weapon or resulted in bodily injury, a statutory maximum of 10 years. Section 1437(c) seems sufficiently similar to other offenses referenced to § 2A2.4 to warrant reference to this guideline.

(15) Proposes several changes to § 2G1.1 (Promoting Prostitution or Prohibited Sexual Conduct) to address more adequately the portion of section 112(b) of the Victims of Trafficking and Violence Protection Act of 2000 (the ''Act''), Pub. L. 106–386, pertaining to the new offense at 18 U.S.C. § 1591 (Sex Trafficking of Children by Force, Fraud or Coercion). Section 1591 prohibits knowingly transporting or harboring any person, or benefitting from such transporting or harboring, knowing either that force, fraud, or coercion will be used to cause that person to engage in a commercial sex act, or that the person is not 18 years old and will be forced to engage in a commercial sex act.

In response to the Act, the Commission, in March 2001, passed an amendment that (A) referenced 18 U.S.C. § 1591 to §§ 2G1.1 (Promoting Prostitution or Prohibited Sexual Conduct) and 2G2.1 (Sexually Exploiting a Minor by Production of Sexually Explicit Visual or Printed Material); and (B) provided an encouraged upward departure in § 2G1.1 to address cases in which (i) the defendant was convicted under 18 U.S.C. § 1591 and the offense involved a victim who had not attained the age of 14 years; or (ii) the offense involved more than 10 victims. Staff had recommended additional changes to § 2G1.1 at that time but because adequate public notice regarding those changes had not been provided, staff recommended that the changes be made during this amendment cycle.

This amendment proposes three substantive changes to § 2G1.1. First, this amendment broadens the conduct covered by the guideline to all commercial sex acts. Currently, the conduct covered by the guideline is limited to prostitution. Second, this amendment expands the ''force or coercion'' prong of § 2G1.1(b)(1) to also cover offenses involving fraud. This change addresses the increased punishment provided by section 1591 for offenses effected by ''force, fraud, or coercion''. Third, after reviewing again the statute and the encouraged upward departure note that the Commission passed in March, staff recommends deleting the portion of the note

pertaining to the age of the victim because it encourages a departure for conduct arguably covered by the guideline in subsection (b)(2).

Section 5D1.2 is amended in subsection (c) by inserting ''(Policy Statement)'' before ''If the instant''.

Section 2B4.1 is amended by striking subsection (b)(2) in its entirety and inserting the following:

''(2) (Apply the greater) If—

(A) the defendant derived more than $1,000,000 in gross receipts from one or more financial institutions as a result of the offense, increase by 2 levels; or

(B) the offense substantially jeopardized the safety and soundness of a financial institution, increase by 4 levels.

If the resulting offense level determined under subdivision (A) or (B) is less than level 24, increase to level 24.''

The Commentary to § 2B4.1 captioned ''Application Notes'' is amended by striking Notes 4 and 5 and inserting the following:

''4. Gross Receipts Enhancement under Subsection (b)(2)(A).—

(A) In General.—For purposes of subsection (b)(2)(A), the defendant shall be considered to have derived more than $1,000,000 in gross receipts if the gross receipts to the defendant individually, rather than to all participants, exceeded $1,000,000.

(B) Definition.—'Gross receipts from the offense' includes all property, real or personal, tangible or intangible, which is obtained directly or indirectly as a result of such offense. See 18 U.S.C. § 982(a)(4).

5. Enhancement for Substantially Jeopardizing the Safety and Soundness of a Financial Institution under Subsection (b)(2)(B).—For purposes of subsection (b)(2)(B), an offense shall be considered to have substantially jeopardized the safety and soundness of a financial institution if, as a consequence of the offense, the institution (A) became insolvent; (B) substantially reduced benefits to pensioners or insureds; (C) was unable on demand to refund fully any deposit, payment, or investment; (D) was so depleted of its assets as to be forced to merge with another institution in order to continue active operations; or (E) was placed in substantial jeopardy of any of subdivisions (A) through (D) of this note.''.

Section 2C1.7 is amended in subsection (b)(1)(A) by striking the period at the end and inserting ''; or''.

Section 2Q1.6 is amended in subsection (a)(3) by inserting at the end ''or''.

The Commentary to § 2D1.9 captioned ''Statutory Provisions'' is amended by striking ''(e)'' after ''841'' and inserting ''(d)''.

Section 2D1.11(a) is amended by striking ''below'' and inserting ''or (e), as appropriate''.

Section 2D1.11 is amended in the Notes before the Commentary in Note (A) by striking ''of this guideline'' and inserting ''or (e) of this guideline, as appropriate''.

The Commentary to § 2D1.11 captioned ''Statutory Provisions'' is amended by striking ''(d)'' after ''841'' and inserting ''(c)''; and by striking ''(g)'' and inserting ''(f)''.

The Commentary to § 2D1.13 captioned ''Statutory Provisions'' is amended by striking ''(d)'' and inserting ''(c)''; and by striking ''(g)'' and inserting ''(f)''.

Appendix A (Statutory Index) is amended in the line referenced to ''21 U.S.C. § 841(d)(1),(2)'' by striking ''(d)'' and inserting ''(c)'';

In the line referenced to ''21 U.S.C. § 841(d)(3)'' by striking ''(d)'' and inserting ''(c)'';

In the line referenced to ''21 U.S.C. § 841(e)'' by striking ''(e)'' and inserting ''(d)''; and

In the line referenced to ''21 U.S.C. § 841(g)'' by striking ''(g)'' and inserting ''(f)''.

The Commentary to § 2N2.1 captioned ''Application Notes'' is amended in Note 2 by striking ''theft, property destruction, or''.

Section 2T1.1 is amended in the Notes following subsection (c)(1) in Note D by striking ''subdivisions'' and inserting ''subdivision''.

Section 5B1.3(a) is amended by adding at the end the following new subdivision:

''(10) the defendant shall submit to the collection of a DNA sample from the defendant at the direction of the United States Probation Office if the collection of such a sample is authorized pursuant to section 3 of the DNA Analysis Backlog Elimination Act of 2000 (42 U.S.C. § 14135a).''.

Section 5D1.3(a) is amended by adding at the end the following new subdivision:

''(8) the defendant shall submit to the collection of a DNA sample from the defendant at the direction of the United States Probation Office if the collection of such a sample is authorized pursuant to section 3 of the DNA Analysis Backlog Elimination Act of 2000 (42 U.S.C. § 14135a).''.

The Commentary to § 5E1.2 captioned ''Application Notes'' is amended in Note 5 by striking ''; and 42 U.S.C. § 7413(c), which authorizes a fine of up to $25,000 per day for violations of the Clean Air Act''.

The Commentary to § 5F1.7 is amended by inserting before the first paragraph ''Background''.

Chapter Seven, Part A, is amended in the second paragraph of 2(b) captioned ''Supervised Release'' by striking ''intermittent confinement'' and inserting ''residency in, or participation in the program of, a community corrections facility*''; and by adding at the end the following:

''***Note:** Section 3583(d) of title 18, United States Code, provides that '[t]he court may order, as a further condition of supervised release* * *any condition set forth as a discretionary condition of probation in section 3563(b)(1) through (b)(10) and (b)(12) through (b)(20), and any other condition it considers to be appropriate.' Subsection (b)(11) of section 3563 is explicitly excluded as a condition of supervised release. Before the enactment of the Antiterrorism and Effective Death Penalty Act of 1996, the condition at subsection (b)(11) was intermittent confinement. The Act deleted 18 U.S.C. § 3563(b)(2), authorizing the payment of a fine as a condition of probation, and re-designated the remaining conditions of probation set forth in 18 U.S.C. § 3563(b); intermittent confinement is now set forth at subsection (b)(10), whereas subsection (b)(11) sets forth the condition of residency at a community corrections facility. It would appear that intermittent confinement now is authorized as a condition of supervised release.

However, there is some question as to whether Congress intended this result. Although the Antiterrorism and Effective Death Penalty Act re-designated the remaining paragraphs of section 3563(b), it failed to make the corresponding re-designations in 18 U.S.C. § 3583(d), regarding discretionary conditions of supervised release. While imposition of intermittent confinement as a condition of supervised release does not violate the letter of the law as it is currently written, imposition of the condition arguably may not be consistent with its long-standing intent.''.

The Commentary to § 7B1.3 captioned ''Application Notes'' is amended in Note 5 by striking ''18 U.S.C. § 3563(b)(11). Intermittent confinement is not authorized as a condition of supervised release. 18 U.S.C. § 3583(d).'' and inserting ''18 U.S.C. § 3563(b)(10)''.

***Note:** Section 3583(d) of title 18, United States Code, provides that'[t]he court may order, as a further condition of supervised release* * *any condition set forth as a discretionary condition of probation in section 3563(b)(1) through (b)(10) and (b)(12) through (b)(20), and any other condition it considers to be appropriate.' Subsection (b)(11) of section 3563 is explicitly excluded as a condition of supervised release. Before the enactment of the Antiterrorism and Effective Death Penalty Act of 1996, the condition at subsection (b)(11) was intermittent confinement. The Act deleted 18 U.S.C. § 3563(b)(2), authorizing the payment of a fine as a condition of probation, and re-

designated the remaining conditions of probation set forth in 18 U.S.C. § 3563(b); intermittent confinement is now set forth at subsection (b)(10), whereas subsection (b)(11) sets forth the condition of residency at a community corrections facility. It would appear that intermittent confinement now is authorized as a condition of supervised release.

However, there is some question as to whether Congress intended this result. Although the Antiterrorism and Effective Death Penalty Act re-designated the remaining paragraphs of section 3563(b), it failed to make the corresponding re-designations in 18 U.S.C. § 3583(d), regarding discretionary conditions of supervised release. While imposition of intermittent confinement as a condition of supervised release does not violate the letter of the law as it is currently written, imposition of the condition arguably may not be consistent with its long-standing intent.''.

The Commentary to § 5F1.5 captioned ''Background'' is amended in the first paragraph by striking ''(b)(6)'' and inserting ''(b)(5)'' each place it appears.

The Commentary to § 5F1.5 captioned ''Background'' is amended by striking the last paragraph in its entirety and inserting the following:

''The appellate review provisions permit a defendant to challenge the imposition of a probation condition under 18 U.S.C. § 3563(b)(5) if the sentence includes a more limiting condition of probation or supervised release than the maximum established in the guideline. See 18 U.S.C. § 3742(a)(3). The government may appeal if the sentence includes a less limiting condition of probation than the minimum established in the guideline. 18 U.S.C. § 3742(b)(3).''.

Appendix A (Statutory Index) is amended by inserting after the line referenced to ''18 U.S.C. § 2244'' the following:

''18 U.S.C. § 2245 2A1.1''.

Section 4B1.4(b)(3)(A) is amended to read as follows:

''(3) (A) 34, if the defendant used or possessed the firearm or ammunition in connection with a crime of violence or controlled substance offense, as defined in § 4B1.2(a) and (b), respectively, or if the firearm possessed by the defendant was of a type described in 26 U.S.C. § 5845(a)*; or''.

Section 2B1.1 captioned ''Application Notes'' is amended in Note 7 by striking ''(d)(3)'' and inserting ''(d)(4)''.

Appendix A (Statutory Index) is amended by inserting after the line referenced to ''16 U.S.C. § 1417(a)(5),(6),(b)(2)'' the following:

''16 U.S.C. § 1437(c) 2A2.4'';

by inserting after the line referenced to ''42 U.S.C. § 5157(a)'' the following:

''42 U.S.C. § 5410(b) 2N2.1'';

and by inserting after the line referenced to ''42 U.S.C. § 9603(d)'' the following:

''42 U.S.C. § 149052 B1.1''.

Chapter Two, Part G, Subpart 1 is amended in the title by striking ''Prostitution'' and inserting ''A Commercial Sex Act''.

Section 2G1.1 is amended in the title by striking ''Prostitution'' and inserting ''A Commercial Sex Act''.

Section 2G1.1 is amended in the guideline, the Commentary captioned ''Application Notes'', and the Commentary captioned ''Background'' by striking ''prostitution'' each place it appears and inserting ''a commercial sex act''.

—Section 2G1.1(b)(1) is amended by striking ''by threats or drugs or in any manner''.

—The Commentary to § 2G1.1 captioned ''Application Notes'' is amended in Note 1 by inserting after ''For purposes of this guideline—'' the following:

''Commercial sex act'' has the meaning given that term in 18 U.S.C. § 1591(c)(2).''

The Commentary to § 2G1.1 captioned ''Application Notes'' is amended in the first sentence of Note 2 by inserting ''fraud,'' after ''force,''; and by striking the comma after ''coercion''.

The Commentary to § 2G1.1 captioned ''Application Notes'' is amended in Note 12 by striking ''in either of the following circumstances:'' and all that follows through ''more than 10 victims'' and inserting ''if the offense involved more than 10 victims''.

[FR Doc. 01–29467 Filed 11–26–01; 8:45 am]

BILLING CODE 2211–01–U

Federal Register

Tuesday,
November 27, 2001

Part IV

Department of the Treasury

Departmental Offices; Interim Guidance Concerning Compliance by Covered U.S. Financial Institutions With New Statutory Anti-Money Laundering Requirements Regarding Correspondent Accounts Established or Maintained for Foreign Banking Institutions; Notice

DEPARTMENT OF THE TREASURY

Departmental Offices; Interim Guidance Concerning Compliance by Covered U.S. Financial Institutions With New Statutory Anti-Money Laundering Requirements Regarding Correspondent Accounts Established or Maintained for Foreign Banking Institutions

AGENCY: Department of the Treasury, Departmental Offices.

ACTION: Notice.

SUMMARY: This notice provides interim guidance to financial institutions on how to comply with the requirements of sections 313 and 319(b) of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT) Act of 2001 (Pub. L. 107–56). These anti-money laundering provisions concern the relationship between U.S. financial institutions and foreign banking institutions.

DATES: This notice is effective beginning November 27, 2001 and will remain in effect until superseded by regulations or a subsequent notice.

FOR FURTHER INFORMATION CONTACT: Gary W. Sutton, Senior Banking Counsel, Office of the Assistant General Counsel (Banking and Finance), 202–622–1976 or William D. Langford, Attorney-Advisor, Office of the Assistant General Counsel (Enforcement), 202–622–1932.

SUPPLEMENTARY INFORMATION: This notice provides interim guidance to U.S. financial institutions on the steps necessary for them to comply with the requirements of 31 U.S.C. 5318(j) and (k), as enacted by sections 313 and 319(b) of the USA PATRIOT Act of 2001, respectively. Although this notice may be relied upon by financial institutions until superseded by regulations or a subsequent notice, no inference may be drawn from this notice concerning the scope and substance of regulations that the Department of the Treasury will issue concerning sections 5318(j) and (k).

I. Background

A. Statutory Background

On October 26, 2001, the President signed into law the USA PATRIOT Act. Title III of the USA PATRIOT Act makes a number of amendments to the anti-money laundering provisions of the Bank Secrecy Act (BSA), which is codified in subchapter II of chapter 53 of title 31, United States Code. These amendments are intended to make it easier to prevent, detect, and prosecute international money laundering and the financing of terrorism. Two of these provisions become effective on December 5, 2001.

First, section 313(a) of the USA PATRIOT Act adds a new subsection (j) of 31 U.S.C. 5318 that prohibits certain financial institutions from providing correspondent accounts to foreign ''shell banks'' and requires those financial institutions to take reasonable steps to ensure that correspondent accounts provided to foreign banks are not being used to indirectly provide banking services to foreign ''shell banks''. Second, section 319(b) of the USA PATRIOT Act adds a new subsection (k) to 31 U.S.C. 5318 that requires certain financial institutions that provide correspondent accounts to a foreign bank to maintain records of the foreign bank's owners and agent in the United States designated to accept service of legal process.

Under the USA PATRIOT Act, the Secretary of the Treasury (Secretary) is authorized to interpret and administer these provisions. In light of the December 25, 2001 effective date of sections 5318(j) and (k), the Secretary, in consultation with the federal financial regulators [1] and the Attorney General, is publishing this notice to provide interim guidance to financial institutions in meeting their compliance obligations under these provisions. As discussed below, this notice describes a certification that financial institutions may use as an interim means to assist them in meeting their obligations related to dealing with foreign shell banks under section 5318(j) and recordkeeping under section 5318(k). It should be noted that this certification will not satisfy a financial institution's obligations under any other provisions of the USA PATRIOT Act, including obligations to conduct due diligence under 31 U.S.C. 5318(i), as added by section 312 of the USA PATRIOT Act, or any other applicable law or regulation.

Although the prohibition in section 5318(j) becomes effective on December 25, 2001, the Department of the Treasury expects that covered financial institutions will promptly terminate any correspondent account with any foreign bank that it knows to be a shell bank that is not a regulated affiliate as described in this notice.

[1] The Office of the Comptroller of the Currency, the Office of Thrift Supervision, the Board of Governors of the Federal Reserve System, the Federal Deposit Insurance Corporation, the Commodities Futures Trading Commission, and the Securities and Exchange Commission.

1. What Are the Requirements of Section 5318(j)?

31 U.S.C. 5318(j), as added by section 313 of the USA PATRIOT Act, provides that a ''covered financial institution'' shall not establish, maintain, administer, or manage a correspondent account in the United States for, or on behalf of, a foreign bank that does not have a physical presence in any country (shell bank). In addition, the USA PATRIOT Act requires a covered financial institution to take reasonable steps to ensure that any correspondent account established, maintained, administered, or managed by the covered financial institution in the United States for a foreign bank is not being used by that foreign bank to indirectly provide banking services to a foreign shell bank that is not a regulated affiliate.

What Is a Covered Financial Institution?

For purposes of section 5318(j), a ''covered financial institution'' is: (1) Any insured bank (as defined in section 3(h) of the Federal Deposit Insurance Act (12 U.S.C. 1813(h))); (2) a commercial bank or trust company; (3) a private banker; (4) an agency or branch of a foreign bank in the United States; (4) a credit union; (5) a thrift institution; or (6) a broker or dealer registered with the Securities and Exchange Commission under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*).

What Is a Foreign Shell Bank?

For purposes of section 5318(j), a foreign shell bank is a foreign bank without a physical presence in any country. Under section 5318(j), a ''physical presence'' is a place of business that is maintained by a foreign bank and is located at a fixed address, other than solely an electronic address, in a country in which the foreign bank is authorized to conduct banking activities, at which location the foreign bank: (1) Employs one or more individuals on a full-time basis; (2) maintains operating records related to its banking activities; and (3) is subject to inspection by the banking authority that licensed the foreign bank to conduct banking activities.

What Foreign Shell Banks Are Excepted From the Limitations on Correspondent Accounts?

The limitations on the direct and indirect provision of correspondent accounts to foreign shell banks do not apply to a foreign shell bank that is a regulated affiliate. A regulated affiliate is a foreign shell bank that (1) is an affiliate of a depository institution,

credit union, or foreign bank that maintains a physical presence in the United States or a foreign country, as applicable; and (2) is subject to supervision by a banking authority in the foreign country regulating such affiliated depository institution, credit union, or foreign bank. An affiliate is a foreign bank that is controlled by or is under common control with a depository institution, credit union, or foreign bank.

What Is a Correspondent Account?

31 U.S.C. 5318A(e)(1)(B), as added by section 311 of the USA PATRIOT Act, defines ''correspondent account,'' with respect to banking institutions, as ''an account established to receive deposits from, make payments on behalf of a foreign financial institution, or handle other financial transactions related to such institution.'' This definition applies for purposes of this notice and the certification.

It is the expectation of the Department of the Treasury that a covered financial institution will accord priority to requesting certifications in connection with foreign banks for which it maintains correspondent deposit accounts or their equivalents.

The Department of the Treasury intends to issue a rule under the authority of section 5318A(e)(2) and (4), as added by section 311 of the USA PATRIOT Act, to further define the term ''account'' (1) to prohibit non-bank covered financial institutions (including a broker or dealer registered with the Securities and Exchange Commission under the Securities Exchange Act of 1934) from establishing or maintaining an account for a foreign shell bank that is not a regulated affiliate and (2) to require non-bank covered financial institutions to take reasonable steps to ensure that any account established, maintained, administered, or managed by such institution in the United States for a foreign bank is not being used by that foreign bank to indirectly provide banking services to a foreign shell bank that is not a regulated affiliate.

2. What Are the Requirements of Section 5318(k)?

31 U.S.C. 5318(k), as added by section 319(b) of the USA PATRIOT Act, requires, among other things, that any covered financial institution that maintains a correspondent account in the United States for a foreign bank shall maintain records in the United States identifying (1) the owner(s) of such foreign bank and (2) the name and address of a person who resides in the United States and is authorized to accept service of legal process for records regarding the correspondent account.

What Is a Covered Financial Institution?

Section 5318(k) does not define ''covered financial institution'' for purposes of this recordkeeping requirement. For purposes of this notice and the certification, the term ''covered financial institution'' has the same meaning as provided in section 5318(j) (see above), except that such term does not include a broker or dealer registered with the Securities and Exchange Commission under the Securities Exchange Act of 1934. The Department of the Treasury intends to propose similar recordkeeping requirements for such brokers and dealers.

What Is a Correspondent Account?

Section 5318(k) defines ''correspondent account'' by reference to the definition of that term in 31 U.S.C. 5318A(e)(1)(B), as added by section 311 of the USA PATRIOT Act, which, as discussed above, means ''an account established to receive deposits from, make payments on behalf of a foreign financial institution, or handle other financial transactions related to such institution.''

As noted above, it is the expectation of the Department of the Treasury that a covered financial institution will accord priority to requesting certifications in connection with foreign banks for which it maintains correspondent deposit accounts or their equivalents.

Who Is an Owner of a Foreign Bank?

Section 5318(k) does not define ''owner'' for purposes of the requirement that a covered financial institution maintain records of the owners of foreign banks to which it provides correspondent accounts. For purposes of this notice and the certification, an ''owner'' means any person who is a ''large direct owner,'' an ''indirect owner,'' and certain ''small direct owners.'' For purposes of these definitions: (1) ''Person'' means any individual, bank, corporation, partnership, limited liability company, or any other legal entity, except that members of the same family [2] shall be considered one person; and (2) ''voting shares or other voting interests'' means shares or other interests that entitle the holder to vote for or select directors (or individuals exercising similar functions).

The definition of ''owner'' as used in this notice and in the certification applies only with respect to the provisions of section 5318(k), which are designed to facilitate the service of legal process. No inference may be drawn as to the applicability of this definition to other provisions of the USA PATRIOT Act, including the enhanced due diligence requirements of 31 U.S.C. 5318(i) (as added by section 312 of the USA PATRIOT Act), which sets forth different standards for reporting ownership information.

Who Is a Small Direct Owner of a Foreign Bank?

A ''small direct owner'' of a foreign bank is a person who owns, controls, or has power to vote less than 25 percent of any class of voting securities or other voting interests of the foreign bank. The identity of a small direct owner need not be reported for purposes of this notice and certification unless two or more small direct owners (1) in the aggregate own 25 percent or more of the voting securities or interests of the foreign bank and (2) are owned by the same indirect owner (see below).

Who Is a Large Direct Owner of a Foreign Bank?

A ''large direct owner'' of a foreign bank is a person who (1) owns, controls, or has power to vote 25 percent or more of any class of voting securities or other voting interests of the foreign bank; or (2) controls in any manner the election of a majority of the directors (or individuals exercising similar functions) of the foreign bank. The identity of each large direct owner is subject to reporting.

Who Is an Indirect Owner of a Foreign Bank?

If any large direct owner of a foreign bank is majority-owned by another person, or by a chain of majority-owned persons, an ''indirect owner'' is any person in the ownership chain of any large direct owner who is not majority-owned by another person.

If any two or more small direct owners of a foreign bank (1) in the aggregate own, coantrol, or have power to vote 25 percent or more of any class of voting securities or other voting interests of the foreign bank and (2) are majority-owned by the same person, or by the same chain of majority-owned persons, the ''indirect owner'' is any person in the ownership chain of the small direct owners who is not majority-owned by another person.

[2] The same family means parents, spouses, children, siblings, uncles, aunts, grandparents, grandchildren, first cousins, second cousins, stepchildren, stepsiblings, parents-in-law and spouses of any of the foregoing.

Each indirect owner is subject to reporting.

Example of Reportable Owners

The following example illustrates the owners of a foreign bank who are covered by this notice and the certification:

FB is a foreign bank. Voting securities of FB are owned by Person C (15 percent), Person D (35 percent), Person E (10 percent), Person F (20 percent), and Person G (20 percent).

Persons C and G are both majority-owned by Person X, which is majority-owned by Person Y, which is majority-owned by Person Z, which is not majority-owned by another person.

Person D is majority-owned by Person V, which is majority-owned by Person W, which is not majority-owned by another person.

Persons E and F are not owned by another person.

Persons C, E, F, and G are small direct owners because each owns less than 25 percent of the voting securities of FB. The identities of Persons C and G are subject to reporting under this notice because (1) in the aggregate they own more than 25 percent of the voting securities of FB and (2) they are majority-owned by the same indirect owner Z. The identities of Persons E and F are not subject to reporting.

Person D is a large direct owner because it owns 25 percent or more of the voting securities of FB. The identity of Person D is subject to reporting under this notice.

Person W is an indirect owner because it is a majority-owner of Person V, which is a majority-owner of Person D. The identity of Person W is subject to reporting under this notice. The identity of Person V is not subject to reporting.

Person Z is an indirect owner because it is a majority-owner of Person Y, which is a majority-owner of Person X, which is a majority-owner of Persons C and G, which are small direct owners that in the aggregate own 25 percent or more of the voting securities of FB. The identity of Person Z is subject to reporting under this notice. The identity of Persons Y and X are not subject to reporting.

B. Description of Certification

What Is Being Certified?

Under paragraph 1 of the certification, a foreign bank that maintains a correspondent account with a covered financial institution certifies either that: (1) it is not a shell bank; (2) it is a shell bank that is a regulated affiliate; or (3) is a shell bank that is not a regulated affiliate, in which case a covered financial instiution is prohibited from establishing or maintaining a correspondent account with the foreign bank.

If a foreign bank certifies that it is not a shell bank, it specifies in Annex I its physical address and its regulator. If the foreign bank certifies that it is a regulated affiliate, it specifies in Annex I the name and address of the non-shell bank with which it is affiliated and the regulator of the non-shell bank and the regulated affiliate.

Under paragraph 2 of the certification, a foreign bank certifies either that: (1) It does not provide banking services to any foreign shell bank, other than a regulated affiliate; or (2) it provides banking services to a foreign shell bank but will not use any of the correspondent accounts with a U.S. financial institution to provide banking services to any foreign shell bank, other than a regulated affiliate.

Under paragraph 3 of the certification, a foreign bank certifies the identity its owner(s) in annex II. Street addresses must be provided; post office boxes are not acceptable.

Under paragraph 4 of the certification, a foreign bank certifies the identity of its agent for service of legal process in the United States, and identifies the agent in Annex III. Street addresses must be provided; post office boxes are not acceptable.

Under paragraph 5 of the certification, a foreign bank certifies that it will notify each financial institution in the United States at which it maintains a correspondent account in writing within 30 calendar days of any change in facts or circumstances previously certified or contained in the annexes to the certification.

Under paragraph 6 of the certification, a foreign bank certifies that it understands that each financial institution in the United States at which it maintains a correspondent account may provide a copy of the certification to the Secretary of the Treasury and the Attorney General of the United States, or their delegees.

Paperwork Reduction Act

The collection of information contained in the certification have been reviewed under the requirements of the Paperwork Reduction Act (44 U.S.C. 3507(j)) and, pending receipt and evaluation of public comments, approved by the Office of Management and Budget (OMB) under control 1505–0184. 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.

Comments concerning the collection of information should be directed to OMB, Attention: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503. Any such comments should be submitted not later than January 28, 2002.

Comments are specifically requested concerning:

Whether the collection of information is necessary for the proper performance of the functions of the Department of the Treasury, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the collection of information (see below);

How to enhance the quality, utility, and clarity of the information to be collected;

How to minimize the burden of complying with the collection of information, including the application of automated collection techniques or other forms of information technology; and

Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

The collection of information in the certification will enable financial institutions, on an interim basis, to comply with the requirements of sections 313 and 319(b) of the USA PATRIOT Act of 2001. This information will be used to verify compliance by financial institutions with these provisions. The respondents are foreign banks that establish or maintain correspondent accounts with U.S. financial institutions. The reporting of this information by foreign banking institutions is voluntary; however failure to provide the information may preclude the establishment or the continuation of correspondent accounts with U.S. financial institutions.

Estimated total annual reporting burden: 180,00 hours.

Estimated number of respondents: 9,000.

Estimated average annual reporting burden per respondent: 20 hours.

Estimated annual frequency of responses: Once.

II. Certification

The following form of certification may be used by a covered financial institution for purposes of this notice. A covered financial institution may use other means to obtain the information necessary to satisfy its obligations under section 5318(j) or 5318(k).

Dated: November 20, 2001.

David D. Aufhauser,

General Counsel.

BILLING CODE 4810–25–M

CERTIFICATION FOR PURPOSES OF SECTIONS 5318(j) AND 5318(k) OF TITLE 31, UNITED STATES CODE

[OMB Control Number 1505-0184]

The information contained in this Certification is sought pursuant to Sections 5318(j) and 5318(k) of Title 31 of the United States Code, as added by sections 313 and 319(b) of the USA PATRIOT Act of 2001 (Public Law 107-56).

The undersigned respondent bank, _____ _____("Respondent Bank"), has established one or more accounts with _____ ("Covered Financial Institution") to receive deposits from, make payments on behalf of, or handle other financial transactions related to Respondent Bank (the "Correspondent Accounts"). The Respondent Bank hereby certifies, by an individual authorized to make such certification, as follows:

1. Respondent Bank (check appropriate box and complete Annex I):

☐ (a) Maintains a place of business that (i) is located at a fixed address (other than solely an electronic address) in a country in which Respondent Bank is authorized by such country to conduct banking activities, at which location Respondent Bank employs one or more individuals on a full-time basis and maintains operating records related to its banking activities; and (ii) is subject to inspection by the banking authority that licensed Respondent Bank to conduct banking activities (hereinafter referred to as a **"physical presence"**);

☐ (b) Does not have a **physical presence** in any country, but the Respondent Bank (i) is an affiliate of a U.S. depository institution, U.S. credit union, or non-U.S. bank that maintains a **physical presence** in a country; and (ii) is also subject to supervision by the same banking authority in the country that regulates such affiliated depository institution, credit union, or non-U.S. bank (the Respondent Bank is thus a **"regulated affiliate"**); or

☐ (c) Does not have a **physical presence** in a country and is not a **regulated affiliate**.

2. Respondent Bank either (check appropriate box):

☐ (a) does not provide banking services to any non-U.S. bank that does not have a **physical presence** in any country and that is not a **regulated affiliate**; or

☐ (b) provides banking services to a non-U.S. bank that does not have a **physical presence** in any country and that is not a **regulated affiliate**, but Respondent Bank will not after December 25, 2001 use any Correspondent Account with the Covered Financial Institution to provide banking services to any non-U.S. bank that does not have a **physical presence** in any country, and that is not a **regulated affiliate**.

3. Respondent Bank has no **owner(s)** (as defined below) except as set forth in Annex II. For purposes of this Certification, an **owner** means any **large direct owner**, any **indirect owner**, and certain **small direct owners**.

A **large direct owner** is a **person** who (1) owns, controls, or has power to vote 25 percent or more of any class of voting securities or other voting interests of the Respondent Bank; or (2) controls in any manner the election of a majority of the directors (or individuals exercising similar functions) of the Respondent Bank.

A **small direct owner** is a person who owns, controls, or has power to vote less than 25 percent of any class of voting securities or other voting interests of the Respondent Bank. The identity of a **small direct owner** need not be set forth in Annex II unless two or more small direct owners (1) in the aggregate own 25 percent or more of the voting securities or interests of the Respondent Bank and (2) are owned by the same **indirect owner**.

If any **direct owner** is majority-owned by another person, or a chain of majority-owned persons, an **indirect owner** is any person in the ownership chain of the **direct owner** who is not majority-owned by another person.

If any two or more **small direct owners** (1) in the aggregate own, control, or have power to vote 25 percent or more of any class of voting securities or other voting interests of the Respondent Bank and (2) and are majority-owned by the same person, or by the same chain of majority-owned persons, an **indirect owner** is any person in the ownership chain of such small direct owners who is not majority-owned by another person.

For purposes of this Certification, (i) **"person"** means any individual, bank, corporation, partnership, limited liability company or any other legal entity; (ii) **voting securities or other voting interests** means securities or other interests that entitle the holder to vote for or select directors (or individuals exercising similar functions); and (iii) members of the same family* shall be considered one **person**.

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* The same family means parents, spouses, children, siblings, uncles, aunts, grandparents, grandchildren, first cousins, second cousins, stepchildren, stepsiblings, parents-in-law and spouses of any of the foregoing.

4. The individual or entity ("Agent") identified in Annex III, resident in the United States at the address (not a post office box) set forth in Annex III, is authorized to accept service of legal process from the Secretary of the Treasury or the Attorney General of the United States pursuant to Section 5318(k) of title 31, United States Code.

5. Respondent Bank shall notify in writing within 30 calendar days each financial institution in the United States at which it maintains a Correspondent Account of any change in facts or circumstances as reported in this Certification and the Annexes hereto.

6. Respondent Bank understands that each financial institution in the United States at which it maintains a Correspondent Account may provide a copy of this Certification to the Secretary of the Treasury and the Attorney General of the United States.

I, _____ (name), certify that I have read and understand this Certification and the Annexes hereto and that the statements made in this Certification and the Annexes hereto are true and correct.

This Certification is made on behalf of _____ (name of Respondent Bank), a banking institution organized under the laws of _____ (specify country).

I understand that the statements contained in this Certification and the Annexes hereto may be transmitted to one or more departments or agencies of the United States of America for purpose of fulfilling such departments' and agencies' governmental functions.

_____
[Signature]

_____
[Title]

Executed on this _____ day of _____, 200__.

Received, reviewed and accepted by:

Name: _____
Title: _____
For:

_____
[Name of Covered Financial Institution]

_____
Date

Annex I

1. To be completed if Respondent Bank checked paragraph 1(a) of the Certification:

(A) Respondent Bank maintains a place of business at

_____
[Street Address]

in _____ .
[Country]

(B) The banking authority that has the right to inspect the place of business referred to in (A) is

_____ .
[Name of Banking Authority]

2. To be completed if Respondent Bank checked paragraph 1(b) of the Certification:

(A) Respondent Bank's affiliate that is regulated is _____, which maintains a **physical presence** at
[Name of Affiliate]

_____
[Street Address]

in _____ .
[Country]

(B) The banking authority that supervises both the Respondent Bank and its affiliate is

_____ .
[Name of Banking Authority]

Annex II

Name and Address
of Owner(s)

Name	***Address*** (No Post Office Boxes)

Attach Additional Sheets if Necessary

Annex III

Name and Address
of Agent Designated to Accept Service of Legal Process

Name	*Address* (No Post Office Boxes)	*Phone No.*	*Fax No.*	*E-mail Address*

[FR Doc. 01–29468 Filed 11–21–01; 3:04 pm]
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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.

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Air programs:
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LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with ''P L U S'' (Public Laws Update Service) on 202–523–6641. This list is also available online at *http://www.nara.gov/fedreg/plawcurr.html*.

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S. 1447/P.L. 107–71

Aviation and Transportation Security Act (Nov. 19, 2001; 115 Stat. 597)

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