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

DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

7 CFR Part 1482

RIN 0551–AA60

Program to Assist U.S. Producers in Developing Domestic Markets for Value-Added Wheat Gluten and Wheat Starch Products

AGENCY: Commodity Credit Corporation, USDA.

ACTION: Interim rule.

SUMMARY: This interim rule amends 7 CFR Chapter XIV to establish a two-year program to assist U.S. producers to pay for certain costs incurred in developing products and markets for value-added wheat gluten and wheat starch products.

DATES: This rule is effective June 5, 2001. Comments should be received on or before July 9, 2001 to be assured of consideration.

ADDRESSES: Comments should be mailed or delivered to Mark Petry, Europe, Africa, and Middle East Division, Foreign Agricultural Service, 1400 Independence Avenue SW, STOP 1024, U.S. Department of Agriculture, Washington, DC 20250. Comments received may be inspected between 10:00 a.m. and 4:00 p.m. at room 5514–S, 1400 Independence Avenue SW, Washington, DC 20250.

FOR FURTHER INFORMATION CONTACT: For policy questions, contact Mark Petry, at the address above, or telephone at (202)720–1329, or e-mail at *Petrym@fas.usda.gov.* For program operations questions, contact Barry Klein (202)720–4647 or email at *Barry.Klein@usda.gov.* Persons with disabilities who require this final rule in an alternative means of communication (Braille, large print, audiotape, etc.) should contact the USDA Target Center at (202)720–2600 (voice and TDD).

SUPPLEMENTARY INFORMATION:

Executive Order 12372

This program is not subject to the provision of Executive Order 12372, which requires intergovernmental consultation with State or local officials (See notice related to 7 CFR part 3015, subpart V, published at 48 FR 29115, June 24, 1983).

Executive Order 12988

This rule has been reviewed under Executive Order 12988. The provisions of this rule do not have preemptive effect with respect to any state or local laws, regulations, or policies which conflict with such provisions or which otherwise impede their full implementation. This rule does not have retroactive effect. Administrative proceedings must be exhausted before parties may seek judicial review.

Executive Order 12866

This rule is issued in conformance with Executive Order 12866. It has been determined significant for the purposes of E.O. 12866 and, therefore, has been reviewed by the Office of Management and Budget (OMB).

Regulatory Flexibility Act

The Regulatory Flexibility Act ensures that regulatory and information requirements are tailored to the size and nature of small businesses, small organizations, and small governmental jurisdictions. This rule will not have a significant economic impact on a substantial number of small entities. Participation in the programs is voluntary. The direct and indirect costs associated with participating in the program that are not reimbursable by the CCC to eligible producers are likely to be very small as a percentage of revenue and in terms of absolute costs. The minimal regulatory requirements impact large and small businesses equally, and the program should improve small businesses' cash flow and liquidity.

Paperwork Reduction Act

CCC did not seek approval from the OMB with respect to the Paperwork Reduction Act because it has determined that no more than three entities are eligible to participate in the program established by this rule.

Background

Temporary Safeguard Measure

In March 1998, the U.S. International Trade Commission (ITC) transmitted to the President a unanimous affirmative determination that wheat gluten was being imported into the United States in such increased quantities as to be a substantial cause of serious injury to the domestic wheat gluten industry. The President imposed a quota on wheat gluten imports from June 1, 1998 through June 1, 2001 as a safeguard relief measure pursuant to section 203 of the Trade Act of 1974. In November 2000, the U.S. wheat gluten industry filed a request with the ITC for a two-year extension of the import quota to June 1, 2003. On April 2, 2001, the ITC determined that action under section 203 continued to be necessary to prevent or remedy serious injury and there was evidence that the domestic wheat gluten producers were making a positive adjustment to import competition. This rule assists the U.S. wheat gluten industry in completing the process of adjustment to import competition by developing value-added products.

Authority

Among other activities, the Commodity Credit Corporation Charter Act (15 USC 714c) authorizes the Commodity Credit Corporation (CCC) to use its general powers to increase domestic consumption of agricultural commodities by aiding in the expansion of domestic markets or by aiding in the development of new and additional markets, marketing facilities, and uses for such commodities. This rule will use CCC funds for the purpose of increasing domestic consumption of value-added products made from wheat gluten and wheat starch and developing new and additional markets, marketing facilities and uses for these products.

Interim Rule

Because the section 201 import quota expires June 1, 2001, it has been determined that this interim rule will be effective upon filing at the **Federal Register**. This action is intended to help the U.S. wheat gluten industry to adjust more quickly to increased import competition that is expected to occur immediately upon the quota's expiration.

The rule provides for a two-year program to assist U.S. wheat gluten producers in fully adjusting to import competition by transitioning the industry from production of basic bulk commodities to production of value-added commodities where the market potential is more viable. U.S. producers of wheat gluten, who meet the eligibility requirements of the rule and submit the required market development plans, will receive an annual lump sum payment by CCC to conduct specific program activities aimed at facilitating the transition to value-added wheat gluten products for sale in the domestic market.

The Department invites comments on all aspects of this rule including: eligibility criteria; contents and requirements of the adjustment plan; sufficiency of the program in assisting adjustment to import competition; relevance to the adjustment plans previously submitted to the ITC; and strength of requirements with respect to ensuring proper usage of program funds.

List of Subjects in 7 CFR Part 1482

Agricultural commodities, production, reporting and record keeping requirements, wheat.

Interim Rule

Accordingly, the regulations at 7 CFR Chapter XIV are amended by adding a new part 1482 to Subchapter B as follows:

PART 1482—VALUE-ADDED WHEAT GLUTEN AND WHEAT STARCH PRODUCT MARKET DEVELOPMENT PROGRAM

Sec.

1482.1 Applicability.
1482.2 Administration.
1482.3 Definitions.
1482.4 Eligibility.
1482.5 Application.
1482.6 Costs.
1482.7 Reports.
1482.8 Payment.
1482.9 Debarment and Suspension.
1482.10 Misrepresentation and scheme or device.
1482.11 Appeals.
1482.12 Expiration.

Authority: 15 USC 714c.

§ 1482.1 Applicability.

(a) This program is applicable until June 5, 2003. This program sets forth the terms and conditions under which the Commodity Credit Corporation (CCC) shall provide payments to U.S. producers participating in the Value-Added Wheat Gluten and Wheat Starch Product Market Development Program for the costs of conducting specific market development activities incurred in the United States with respect to U.S. production of wheat gluten.

(b) Payments shall be made only for wheat gluten and wheat starch products produced or advanced in value in the United States.

§ 1482.2 Administration.

(a) The Value-Added Wheat Gluten and Wheat Starch Product Market Development Program shall be administered under the general supervision of the Executive Vice President, CCC, and shall be carried out by the Deputy Administrator, Commodity Operations, Farm Service Agency (FSA).

(b) The Executive Vice-President, CCC, or the Deputy Administrator, FSA, or a designee, may waive or modify deadlines and other program requirements in cases where lateness or failure to meet other requirements does not adversely affect the operation of the Value-Added Wheat Gluten and Wheat Starch Product Market Development Program.

§ 1482.3 Definitions.

The definitions set forth in this section shall be applicable for purposes of administering the Value-Added Wheat Gluten and Wheat Starch Product Market Development Program.

(a) *Adjustment Plan* means a defined program of activities aimed at improving the economic viability of producers of value-added wheat gluten or wheat starch products.

(b) *Agency* means the Farm Service Agency (FSA).

(c) *Agreement* means the Value-Added Wheat Gluten and Wheat Starch Product Market Development Program Application and Contract.

(d) *Modified wheat gluten or modified wheat starch* means any processed product derived from vital wheat gluten or wheat starch that has been obtained through refining or processing that adds value to the basic product.

(e) *Value-Added* means changes in vital wheat gluten or wheat starch that result in a further processed product having a higher market value than the vital wheat gluten or wheat starch.

(f) *Wheat gluten producer* means agricultural processors, including producer-owned corporations, that produce vital wheat gluten.

§ 1482.4 Eligibility.

(a) To be eligible to receive payments, a wheat gluten producer must:

(1) Have produced in the United States not less than 1,000,000 pounds of vital wheat gluten from July 1, 1998 through June 30, 2000.

(2) Have been engaged in the business of producing and marketing vital wheat gluten or modified wheat gluten from July 1, 1998 through June 30, 2000.

(3) Have reported specific adjustment efforts as part of the 1998 adjustment plan submitted by the Wheat Gluten Industry Council to the International Trade Commission in Investigation Number TA–201–67.

(4) Submit a timely application and comply with the terms and conditions of the program and instructions issued by CCC and FSA.

b. [Reserved]

§ 1482.5 Application.

(a) To receive payments, eligible producers must submit an application within the application period announced by CCC. The application must include the following:

(1) Name of the applicant and name of firm, if applicable;

(2) Address of the applicant and firm;

(3) Name of agent for service of process;

(4) Telephone and fax numbers for the applicant and firm;

(5) Internal Revenue Service tax identification number under which the applicant is conducting business;

(6) Bank account number for electronic submission of funds (optional)

(7) Quantity of vital wheat gluten produced from July 1, 1998 through June 30, 2000;

(8) Submission of information in paragraph (b) of this section.

(9) Information as to the applicant's eligibility under § 1482.4

(b) Eligible producers must submit a proposal for a Value-Added Wheat Gluten and Wheat Starch Product Market Development Program Agreement. The proposal must include the following information:

(1) Nature of the adjustment plan through production development and market activities;

(2) Specific listing of activities and estimated costs;

(3) Goals for completion during the two-year program.

§ 1482.6 Costs.

(a) Costs of market development activities set forth in an applicant's Agreement for which CCC funds may be used to pay include, but are not limited to, the following:

(1) The cost of producing and distributing advertising material;

(2) The cost of product reformulation and testing;

(3) The cost of developing and expanding uses for existing value-added products;

(4) The cost of product demonstrations;

(5) Participation fees for retail and trade exhibitions and shows;

(6) The cost of educational training;

(7) The cost of food service promotions;

(8) Salaries associated with contractors and employees engaged in the above activities; and

(9) Capital costs relating to expanding production of modified wheat gluten or modified wheat starch for value-added products.

(b) Costs that may not be paid using CCC funds are:

(1) Fees paid for helping to prepare the application for program benefits;

(2) Political fund raising activities; and

(3) Costs that CCC determines are not consistent with the intent of the program.

§ 1482.7 Reports.

(a) A producer submitting an application must maintain accurate records and accounts that will document that all eligibility requirements under this Part and other requirements as may be determined by CCC are met. Such records and accounts must be retained for three years after the date of payment to the wheat gluten or wheat starch producer under this program. Such records shall be available at all reasonable times for an audit or inspection by authorized representatives of CCC, U.S. Department of Agriculture, or the Comptroller General of the United States. Failure to keep, or make available, such records may result in refund to CCC of all payments received plus interest thereon, as determined by CCC.

(b) Producers participating in the Value-Added Wheat Gluten and Wheat Starch Product Market Development Program must submit a quarterly report listing completion of activities and costs incurred under the program.

(c) Participating producers must also submit a project performance report 60 days after the end of the first year of the program and 60 days after the end of the second year of the program. The report should explain the activities undertaken to adjust to import competition that were included in the Agreement. CCC will review the report following the first program year. If a participating producer has not made significant progress in completing the stated activities in the first program year as determined by CCC, CCC may cancel the producer's eligibility for the second program year, and CCC may require the producer to refund with interest all or some of the funds received from CCC. If a participating producer has not made significant progress in completing the stated activities in the second program year as determined by CCC, CCC may require the producer to refund with interest some or all of the funds received from CCC in the second year of the program.

§ 1482.8 Payment.

(a) The total amount of CCC funds available to eligible producers for the first year of this program is $27 million and the total amount available for the second (final) year of this program is $13 million.

(b) The maximum payment rate to an applicant will be based on an applicant's average annual production of vital wheat gluten from July 1, 1998 through June 30, 2000 relative to the total average annual U.S. production of vital wheat gluten of all eligible applicants.

(c) After receipt and approval of an eligible producer's application and proposal, CCC will issue payment for the first program year to the applicant. Upon satisfactory completion of the activities included in the producer's Agreement for the first program year, as determined by CCC after receipt of the report required in § 1482.7 (c), CCC will issue payment for the second program year to the producer.

§ 1482.9 Debarment and suspension.

The Government-wide debarment and suspension (Nonprocurement) regulations and Government Requirements for Drug-Free Workplace (Grants), 7 CFR part 3017, Subparts A through E, apply to this Part.

§ 1482.10 Misrepresentation and scheme or device.

(a) A producer shall be ineligible to receive payments under this program if CCC determines the producer:

(1) Adopted any scheme or device which tends to defeat the purpose of the program in this Part;

(2) Made any fraudulent representation; or

(3) Misrepresented any fact affecting a program determination.

(b) Any funds disbursed pursuant to this Part to a producer engaged in a misrepresentation, scheme, or device, or to any other person as a result of the producer's actions, shall be refunded with interest together with such other sums as may become due, plus damages as may be determined by CCC.

(c) Interest charged under this part shall accrue at the rate of interest which the United States Treasury charges CCC for funds. Such interest shall accrue from the date CCC made such funds available to the date of repayment or the date interest increases as determined in accordance with applicable regulations.

(d) CCC may waive the accrual of interest and/or damages if CCC determines that the cause of the erroneous determination was not due to any action of the producer.

(e) Any producer or person engaged in an act prohibited by this Part and any producer or person receiving payment under this Part, in part because of such act, shall be jointly and individually liable for any refund due under this Part and for related charges.

(f) The remedies provided in this Part shall be in addition to other civil, criminal, or administrative remedies which may apply.

(g) Other limitations may apply.

§ 1482.11 Appeals.

(a) Any producer who is subject to an adverse determination made under this Part shall have a right to appeal the determination by filing a written request with the Deputy Administrator of the Farm Service Agency at the following address: Deputy Administrator, Commodity Operations, Farm Service Agency, United States Department of Agriculture, STOP 0550, 1400 Independence Avenue, SW., Washington, DC 20250–0550.

(b) Any producer who believes that it has been adversely affected by a determination under this Part must seek review with the Deputy Administrator within thirty days of such determination, unless provided with notice by CCC which provides a different time for appealing.

(c) Any producer who believes that it has been adversely affected by a determination by the Agency must seek review with the Deputy Administrator before any other review may be requested by a court of competent jurisdiction.

§ 1482.12 Expiration.

This program will expire June 5, 2003. The program shall not be extended.

Signed at Washington, D.C. on June 4, 2001.

J.B. Penn,

President, Commodity Credit Corporation.

[FR Doc. 01–14431 Filed 6–5–01; 10:16 am]

BILLING CODE 3410–10–P

SMALL BUSINESS ADMINISTRATION

13 CFR Part 115

RIN 3245–AE74

Surety Bond Guarantee Program

AGENCY: Small Business Administration (SBA).

ACTION: Direct final rule.

SUMMARY: SBA revises our Surety Bond Guarantee Program rules to conform them to two recently-enacted statutory changes. First, the law increases the eligible contract amount from $1.25 million to $2 million. Second, the law extends the authorization period of the Pilot Preferred Surety Bond (PSB) Program from September 30, 2000 to September 30, 2003.

DATES: The rule will become effective on August 7, 2001. Unless adverse comment is received by July 9, 2001. If an adverse comment is received, SBA will publish a timely withdrawal of the rule in the **Federal Register**.

ADDRESSES: Send written comments to Barbara Brannan, Special Assistant, Office of Surety Guarantees, U.S. Small Business Administration, 409 3rd Street, SW, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Robert J. Moffitt, Associate Administrator, Office of Surety Guarantees, (202) 205–6540.

SUPPLEMENTARY INFORMATION: This direct final rule implements provisions of section 805 of the Small Business Reauthorization Act of 2000 (Act), Public Law 106–554, 114 Stat. 2763A–653 (December 21, 2000), relating to SBA's Surety Bond Guarantee (SBG) Program. The Act increases the contract amount eligible for SBA-guaranteed bonding from $1.25 million to $2 million. This rule revises section 115.12(e) ''Amount of contract'' to effect that change and makes the necessary conforming changes to other relevant sections of SBA's SBG Program rules.

This Act also extends the duration of the Pilot Preferred Surety Bond (PSB) Program for an additional three years. The PSB Program is a pilot program in which SBA-selected sureties are authorized to issue, service and monitor surety bonds without SBA's prior approval. This rule revises section 115.61 to extend the duration of the Pilot PSB Program from September 30, 2000 to September 30, 2003.

This rule makes no changes to the current regulations other than those necessary to conform to the statute. SBA is publishing this regulation as a direct final rule because SBA believes the rule is non-controversial since it is merely conforming the rules to implement provisions of the Act that became effective on December 21, 2000. SBA believes that this rule will not elicit any significant adverse comments.

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

OMB has determined that this final rule does not constitute a ''significant regulatory action'' for purposes of Executive Order 12866. ''Significant regulatory action'' means any regulatory action that is likely to result in a rule that may have an annual effect on the economy of $100 million or more; does not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; does not materially alter the budgetary impact of entitlements, grants, user fees or loan programs or the rights and obligations thereof; and does not raise any novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866. In fiscal year 1999, SBA guaranteed 2,399 final bonds valued at $426.1 million, with an average contract amount of $177,602. In fiscal year 2000, SBA guaranteed 1,795 final bonds valued at $328.9 million, with an average contract amount of $183,247. For fiscal years 1999 and 2000, SBA guaranteed an aggregate of only seven (7) surety bond contracts in the former statutory maximum amount of $1.25 million. Based upon SBA's experience with, and its understanding of, the surety industry, SBA projects the guarantee of no more than 10 surety bond contracts in the new statutory maximum amount of $2.0 million per year. At most, this projection would result in an aggregate increase in guaranteed amount of less than $7.5 million each year ($10 \times \$750{,}000 = \$7.5$ million). The extension of the PSB Program will result in no discernable effect on the economy. Neither of the statutory amendments implemented by this direct final rule raises any other significant regulatory action concerns.

SBA has determined that this final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601–612. This rule merely implements provisions of the Act increasing the maximum surety bond contract amount that can participate in the SBG Program and extending the authorization period of the PSB Program. This rule does not impose costs upon the businesses that might be affected by it. Therefore, it will not have an annual economic effect of $100 million or more, result in a major increase in costs or prices, or have a significant adverse effect on competition or the United States economy. Few of the small business contracting concerns participating in the SBG Program are projected to take advantage of the new statutory increase in the contract amount. This is a tiny fraction of the total of 13–16 million small business concerns in the United States. The rule contains no new information collections, recordkeeping requirements, or changes in forms.

For purposes of Executive Order 12988, SBA has determined that this final rule is drafted, to the extent practicable, in accordance with the standards set forth in Section 3 of the Order.

For purposes of Executive Order 13132, SBA has determined that this final rule will have no federalism implications.

For purposes of the Paperwork Reduction Act, 44 U.S.C. Ch. 35, SBA has determined that this final rule contains no new reporting or recordkeeping requirements.

List of Subjects in 13 CFR Part 115

Claims, Reporting and recordkeeping requirements, Small businesses, Surety bond.

For the reasons set forth above, part 115 of Title 13, Code of Federal Regulations (CFR) is amended as follows:

PART 115—SURETY BOND GUARANTEES

1. The authority citation for Part 115 is revised to read as follows:

Authority: 5 U.S.C. app 3; 15 U.S.C. 687b, 687c, 694a, 694b; 694b note, Pub. L. 106–554, 114 Stat. 2763A–653.

§§ 115.12, 115.19, 115.31, 115.60 and 115.68 [Amended]

2. Amend Sections 115.12(e)(1); 115.12(e)(3); 115.19(a); 115.31(d); 15.60(a)(1); and 115.68 by removing the ''$1,250,000'' each time it appears and inserting in its place ''$2,000,000''.

§ 115.31 [Amended]

3. Revise the final sentence of section 115.31(d) to read ''For example if a Contract amount increases to $2,100,000, SBA's share of the Loss under an 80% guarantee is limited to 76.1% [2,000,000 / 2,100,000 = 95.2% $\times$ 80% = 76.1%].''

§ 115.61 [Amended]

4. Amend section 115.61 by removing the year ''2000'' both times it appears and replacing it with the year ''2003'.

Dated: May 24, 2001.

John Whitmore,

Acting Administrator.

[FR Doc. 01–14445 Filed 6–7–01; 8:45 am]

BILLING CODE 8025–01–U

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD07–01–046]

RIN 2115–AE46

Special Local Regulations: Skull Creek, Hilton Head, SC

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: Temporary Special Local Regulations are being adopted for the Skull Creek July 4th celebration Fireworks Display, Skull Creek, Hilton Head, SC. These regulations are needed to provide for the safety of life on navigable waters during the event.

DATES: This rule becomes effective at 8:30 p.m. and terminates at 10:30 p.m. on July 4, 2001.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket are part of [CGD07–01–046] and are available for inspection or copying at Coast Guard Group Charleston, 196 Tradd St., Charleston SC 29401 between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: ENS Bill Walsh, Coast Guard Group Charleston at 843–724–7600 x203.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. Publishing an NPRM would be contrary to national safety interests since immediate action is needed to minimize potential danger to the public because there will be numerous spectator craft in the area.

For the same reasons, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

Background and Purpose

These regulations are required to provide for the safety of life on navigable waters because of the inherent danger of fireworks during the Skull Creek July 4th celebration on Skull Creek, Hilton Head, SC. The event sponsor expects approximately 120 spectator craft to observe the show. The fireworks barge will be located in approximate position 32 13.95′ N, 080 45.1′ W, offshore from Hudsons Seafood. This rule creates a regulated area that will prohibit non-participating vessels from entering the regulated area during the event.

Regulatory Evaluation

This regulation is not a significant regulatory action under section 3(f) of Executive Order 12866 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. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The regulated area will only be in effect for approximately 2 hours.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612) we considered whether this rulemaking will have a significant economic impact on a substantial number of small entities. Small entities include small business, not-for-profit organizations that are independently owned and operated and are not dominant under their fields, and governmental jurisdictions with populations of less than 50,000.

This rule will affect the following entities, some of which may be small entities: the owners and operators of vessels intending to transit or anchor in a portion of the Skull Creek intercoastal waterway from 8:30 p.m. to 10:30 p.m., July 4, 2001. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities because the rule will only be in effect for 2 hours.

Assistance for Small Entities

Under section 213 (a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–221), we offer to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. Small entities may contact the person listed under **FOR FURTHER INFORMATION CONTACT** for assistance in understanding and participating in this rulemaking. We also have a point of contact for commenting on actions by employees of the Coast Guard. Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–GAIR (1–888–734–3247)

Collection of Information

This rule contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501—3520).

Federalism

We have analyzed this rule under Executive Order 13132 and have determined that this rule does not have implications for federalism under that order.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local, or tribal government or the private sector to incur direct costs without the Federal Government's having first provided the funds to pay those unfunded mandate costs. This rule will not impose an unfunded mandate.

Taking of Private Property

This rule will 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.

Civil Justice Reform

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

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or safety that may disproportionately affect children.

Environment

The Coast Guard has considered the environmental impact of this action and

has determined pursuant to Figure 2–1, paragraph 34(h) of Commandant Instruction M16475.1C, that this action is categorically excluded from further environmental documentation.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because 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.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—MARINE EVENTS

1. The authority citation for Part 100 continues to read as follows:

Authority: 33 U.S.C. 1233 through 1236, 49 CFR 1.46, and 33 CFR 100.35.

2. Add temporary § 100.35T–07–046 to read as follows:

§ 100.35T–07–046 Skull Creek July 4th celebration, Skull Creek, Hilton Head SC.

(a) *Regulated Area:* A regulated area is established for the waters in Skull Creek, Hilton Head, SC, encompassing an area within a 500 foot radius from position 32 13.95′N, 080 45.1′W. All coordinates referenced use Datum: NAD 1983.

(b) *Coast Guard Patrol Commander.* The Coast Guard Patrol Commander is a commissioned, warrant, or petty officer of the Coast Guard who has been designated by Commanding Officer, Group Charleston, SC.

(c) *Special Local Regulations:* Entry into the regulated area by other than event participants is prohibited, unless otherwise authorized by the Patrol Commander. Spectator craft are required to remain in a spectator area to be established by the event sponsor The Club Group, LTD.

(d) *Dates:* These regulations become effective at 8:30 p.m. and terminate at 10:30 p.m. on July 4, 2001.

Dated: May 31, 2001.

T.W. Allen,

Rear Admiral, U.S. Coast Guard, Commander, Seventh Coast Guard District.

[FR Doc. 01–14498 Filed 6–7–01; 8:45 am]

BILLING CODE 4910–15–U

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD01–01–076]

Drawbridge Operation Regulations: Annisquam River, Blynman Canal, MA

AGENCY: Coast Guard, DOT.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, First Coast Guard District, has issued a temporary deviation from the drawbridge operation regulations for the SR 127 Bridge, mile 0.0, across the Annisquam River, Blynman Canal, in Gloucester, Massachusetts. This deviation from the regulations allows the bridge owner to keep the bridge in the closed position from June 18, 2001 through June 27, 2001, at various times to facilitate the emergency repair of the bridge power supply cable.

DATES: This deviation is effective from June 18, 2001 through June 27, 2001.

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

SUPPLEMENTARY INFORMATION: The SR 127 Bridge, at mile 0.0, across the Annisquam River Blynman Canal in Gloucester, Massachusetts, has a vertical clearance of 7 feet at mean high water, and 16 feet at mean low water in the closed position.

The existing drawbridge operation regulations require the draw to open on signal at all times.

The bridge owner, Massachusetts Highway Department (MHD), requested a temporary deviation from the drawbridge operating regulations to facilitate the emergency repair of the bridge power supply cable.

The contractor must work five four-hour days from June 18, 2001 through June 22, 2001, during daylight hours, at slack tide in order to excavate the underwater trench for the new power supply cable. The working hours will vary each day depending upon the time period that slack tide occurs. During these four-hour work periods each day the bridge will not open for vessel traffic.

The bridge will operate according to its normal schedule, opening on demand, from June 23, 2001 through 7 a.m. June 25, 2001. From 7 a.m. June 25, 2001 through midnight on June 27, 2001 the bridge will not open for vessel traffic in order to change over to the new cable and connect all the power supply wires at the bridge.

This deviation to the operating regulations allows the owner of the SR 127 Bridge to keep the bridge in the closed position four-hours a day during daylight hours at slack tide from June 18, 2001 through June 22, 2001 and from 7 a.m. on June 25, 2001 through midnight on June 27, 2001.

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

Dated: May 24, 2001.

G.N. Naccara,

Rear Admiral, U.S. Coast Guard, Commander, First Coast Guard District.

[FR Doc. 01–14497 Filed 6–7–01; 8:45 am]

BILLING CODE 4910–15–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 9

[FRL–6958–8]

OMB Approvals Under the Paperwork Reduction Act; Technical Amendment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this technical amendment amends the table that lists the Office of Management and Budget (OMB) control numbers issued under the PRA for Standards of Performance for New Stationary Sources (NSPS) Smelters including: Primary Copper, Subpart P; Primary Zinc, Subpart Q; Primary Lead, Subpart R; and Ferroalloy Production Facilities, Subpart Z.

EFFECTIVE DATE: This final rule is effective June 8, 2001.

FOR FURTHER INFORMATION CONTACT: Deborah Thomas by phone at (202) 564–5041; by facsimile at (202) 564–0050 or e-mail at *thomas.deborah@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA is amending the table of currently approved information collection request (ICR) control numbers issued by OMB for various regulations. The amendment updates the table to list those information collection requirements promulgated under the NSPS Smelters including Primary Copper, Lead, and Zinc Smelters, and Ferroalloy Production Facilities. The affected regulations are codified at 40 CFR 60.160–166, 60.170–176, 60.180–186, 60.260–266. EPA will continue to

present OMB control numbers in a consolidated table format to be codified in 40 CFR part 9 of the Agency's regulations. The table lists CFR citations with reporting, recordkeeping, or other information collection requirements, and the current OMB control numbers. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the requirements of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and OMB's implementing regulations at 5 CFR part 1320.

This ICR was previously subject to public notice and comment prior to OMB approval. Due to the technical nature of the table, EPA finds that further notice and comment is unnecessary. As a result, EPA finds that there is ''good cause'' under section 553(b)(B) of the Administrative Procedure Act, 5 U.S.C. 553(b)(B), to amend this table without prior notice and comment.

I. Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and is therefore not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty, contain any unfunded mandate, or impose any significant or unique impact on small governments as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). This rule also does not require prior consultation with State, local, and tribal government officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993) or Executive Order 13084 (63 FR 27655 (May 10, 1998), or involve special consideration of environmental justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994). Because this action is not subject to notice-and-comment requirements under the Administrative Procedure Act or any other statute, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5–501 of the Order has the potential to influence the regulation. This rule is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 808 allows the issuing agency to make a good cause finding that notice and public procedure is impracticable, unnecessary or contrary to the public interest. This determination must be supported by a brief statement. 5 U.S.C. 808(2). As stated previously, EPA has made such a good cause finding, including the reasons therefor, and established an effective date of June 8, 2001. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

Dated: March 15, 2001.

Oscar Morales,

Director, Collection Strategies Division.

For the reasons set out in the preamble, 40 CFR part 9 is amended as follows:

PART 9—[AMENDED]

1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.*, 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.*, 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

2. In § 9.1 the table is amended by adding new entries in numerical order in the Standards of Performance for New Stationary Sources heading to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control No.
* * * * *	
Standards of Performance for New Stationary Sources [1]	
* * * * *	
60.165 (a) (d)	2060–0110
60.175 (b) (c)	2060–0110
60.185 (b) (c)	2060–0110
* * * * *	
60.264 (b) (c)	2060–0110
60.265 (a)	2060–0110
* * * * *	

[1] The ICRs referenced in this section of the Table encompass the applicable general provisions contained in 40 CFR part 60, subpart A, which are not independent information collection requirements.

* * * * *

[FR Doc. 01–14472 Filed 6–7–01; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 435

[FRL–6987–5]

RIN 2040–AD14

Effluent Limitations Guidelines and New Source Performance Standards for the Oil and Gas Extraction Point Source Category; OMB Approval Under the Paperwork Reduction Act: Technical Amendment; Correction

AGENCY: Environmental Protection Agency.

ACTION: Final rule; correction.

SUMMARY: EPA is correcting minor errors in the preamble and the effluent limitations guidelines and standards for the oil and gas extraction point source category, which was published as a final rule in the **Federal Register** on January 22, 2001 (66 FR 6850).

DATES: These corrections shall become effective on June 8, 2001.

FOR FURTHER INFORMATION CONTACT: Mr. Carey A. Johnston, Office of Water Engineering and Analysis Division (4303), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, DC 20460, (202) 260–7186, johnston.carey@epa.gov.

SUPPLEMENTARY INFORMATION: On January 22, 2001 (66 FR 6850), EPA published in the **Federal Register** final effluent limitations and standards for

the oil and gas extraction point source category. The preamble and the final rule contained minor errors. These errors consisted of omission of several pages of the preamble text in the printed version of the preamble and minor typographical errors in the analytical methods contained in the rule. This action corrects those errors. The missing preamble pages were presented in the Development Document (EPA–821–B–00–013) or in the response to comments document supporting the rule but were inadvertently omitted in the **Federal Register**. The minor typographical errors in the analytical methods consist of two missing commas and one reversed inequality sign. The correction of the two missing commas clarifies two equations used in an analytical method for calculating base fluid retained on cuttings. The correction of the reversed inequality sign clarifies the quality control procedures for formulating positive controls in the crude oil contamination detection analytical method. EPA is not substantively altering the final rule or expanding the regulatory burden through correction of these minor errors.

Section 553(b)(B) of the Administrative Procedure Act, 5 U.S.C. 553(b)(B), provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment. EPA has determined that there is good cause for taking today's action without prior proposal and opportunity for comment because there is no substantive effect on the rule from this action; this action merely corrects errors in a portion of the preamble to the rule and in the analytical methods to the rule that already went through public notice and comment and do not increase the regulatory burden of the rule. All of the discussion inadvertently omitted from the printed preamble were contained in the record for the final rule as part of the final development document and response to comments document for the rule.

Correction of the reversed inequality sign makes the quality control criteria of the analytical method that is specified in appendix 6 to subpart A of part 435 consistent with the method's intended purpose as proposed and promulgated in the final rule. In the proposed rule and final rule, section 1.4 of appendix 6 states that the method was, ''designed to show positive contamination for 5% of representative crude oils at a concentration of 0.1% in drilling fluid (vol/vol), 50% of representative crude oils at a concentration of 0.5%, and 95% of representative crude oils at a concentration of 1%.'' In addition, in the proposed rule and final rule section 9.2 of appendix 6 specifies that a laboratory that properly practices the method must detect crude oil contamination in greater than 75% of control samples containing 1% crude oil. The proposal Development Document (EPA–821–B–98–021) also states, ''For the proposed rule, the majority of formation oils would cause failure when present in SBFs at a concentration of about 0.5%.'' Despite the proposal Development Document and sections 1.4 and 9.2 of the proposed and final rule, the Agency inadvertently reversed the inequality sign specifying the detection criteria for control samples containing 2% crude oil, which resulted in a quality control requirement that does not reflect the intent of sections 1.4 and 9.2 or the proposal Development Document. The Agency's intention was to specify that a laboratory that properly practices the method must detect crude oil contamination in greater than 90% of control samples containing 2% crude oil. This correction does not expand the regulatory burden because no change is made to the analytical procedures that laboratories must use for compliance monitoring. The correction changes only the criterion for interpreting quality control results for control samples containing 2% crude oil.

Thus, notice and public procedure are unnecessary. EPA finds that this constitutes good cause under 5 U.S.C. 553(b)(B). For the same reasons, EPA believes there is good cause under 5 U.S.C. 553(d)(3) to make this rule immediately effective.

Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and is therefore not subject to review by the Office of Management and Budget. Because, as described above, the agency has made a ''good cause'' finding that this action is not subject to notice-and-comment requirements under the Administrative Procedure Act or any other statute, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), or to sections 202 and 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). In addition, this action does not significantly or uniquely affect small governments or impose a significant intergovernmental mandate, as described in sections 203 and 204 of UMRA. This rule also does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 6, 2000). This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant.

This technical correction action does not involve technical standards; 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 rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). EPA's compliance with the statutes and Executive Orders that were in effect when the underlying rule was developed is discussed in the January 22, 2001 **Federal Register** document.

The Congressional Review Act (5 U.S.C. 801 *et seq.*), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 808 allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes a good cause finding that notice and public procedure is impracticable, unnecessary or contrary to the public interest. This determination must be supported by a brief statement. 5 U.S.C. 808(2). As stated previously, EPA has made such a good cause finding, including the reasons therefor, and established an effective date of June 8, 2001. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 435

Environmental protection, Oil and gas extraction, Waste treatment and disposal, Water pollution control.

Dated: May 18, 2001.

Diane C. Regas,

Acting Assistant Administrator.

The following corrections are made in FRL–6929–8, Effluent Limitations

Guidelines and New Source Performance Standards for the Oil and Gas Extraction Point Source Category; OMB Approval Under the Paperwork Reduction Act: Technical Amendment (FR Doc. 01–361), which were published in the **Federal Register** on January 22, 2001 (66 FR 6850).

Preamble Corrections

1. On page 6871, in column 1, line 25, insert the following text between the two phrases ''In addition, because of the uncertainty about ester performance, operators may not be encouraged to switch from OBFs or WBFs to SBF'' and ''when properly installed and maintained.'':
If only vegetable ester- or low viscosity ester-based SBFs could be discharged. As previously stated, EPA is promoting the appropriate conversion from OBF- and WBF-drilling to SBF-drilling in order to reduce pollutant loadings and NWQI. Due to demonstrated or potential technical limitations of vegetable esters or low viscosity esters, EPA estimates that the pollutant loadings and NWQIs associated with establishing vegetable esters or low viscosity esters as the basis for stock limitations are similar to the pollutant loadings and NWQIs associated with the zero discharge option for all SBF-cuttings (*see* section V.F). EPA finds these increases in pollutant loadings and NWQIs as unacceptable.

d. Biodegradation Rate Technical Availability

EPA is today promulgating a biodegradation stock base fluid limitation that would only allow the discharge of SBF-cuttings using SBF base fluids that degrade as fast or greater than C_{16}-C_{18} IOs. Alternatively, this limitation could be expressed in terms of a ''biodegradation rate ratio'' which is defined as the percent degradation of C_{16}-C_{18} IOs divided by the percent degradation of stock base fluid being tested, both at 275 days. EPA is promulgating a biodegradation rate ratio of less than 1.0. As stated in the April 2000 NODA (65 FR 21550), EPA is promulgating the use of the marine anaerobic closed bottle biodegradation test (i.e., ISO 11734:1995) with modifications for compliance with this biodegradation BAT limitation. One of the modifications to this test is that natural marine or estuarine sediments be used in place of digested sludge as an inoculum. The revised method also requires that the volatile solids of the sediments must be no less than 2% and EPA recommends ASTM D2974 or its equivalent. To meet this limitation through product substitution, the base fluids currently available for use include vegetable esters, low viscosity esters, linear alpha olefin, and internal olefins.

EPA finds this limit to be technically available and economically achievable through product substitution because information in the rulemaking record supports the findings that vegetable esters, low viscosity esters, and internal olefins have performance characteristics enabling them to be used in the wide variety of drilling situations in offshore U.S. waters and meet today's promulgated limit. Marketing data given to EPA shows that internal olefin SBFs are the most popular SBFs used in the GOM.

The marine anaerobic closed bottle biodegradation test (*i.e.,* ISO 11734:1995) is incorporated by reference into the effluent limitations guidelines and is available from the American National Standards Institute, 11 West 42nd Street, 13th Floor, New York, NY 10036. Additionally, EPA modified the marine anaerobic closed bottle biodegradation test to make the test more applicable to a marine environment. These modifications are listed in appendix 4 of subpart A of 40 CFR part 435 and include: (1) The laboratory shall use sea water in place of freshwater; (2) the laboratory shall use marine sediment in place of digested sludge as an inoculum; and (3) the laboratory shall run the test for 275 days.

EPA selected the closed bottle test because it models the ability of a drilling fluid to degrade anaerobically. Industry comments to the April 2000 NODA report the results of seabed surveys (Docket No. W–98–26, Record No. IV.A.a.13, Attachment Ester-52). These seabed surveys and the scientific literature indicate that the environments under cuttings piles are anaerobic and that the recovery of seabeds did not occur in acceptable periods of time when drilling fluids (e.g., diesel oils, mineral oils) cannot anaerobically degrade (*i.e.,* the anaerobic biodegradation rates are zero or very low). The scientific literature also indicates that there is no known mechanism for initiation of anaerobic alkane biodegradation (Docket No. W–98–26, Record No.IV.A.a.13, Attachment BIODEG–62). The general anaerobic microbiology literature indicates that metabolic pathways are just beginning to be determined for anaerobic biodegradation of linear alkanes (i.e., linear paraffins). The anaerobic biodegradability of the SBF base fluid represents an essential prerequisite for the prevention of long-term persistence of SBFs and deleterious impacts on marine sediments (Docket No. W–98–26, Record No.I.D.b.26). Therefore, EPA considers the control of anaerobic degradation as the most environmentally relevant way to ensure the biodegradation of SBF under cuttings piles and other anaerobic environments for the recovery of benthic organisms and environments in an acceptable period.

EPA has selected the C_{16}-C_{18} IO as the basis for the biodegradation rate ratio limitation instead of the vegetable ester or low viscosity ester for several reasons: (1) EPA does not believe that vegetable esters can be used in all drilling situations; and (2) EPA does not have sufficient field testing information that low viscosity esters can be used in all drilling situations (*see* section V.F.1.a). Operators may not be encouraged to switch from OBFs or WBFs to SBF if only vegetable ester- or low viscosity ester-based SBFs could be discharged. As previously stated, EPA is promoting the appropriate conversion from OBF- and WBF-drilling to SBF-drilling in order to reduce pollutant loadings and NWQI. Due to demonstrated or potential technical limitations of vegetable esters or low viscosity esters, EPA estimates that the pollutant loadings and NWQIs associated with establishing vegetable esters or low viscosity esters as the basis for stock limitation are similar to the pollutant loadings and NWQIs associated with the zero discharge option for all SBF-cuttings (*see* section V.F). EPA finds these increases in pollutant loadings and NWQIs as unacceptable. Nevertheless, due to EPA's information (primarily laboratory data) that indicates that esters provide better environmental performance in terms of sediment toxicity and biodegradation, EPA is promulgating a higher ROC limitation and standard where esters are used to encourage operators to use esters when possible.

EPA also selected C_{16}-C_{18} IO as the basis for the biodegradation rate ratio limitation instead of other SBFs (*e.g.,* paraffins, enhanced mineral oils, PAOs) as SBFs with biodegradation rate similar to or better than the C_{16}-C_{18} IO (*e.g.,* C_{16}-C_{18} IO, esters) show acceptable levels of anaerobic biodegradation. As previously stated, controlling anaerobic degradation is the most environmentally relevant way to ensure the biodegradation of SBF under cuttings piles and other anaerobic environments for the recovery of benthic organisms and environments in an acceptable period. Industry marine anaerobic closed bottle testing data demonstrate that some SBFs show very little or no anaerobic biodegradation (*e.g.,* paraffins,

enhanced mineral oils, PAOs). EPA finds that the C_{16}-C_{18} IO has greater anaerobic biodegradation than other SBFs (e.g., paraffins, enhanced mineral oils, PAOs) and, unlike esters, is currently the most popular SBF in the market.

e. Economic Achievability of Stock Base Fluid Controls

EPA finds that the promulgated stock base fluid controls are economically achievable. Industry representatives have told EPA that while the synthetic base fluids are more expensive than diesel and mineral oil base fluids, the savings in discharging the SBF-cuttings versus land disposal or re-injection of OBF-cuttings (as required under current regulations) more than offsets the increased cost of SBFs. Moreover, the reduced time to complete a well with SBF as compared with OBF- and WBF-drilling can be significant (i.e., days to weeks). This reduction in time translates into lower rig rental costs for operators. Thus, operator costs are lower even with the more expensive SBF provided the drill cuttings with adhering SBF can be discharged. The stock base fluid limitations outlined above and promulgated today are technically achievable through product substitution with the use of the currently widely used SBFs based on internal olefins ($160/bbl), vegetable esters ($250/bbl), and low viscosity esters ($300/bbl) (Docket No. W–98–26, Record No. IV.B.a.13). For comparison, diesel oil-based drilling fluid costs about $70/bbl, and mineral oil-based drilling fluid costs about $90/bbl. According to industry sources, currently in the Gulf of Mexico the most widely used and discharged SBFs are, in order of use, based on internal olefins, linear alpha olefins, and vegetable esters. Since the stock limitations allow the continued use of the IO- and ester-based SBFs, EPA attributes no additional cost due to the stock base fluid requirements other than monitoring (testing and certification) costs. EPA estimates that dischargers will satisfy: (1) The base fluid stock sediment toxicity and biodegradation limitations by having suppliers monitor once annually; and (2) the PAH and formation oil limitations by having suppliers monitor each batch of stock SBF.

EPA also considered NWQIs in selecting the controlled discharge option for SBF-cuttings (*i.e.,* BAT/NSPS Option 2). See section VIII.

2. Discharge Limitations Technical Availability and Economic Achievability

a. Formation Oil Contamination of SBF-Cuttings. EPA is today promulgating a BAT limitation of zero discharge to control formation oil contamination on SBF-cuttings. EPA is also today promulgating a screening method (Reverse Phase Extraction (RPE) method presented in appendix 6 to subpart A of part 435) and a compliance assurance method (Gas Chromatograph/Mass Spectrometer (GC/MS) method presented in appendix 5 to subpart A of part 435) to demonstrate compliance with this zero discharge requirement.

Formation oil is an ''indicator'' pollutant for the many toxic and priority pollutant pollutants present in formation (crude) oil (e.g., aromatic and polynuclear aromatic hydrocarbons). The RPE method is a fluorescence test and is appropriately ''weighted'' to better detect crude oils. These crude oils contain more toxic aromatic and PAH pollutants and show brighter fluorescence (*i.e.,* noncompliance) in the RPE method at lower levels of crude oil contamination. Under the final rule, approximately 5% of all (all meaning a large representative sampling) formation oils would fail (not comply) at 0.1% contamination of SBFs and 95% of all formation oils will fail at 1.0% contamination of SBFs. The majority of formation oils will fail at 0.5% contamination of SBFs. Since the RPE method is a relative brightness test, GC/MS is today promulgated as a confirmatory compliance assurance method when the results from the RPE compliance method are in doubt by either the operator or the enforcement authority. Results from the GC/MS method will supersede those of the RPE method. EPA is also requiring that dischargers verify and document that a SBF is free of formation oil contamination before initial use of the SBF. The GC/MS method will be used to verify and document the absence of formation oil contamination in SBFs.

EPA intends that the BAT limitation promulgated on formation (crude) oil contamination in SBF is no less stringent that the existing BAT limitation on WBF through the static sheen test (appendix 1 of subpart A of 40 CFR part 435). In most cases the static sheen test detects formation oil contamination in WBF down to 1% and in some cases down to 0.5%. Based on the available information, EPA believes that only a very minimal amount of SBF will be non-compliant with this limitation and therefore be required to be disposed of onshore or by injection. EPA thus finds that this limitation is technically available. EPA also finds this option to be economically achievable because there is no reason why formation oil contamination would occur more frequently under this rule than under the current rules which industry can economically afford. EPA has determined that essentially no costs are associated with this requirement other than monitoring and reporting costs, which are minimal costs for this industry, but are incorporated into the cost and economic analyses.

b. Retention of SBF on SBF-Cuttings. EPA is today promulgating BAT limitations controlling the amount of SBF discharged with SBF-cuttings for the Offshore subcategory where SBF-cuttings may be discharged. As previously stated, limiting the amount of SBF content in discharged cuttings controls: (1) The amount of toxic and non-conventional pollutants in SBF which are discharged to the ocean; (2) the biodegradation rate of discharged SBF; and (3) the potential for SBF-cuttings to develop cuttings piles and mats which are deleterious to the benthic environment. The BAT limitations promulgated today for controlling the amount of SBF discharged with SBF-cuttings are averaged by hole volume over the well sections drilled with SBF. Those portions of the SBF-cuttings wastestream that are retained for zero discharge (*e.g.,* fines) are factored into the weighted well average with a retention value of zero.

EPA evaluated the costs, cost savings, and technical performance of several technologies to recover SBF from the SBF-cuttings discharge (*see* SBF Development Document and SBF Statistical Support Document). EPA also investigated the use of Best Management Practices (BMPs) to reduce the amount of SBF discharge on SBF-cuttings. Typical BMPs for SBF-cuttings include regulating the flow and dispersion across solid control equipment screens and properly maintaining these screens. EPA also considered NWQIs (*e.g.,* land disposal requirements, fuel use, air emissions, safety, and other considerations) in setting the SBF retention on SBF-cuttings BAT limitation.

As previously stated in section II.C, the drilling fluid and drill cuttings undergo an extensive separation process by the solids control system to remove drilling fluid from the drill cuttings. The solids control system is necessary to maintain constant drilling fluid properties and/or change them as required by the drilling conditions. Drilling fluid recovered from the solids

control equipment is recycled into the active mud system (e.g., mud pits, mud pumps) and back downhole. Drill cuttings discarded from the solids control equipment are a waste product. Drill cuttings are also cleaned out of the mud pits and from the solid separation equipment during displacement of the drilling fluid system (i.e., accumulated solids).

Most drilling operators use, at a minimum, a solids control system typically consisting of primary and secondary shale shakers in series with a ''fines removal unit'' (e.g., mud cleaner, decanting centrifuge). The primary and secondary shale shakers remove the larger and smaller cuttings respectively. The fines removal unit removes the ''fines'' (i.e., low gravity solids) down to about 5 microns (10^{-6} meters). Solids less than 5 microns are labeled as ''entrained'' and are unable to be removed by solids control equipment. Because of their small size and large surface area per unit volume, the fines retain more drilling fluid than an equal amount of larger cuttings coming off the shale shakers. This solid control equipment configuration was labeled as ''baseline'' (i.e., representative of current industry practice) in the April 2000 NODA (65 FR 21559). EPA continues to use this solid control equipment configuration as baseline in the analyses supporting today's final rule.

EPA assessed the baseline performance using industry submitted ROC data received before and in response to the April 2000 NODA. EPA received sufficient additional cuttings retention data from GOM sources to re-evaluate the discharges of the baseline solids control equipment (e.g., primary shale shaker, secondary shale shaker, fines removal unit) to calculate a revised baseline long-term average retention value of 10.2% by weight of SBF on cuttings. Despite the revision of the retention data, the revised long-term average retention value is only slightly different than the 11% originally calculated for the February 1999 proposal and the 11.4% calculated for the April 2000 NODA. This relative convergence of the various calculated baseline performance averages provides further confidence in the accuracy of the baseline model and associated data.

Operators also recover additional drilling fluid from drill cuttings discarded from the shale shakers through the use of cuttings dryers (e.g., vertical or horizontal centrifuges, squeeze press mud recovery units, High-G linear shakers). Since the February 1999 proposal and April 2000 NODA, the GOM offshore drilling industry has increased its use of ''add-on'' cuttings drying equipment (i.e., ''cuttings dryers'') to reduce the amount of SBF adhering to the SBF-cuttings prior to discharge. Specifically, in response to the April 2000 NODA, EPA received ROC data from approximately 45 GOM SBF well projects that used cuttings dryers (e.g., vertical or horizontal centrifuges, squeeze press mud recovery units, High-G linear shakers) to reduce the amount of SBF discharged (*see* SBF Statistical Support Document). These 45 GOM SBF well projects represent a broad representation of typical factors affecting solids control equipment performance which include: (1) GOM formation types (e.g., shale, sand, salt); (2) rig types (e.g., drill tension leg platform, semi-submersible); (3) drilling operation types (i.e., exploratory or development); (4) water depth (i.e., shallow or deep); and (5) rates of penetration (ROP). Current data available to EPA indicates that these cuttings dryers can operate consistently and efficiently.

2. On page 6874, in column 3, line 14, correct the sentence to read ''c. Sediment Toxicity of SBF Discharged with Cuttings.''

PART 435—[CORRECTED]

Appendix 5 to Subpart A—[Corrected]

3. On page 6908, in column 2, in appendix 5 to subpart A of part 435 in 9.2. in line 15, correct the line to read ''2% oil—Detected in >90% of samples''.

Appendix 7 to Subpart A—[Corrected]

4. On page 6912, in appendix 7 to subpart A of part 435, in 4. calculations, in the last paragraph of 7., correct equations 11 and 13 to read as follows:

Appendix 7 to Subpart A of Part 435—API Recommended Practice 13B–2

* * * * *

4. Calculations

* * * * *

7. * * *

$$G_{WELL} = (1 + (\left[i = 1 \text{ to } j = n \sum (\%BF_{Tj}) \right] / n)) \times V_{WELL}(bbl) \times 396.9(kg/bbl) \qquad [11]$$

* * * * *

$$\%BF_{WELL} = ((1 - X_{SVD}) \times \left[i = 1 \text{ to } j = n \sum \left(\%BF_{Tj} \right) \right] / n \ ]) + X_{SVD} \times \%BF_{SVD} \qquad [13]$$

* * * * *

[FR Doc. 01–13413 Filed 6–7–01; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[RI–022b; A–1–FRL–6990–6]

Approval and Promulgation of Air Quality Implementation Plans; Rhode Island; Post-1996 Rate of Progress Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving a State Implementation Plan (SIP) revision submitted by the State of Rhode Island. This revision establishes a post-1996 rate of progress (ROP) emission reduction plan for the Providence serious ozone nonattainment area in Rhode Island. The intended effect of this action is to approve this SIP revision as meeting the requirements of the Clean Air Act.

DATES: This direct final rule is effective on August 7, 2001 without further notice, unless EPA receives adverse comment by July 9, 2001. If adverse

comment is received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Comments may be mailed to David Conroy, Unit Manager, Air Quality Planning, Office of Ecosystem Protection (mail code CAQ), U.S. Environmental Protection Agency, EPA-New England, One Congress Street, Suite 1100, Boston, MA 02114–2023. Copies of the documents relevant to this action are available for public inspection during normal business hours, by appointment at the Office of Ecosystem Protection, U.S. Environmental Protection Agency, EPA-New England, One Congress Street, 11th floor, Boston, MA, and at the Office of Air Resources, Department of Environmental Management, 235 Promenade Street, Providence, RI 02908–5767.

FOR FURTHER INFORMATION CONTACT: Robert McConnell, (617) 918–1046.

SUPPLEMENTARY INFORMATION: On September 21, 1998, the State of Rhode Island submitted a formal revision to its SIP. The SIP revision consisted of a post-1996 rate-of-progress (ROP) plan for the Providence serious ozone nonattainment area, which encompasses the entire geographic area of the State.

This Supplementary Information section is organized as follows:

A. What action is EPA taking today?
B. Why was Rhode Island required to reduce emissions of ozone forming pollutants?
C. Which specific air pollutants are targeted by this emission reduction plan?
D. What are the sources of these pollutants?
E. What harmful effects can these pollutants produce?
F. Should I be concerned if I live near an industry that emits a significant amount of these pollutants?
G. To what degree does Rhode Island's plan reduce emissions?
H. How will Rhode Island achieve these emission reductions?
I. Have these emission reductions improved air quality in Rhode Island?
J. Has Rhode Island met its contingency measure obligation?
K. Are conformity budgets contained in the plan?

A. What action is EPA taking today?

EPA is approving a post-1996 rate-of-progress (ROP) emission reduction plan submitted by the State of Rhode Island for the Providence serious ozone nonattainment area as a revision to the State's SIP.

The post-1996 ROP plan documents how Rhode Island complied with the provisions of section 182 (c)(2)(B) of the Federal Clean Air Act (the Act). This section of the Act requires states containing certain ozone nonattainment areas develop strategies to reduce emissions of the pollutants that react to form ground level ozone.

B. Why was Rhode Island Required to Reduce Emissions of Ozone Forming Pollutants?

Rhode Island was required to develop a plan to reduce ozone precursor emissions because it contains an ozone nonattainment area. A final rule published by EPA on November 6, 1991 (56 FR 56694) designated the entire State as nonattainment for ozone, and classified the area as serious. The area was named the Providence area.

Section 182 (c)(2)(B) of the Act requires that serious, severe, and extreme ozone nonattainment areas develop ROP plans to reduce ozone forming pollutant emissions by 3 percent a year, averaged over each consecutive 3 year period beginning in 1996, until the area reaches its attainment date. The first set of emission reductions are required to occur between November 1996 and November 1999, and are referred to as post-1996 ROP plan reductions, which will yield an overall reduction of nine percent of the combined 1990 VOC and NO_X emission levels.

C. Which Specific Air Pollutants Are Targeted by This Emission Reduction Plan?

The State's post-1996 plan is geared towards reducing emissions of volatile organic compounds (VOCs) and nitrogen oxides (NO_X). These compounds react in the presence of heat and sunlight to form ozone, which is a primary ingredient of smog.

D. What Are the Sources of These Pollutants?

VOCs are emitted from a variety of sources, including motor vehicles, a variety of consumer and commercial products such as paints and solvents, chemical plants, gasoline stations, and other industrial sources. NO_X is emitted from motor vehicles, power plants, and other sources that burn fossil fuels.

E. What Harmful Effects Can These Pollutants Produce?

VOCs and NO_X react in the atmosphere to form ozone, the prime ingredient of smog in our cities and many rural areas of the country. Though ozone occurs naturally high in our atmosphere, at ground level it is the prime ingredient of smog. When inhaled, even at very low levels, ozone can:

Cause acute respiratory problems;
Aggravate asthma;
Cause significant temporary decreases in lung capacity in some healthy adults;
Cause inflammation of lung tissue;
Lead to hospital admissions and emergency room visits; and
Impair the body's immune system defenses.

F. Should I Be Concerned If I Live Near an Industry That Emits a Significant Amount of These Pollutants?

Industrial facilities that emit large amounts of these pollutants are monitored by the State's environmental agency, the Department of Environmental Management (RI-DEM). Many facilities are required to emit air pollutants through stacks to ensure that high concentrations of pollutants do not exist at ground level. Permits issued to these facilities include information on which pollutants are being released, how much may be released, and what steps the source's owner or operator is taking to reduce pollution. The RI-DEM makes permit applications and permits readily available to the public for review. You can contact the RI-DEM for more information about air pollution emitted by industrial facilities in your neighborhood.

G. To What Degree Does Rhode Island's Plan Reduce Emissions?

By 1999, Rhode Island's plan will reduce VOC emissions by 29 percent and NO_X emissions by 17 percent compared to 1990 emission levels. This reduction is attributable to the control strategy outlined in the State's post-1996 plan, and in Rhode Island's ROP plan for the years 1990 to 1996 that achieved a 15 percent reduction in VOC emissions. The reduction is also partly attributable to the Federal Motor Vehicle Control Program (FMVCP). Not all emission reductions from the FMVCP program are creditable towards ROP emission reductions, and RI-DEM's ROP plan accurately accounts for this. EPA approved the Rhode Island 15 percent ROP plan on December 8, 1998 (63 FR 67594).

Rhode Island used the appropriate EPA guidance to calculate the 1999 VOC and NO_X emission target levels, and the amount of reductions needed to achieve its emission target levels.

Table 1 illustrates the steps used by Rhode Island to derive its 1999 emission target levels for VOC and NO_X. The ROP plan indicates that 1999 projected, controlled emissions are below the target levels for the Providence serious nonattainment area.

TABLE 1

[units = tons per summer day (tpsd)]

Description	Pollutant—VOC	Pollutant—NO_X
Step 1: 1990 Inventory	258	101.0
Step 2: ROP Inventory (biogenics subtracted)	185.1	101.0
Step 3: Adjusted inventory: removal of non-creditable reductions [1] and non-reactive VOCs.	−16.0 (FMVCP)	−9.6 (FMVCP)
	−2.6 (non-reactives)	
	Net: 166.5	Net: 91.4
Step 4: Calculate required reduction (State will use both VOC and NO_X rdxns. to meet post-1996 ROP, as shown) [2].	2.5%	6.5%
	4.2	5.9
Step 5: Calculate Total Expected Reductions [3]	4.2	9.6 + 5.9 = 15.5
Step 6: Set Target Level for 1999 [4]	137.3	85.5
Step 7: Project Emissions to 1999	173.3	98.8
Step 8: Projected, Controlled Emissions for 1999	130.1	83.7

[1] States cannot take credit for reductions achieved by Federal Motor Vehicle Control Program (FMVCP) measures (new car emission standards) promulgated prior to 1990 or for reductions resulting from requirements to lower the Reid Vapor Pressure (RVP) of gasoline promulgated prior to 1990.

[2] These reduction percentages were revised pursuant to a letter sent to EPA from the RI–DEM dated 4/02/01. This revision subsequently changes the emission targets shown in step 6.

[3] Rhode Island accounted for the full 9 years of FMVCP reductions in deriving its 1996 VOC target, so no additional FMVCP reductions need to be subtracted in development of the post-1999 ROP target.

[4] For NO_X, target level = Step 2 − Step 5. For VOC, target level = 1996 target of 141.5 − Step 5.

Rhode Island projected its base year emissions to 1999 using growth factors from a variety of sources, including the U.S. Department of Commerce's Bureau of Economic Analysis, and Bureau of Census data to derive population based growth factors.

H. How Will Rhode Island Achieve These Emission Reductions?

Rhode Island's post-1996 control strategy matches the control strategy described in the EPA's December 8, 1998 approval of the State's 15 percent plan, and also includes additional emission reductions from regulations limiting NO_X emissions from stationary point sources, VOC and NO_X emission reductions from federal measures limiting emissions from non-road engines promulgated between 1996 and 1999, and VOC and NO_X reductions from the on-road mobile sector attributable to the State's Low Emission Vehicle program. These additional control programs are further described below.

Rhode Island's post-1996 plan also reflects credit from the State's enhanced automobile inspection and maintenance (I&M) program, which was supposed to start by mid-1999. The post-1996 plan estimated that 2.2 tpsd in VOC emission reduction credit and 1.8 tpsd in NO_X emission reduction credit were expected to accrue by the end of 1999 from this program. However, Rhode Island did not actually begin its program until January of 2000, so emission reductions from this program did not occur in the 1996 to 1999 time-frame. This does not create a shortfall in the State's post-1996 ROP plan because Rhode Island's plan contained enough surplus emission reductions to cover its emission reduction obligation after subtraction of the I/M reductions.

NO_X RACT

Rhode Island has adopted a NO_X RACT regulation, the citation for which is Air Pollution Control regulation No. 27, ''Control of Nitrogen Oxide Emissions.'' Facilities covered by the rule needed to comply by May 31, 1995. Rhode Island submitted the rule to EPA as a revision to the State's SIP, and EPA approved it via a direct final rulemaking published on September 2, 1997 (62 FR 46202). Rhode Island determined, and EPA agrees, that this program will reduce NO_X emissions in the State by 6.55 tons per summer day (tpsd) by 1999.

Federal Non-Road Standards

In the June 17, 1994 **Federal Register** (59 FR 31306), EPA established a regulation setting final emission standards for new heavy duty compression ignition (diesel) engines. These rules adopt NO_X and smoke standards for large (>50 HP) non-road diesel engines. Additionally, in the July 3, 1995 **Federal Register** (60 FR 34581), EPA promulgated the first phase of the regulations to control emissions from new non-road spark-ignition engines. The regulation is found at 40 CFR part 90, and is titled, ''Control of Emissions From Non-road Spark-Ignition Engines.'' Rhode Island correctly applied guidance contained in a November 28, 1994 EPA memorandum pertaining to the federal non-road engine control program to determine the VOC and NO_X emission reductions that will occur in the State.

The sale of reformulated gasoline in Rhode Island also reduces VOC non-road emissions in the State. The combined effect of reformulated gasoline and the new non-road standards will lower VOC emissions by 4.0 tpsd in the State, and lower NO_X emissions by 1.3 tpsd.

Rhode Island National Low Emission Vehicle Program

Rhode Island submitted a National Low Emission Vehicle (NLEV) program to EPA as a revision to the State's SIP, and EPA approved the program via a direct final rule published in the **Federal Register** on March 9, 2000 (65 FR 12476). The NLEV program allows auto manufacturers to commit to meet tailpipe standards for cars and light-duty trucks that are more stringent than EPA can mandate. The program will reduce VOC emissions by 0.08 tpsd, and NO_X emissions by 0.12 tpsd.

The Rhode Island post-1996 ROP plan demonstrates that the VOC and NO_X emission reductions from the control strategy will achieve sufficient emission reductions to lower 1999 emission levels below the target levels calculated for each pollutant.

I. Have These Emission Reductions Improved Air Quality in Rhode Island?

Ozone levels have decreased in Rhode Island during the 1990's, due in part to emission reductions achieved by the State's plans. Pollution control measures implemented by States

upwind of Rhode Island have also helped ozone levels decline in the State.

J. Has Rhode Island Met its Contingency Measure Obligation?

Ozone nonattainment areas classified as serious or above must submit to the EPA, pursuant to sections 172(c)(9) and 182(c)(9) of the Act, contingency measures to be implemented if an area misses an ozone SIP milestone or does not attain the national ambient air quality standard by the applicable date.

Table 1 indicates that Rhode Island's post-1996 ROP plan achieves surplus emission reductions. The State's post-1996 ROP plan does not address contingency measures. However, on April 2, 2001, the Rhode Island DEM submitted a letter to EPA indicating the State's intention that surplus emission reductions achieved by the measures in the ROP plan be used to cover the State's contingency measure obligation. This request resulted in a change to the VOC and NO_X emission reduction percentages; the revised percentages are shown in Table 1.

Table 1 indicates a VOC surplus of 7.2 tpsd and a NO_X surplus of 1.8 tpsd. However, as noted in the I&M program discussion in this document, Rhode Island did not begin its I&M program until January 1, 2000. Table 2 illustrates how the surplus emission reductions, adjusted to subtract reductions from the I/M program, can cover the 3% contingency obligation.

TABLE 2

[units = tpsd]

Calculation Step	Providence Area	
	VOC	NO_X
Step 1: Adjusted 1990 Emissions (from Table 1)	166.5	91.4
Step 2: 1999 Target Levels (from Table 1)	137.3	85.5
Step 3: Controlled 1999 Emissions (from Table 1)	130.1	83.7
Step 4: Contingency Obligation (3% of Adjusted inventory)	5.0	0
Step 5: Revised Controlled 1999 Emissions (add 2.2 tpsd VOC and 1.8 tpsd NO_X to the controlled 1999 emissions shown in Table 1 to account for delayed implementation of I&M)	132.3	85.5
Step 6: Final Surplus after Contingency (Step 5–Step 4)	0	0

As can be seen from the above table, the surplus VOC emission reduction would cover the area's 3% contingency obligation, leaving no additional reductions to spare. Therefore, EPA concludes that the Rhode Island post-1996 ROP plan adequately demonstrates that the required 9% post-1996 ROP and 3% contingency reductions have been achieved.

K. Are Conformity Budgets Contained in the Plan?

Section 176(c) of the Act, and 40 CFR 51.452(b) of the Federal transportation conformity rule require states to establish motor vehicle emissions budgets in any control strategy SIP that is submitted for attainment and maintenance of the NAAQS. Rhode Island will use such budgets to determine whether proposed projects that attract traffic will ''conform'' to the emissions assumptions in the SIP.

The Rhode Island post-1996 rate of progress plan contained 1999 on-road motor vehicle emission budgets for VOCs and for NO_X for the Providence serious nonattainment area. The 1999 VOC budget stated in the plan is 41.57 tpsd, and the NO_X budget is 46.40 tpsd. Rhode Island used the EPA's MOBILE 5b emission factor model to determine these budgets. These budgets should be used for making transportation conformity determinations in the State.

II. Final Action

EPA is approving the Rhode Island post-1996 rate-of-progress emission reduction plan as a revision to the State's SIP.

The EPA is publishing this action without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in the proposed rules section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision should relevant adverse comments be filed. This rule will be effective August 7, 2001 without further notice unless the Agency receives relevant adverse comments by July 9, 2001.

If the EPA receives such comments, then EPA will publish a notice withdrawing the final rule and informing the public that the rule will not take effect. All public comments received will then be addressed in a subsequent final rule based on the proposed rule. The EPA will not institute a second comment period on the proposed rule. Only parties interested in commenting on the proposed rule should do so at this time. If no such comments are received, the public is advised that this rule will be effective on August 7, 2001 and no further action will be taken on the proposed rule.

Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

III. Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. This action merely approves state law as meeting federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies 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.*). Because this rule approves 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 rule also 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), nor will it 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), because it merely approves 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 rule also is not subject to Executive Order 13045 (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. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive order. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*)

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by August 7, 2001. Interested parties should comment in response to the proposed rule rather than petition for judicial review, unless the objection arises after the comment period allowed for in the proposal. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Nitrogen dioxide, Ozone.

Dated: May 21, 2001.

Ira W. Leighton,

Acting Regional Administrator, EPA–New England.

40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

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

Subpart OO—Rhode Island

2. Section 52.2088 is added to subpart OO to read as follows:

§ 52.2088 Control strategy: Ozone.

Revisions to the State Implementation Plan submitted by the Rhode Island Department of Environmental Management on September 21, 1998. These revisions are for the purpose of satisfying the rate of progress requirement of section 182(c)(2)(B), and the contingency measure requirements of section 182(c)(9) of the Clean Air Act, for the Providence serious ozone nonattainment area.

[FR Doc. 01–13941 Filed 6–7–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 095–0237a; FRL–6987–3]

Revisions to the Arizona and California State Implementation Plans, Maricopa County Environmental Services Department, Placer County Air Pollution Control District and South Coast Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve revisions to the Maricopa County Environmental Services Department (MCESD) portion of the Arizona State Implementation Plan (SIP), and the Placer County Air Pollution Control District (PCAPCD) and South Coast Air Quality Management District (SCAQMD) portions of the California SIP. These revisions concern volatile organic compound (VOC) emissions from Pharmaceutical, Cosmetic and Vitamin Manufacturing Operations, Fiberboard Manufacturing, and Hydrogen Plant Process Vents. We are approving local rules that regulate these emission sources under the Clean Air Act as amended in 1990 (CAA or the Act).

DATES: This rule is effective on August 7, 2001, without further notice, unless EPA receives adverse comments by July 9, 2001. If we receive such comment, we will publish a timely withdrawal in the **Federal Register** to notify the public that this rule will not take effect.

ADDRESSES: Mail comments to Andy Steckel, Rulemaking Office Chief (AIR–4), U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

You can inspect copies of the submitted SIP revisions and EPA's technical support documents (TSDs) at our Region IX office during normal business hours. You may also see copies of the submitted SIP revisions at the following locations:

Environmental Protection Agency, Air Docket (6102), Ariel Rios Building, 1200 Pennsylvania Avenue, NW., Washington, DC 20460.

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 1001 ''I'' Street, Sacramento, CA 95814.

Maricopa County Environmental Services Department, 1001 N. Central Avenue, Suite 201, Phoenix, Arizona, 85004–1942.

Placer County APCD, DeWitt Center, 11464 ''B'' Ave., Auburn, CA 95603–2603.
South Coast AQMD, 21865 E. Copley Dr., Diamond Bar, CA 91765–4182.

FOR FURTHER INFORMATION CONTACT: Ed Addison, Rulemaking Office (AIR–4), U.S. Environmental Protection Agency, Region IX, (415) 744–1160.

SUPPLEMENTARY INFORMATION: Throughout this document, ''we'', ''us'' and ''our'' refer to EPA.

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I. The State's Submittal

A. What Rules Did the State Submit?

Table 1 lists the rules we are approving with the dates that they were adopted by the local air agencies and submitted by the State agency.

TABLE 1.—SUBMITTED RULES

Local agency	Rule No.	Rule title	Adopted	Submitted
MCESD	349	Pharmaceutical, Cosmetic and Vitamin Manufacturing Operations	04/07/99	08/04/99
PCAPCD	229	Fiberboard Manufacturing	06/28/94	07/13/94
SCAQMD	1189	Hydrogen Plant Process Vents	01/21/00	07/26/00

On August 25, 1999, July 22, 1994, and October 4, 2000, these rule submittals were found to meet the completeness criteria in 40 CFR part 51 Appendix V, which must be met before formal EPA review.

B. Are There Other Versions of These Rules?

There are no previous versions of Rules 349, 229, and 1189 in the SIP.

C. What Is the Purpose of the Submitted Rules?

MCESD Rule 349 applies to the manufacture and blending of materials to make pharmaceutical or cosmetic products or vitamins, including any process that is incidental to such operations, such as tablet coating and finishing.

PCAPCD Rule 229 applies to new and existing facilities that manufacture medium density fiberboard. Currently there is only one facility in Placer County, the SierraPine, Ltd. plant, in Rocklin, CA.

SCAQMD Rule 1189 reduces emissions of volatile organic compounds from hydrogen plants that produce any hydrogen for use in petroleum refining operations. The TSDs have more information about these rules.

II. EPA's Evaluation and Action

A. How Is EPA Evaluating the Rules?

Generally, SIP rules must be enforceable (see section 110(a) of the Act), must require Reasonably Available Control Technology (RACT) for major sources in nonattainment areas (see section 182(a)(2)(A)), and must not relax existing requirements (see sections 110(1) and 193). The MCESD, PCAPCD, and SCAQMD regulate ozone nonattainment areas (see 40 CFR part 81), so Rules 349, 229, and 1189 must fulfill RACT.

Guidance and policy documents that we used to define specific enforceability and RACT requirements include the following:

1. Portions of the proposed post-1987 ozone and carbon monoxide policy that concern RACT, 52 FR 45044, November 24, 1987.
2. ''Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations; Clarification to Appendix D of November 24, 1987 **Federal Register** Notice,'' (Blue Book), notice of availability published in the May 25, 1988 **Federal Register**.
3. ''Requirements for Preparation, Adoption, and Submittal of Implementation Plans,'' U.S. EPA, 40 CFR part 51.
4. ''State Implementation Plans for National Primary and Secondary Ambient Air Quality Standards,'' Section 110 of the Clean Air Act, and Plan Requirements for Nonattainment Areas, Title I Part D of the Clean Air Act, Sections 182(b)(2), 189(a)(1)(C) and 189(b)(1)(B).
5. ''EPA–OAQPS Guideline—Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products,'' December 1978.
6. TSD for RACT Determination as prepared for US EPA Region IX Air and Toxics Division by E.H. Pechan & Associates, Inc. January 18, 1994.
7. ''Determination of RACT for control of Fugitive Emissions of VOCs from Oil and Gas Production and Processing Facilities, Refineries, Chemical Plants, and Pipeline Transfer Stations,'' CARB, December 8, 1993.

B. Do The Rules Meet the Evaluation Criteria?

We believe these rules are consistent with the relevant policy and guidance regarding enforceability, RACT, and SIP relaxations. The TSDs have more information on our evaluation.

C. Public Comment and Final Action

As authorized in section 110(k)(3) of the Act, EPA is fully approving the submitted rules because we believe they fulfill all relevant requirements. We do not think anyone will object to this approval, so we are finalizing it without proposing it in advance. However, in the Proposed Rules section of this **Federal Register**, we are simultaneously proposing approval of the same submitted rules. If we receive adverse comments by July 9, 2001, we will publish a timely withdrawal in the **Federal Register** to notify the pubic that the direct final approval will not take effect and will address the comments in a subsequent final action based on the proposal. If we do not receive timely adverse comments, the direct final approval will be effective without further notice on August 7, 2001. This will incorporate these rules into the federally enforceable SIP.

III. Background Information

A. Why Were These Rules Submitted?

VOCs help produce ground-level ozone and smog, which harm human health and the environment. Section 110(a) of the CAA requires states to submit regulations that control VOC emissions. Table 2 lists some of the national milestones leading to the submittal of these local agency VOC rules.

TABLE 2.—OZONE NONATTAINMENT MILESTONES

Date	Event
March 3, 1978	EPA promulgated a list of ozone nonatttainment areas under the Clean Air Act as amended in 1977. 43 FR 8964; 40 CFR 81.305.
May 26, 1988	EPA notified Governors that parts of their SIPs were inadequate to attain and maintain the ozone standard and requested that they correct the deficiencies (EPA's SIP–Call). See section 110(a)(2)(H) of the pre-amended Act.
November 15, 1990	Clean Air Act Amendments of 1990 were enacted. Pub. L. 101–549, 104 Stat. 2399, codified at 42 U.S.C. 7401–7671q.
May 15, 1991	Section 182(a)(2)(A) requires that ozone nonattainment areas correct deficient RACT rules by this date.

IV. Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. This action merely approves state law as meeting federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies 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.). Because this rule 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 rule 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), nor will it 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), because it merely approves 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 rule also is not subject to Executive Order 13045 (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. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive order. This rule 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, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compound.

Dated: April 27, 2001.

Mike Schulz,

Acting Regional Administrator, Region IX.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for Part 52 continues to read as follows:

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

Subpart D—Arizona

2. Section 52.120 is amended by adding paragraph (c)(94)(i)(F) to read as follows:

§ 52.120 Identification of plan.

* * * * *

(c) * * *

(94) * * *

(i) * * *

(F) Rule 349, adopted on April 7, 1999.

* * * * *

Subpart F—California

3. Section 52.220 is amended by adding paragraphs (c)(198)(i)(B)(*2*) and (c)(280) to read as follows:

§ 52.220 Identification of plan.

* * * * *

(c) * * *

(198) * * *

(i) * * *

(B) * * *

(*2*) Rule 229, adopted on June 28, 1994.

* * * * *

(280) New and amended regulations for the following APCDs were submitted on July 26, 2000, by the Governor's designee.

(i) Incorporation by reference.

(A) South Coast Air Quality Management District.

(*1*) Rule 1189, adopted on January 21, 2000.

[FR Doc. 01–14247 Filed 6–7–01; 8:45 am]

BILLING CODE 6560–50–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[DE001–1000; FRL–6988–3]

Approval of Section 112(l) Authority for Hazardous Air Pollutants; Chemical Accident Prevention Provisions and Risk Management Plans; Delaware; Approval of Accidental Release Prevention Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve the Delaware Department of Natural Resources and Environmental Control's (DNREC's) request to implement and enforce its accidental release prevention program in place of similar Federal requirements. EPA is taking this action under the requirements of the Clean Air Act.

DATES: This direct final rule will be effective August 7, 2001 unless EPA receives adverse or critical comments by July 9, 2001. If adverse comment is received, EPA will publish a timely withdrawal of the rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Written comments on this action should be sent concurrently to: Makeba A. Morris, Chief, Permits and Technical Assessment Branch, Mail Code 3AP11, Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, PA 19103–2029 and Robert A. Barrish, Delaware Department of Natural Resources and Environmental Control, Division of Air and Waste Management, 715 Grantham Lane, New Castle, DE 19720. 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; the Air and Radiation Docket and Information Center, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460; and Delaware Department of Natural Resources & Environmental Control, Division of Air and Waste Management, 715 Grantham Lane, New Castle, DE 19720.

FOR FURTHER INFORMATION CONTACT: Dianne J. Walker, U.S. Environmental Protection Agency, Region 3, 1650 Arch Street (3AP11), Philadelphia, PA 19103–2029, *walker.dianne@epa.gov* (telephone 215–814–3297)

SUPPLEMENTARY INFORMATION:

I. Background

Section 112(r) of the Clean Air Act (CAA) provides for the prevention and mitigation of accidental chemical releases. CAA section 112(r)(3)–(5) mandates that EPA promulgate a list of ''regulated substances'', with threshold quantities. Processes at stationary sources that contain a threshold quantity of a regulated substance are subject to accidental release prevention regulations promulgated under CAA section 112(r)(7). Pursuant to CAA section 112(r)(3) and (5), EPA published a list of substances and threshold quantities on January 31, 1994 (59 FR 4478) and subsequently amended this list on June 20, 1996 (61 FR 31730), August 25, 1997 (62 FR 45129), January 6, 1998 (63 FR 639), May 28, 1999 (64 FR 29167) and March 13, 2000 (65 FR 13243). Pursuant to CAA section 112(r)(7), EPA published the risk management program regulations on June 20, 1996 (61 FR 31668), and subsequently amended the regulations on January 6, 1999 (64 FR 963) and May 26, 1999 (64 FR 28695). The risk management program regulations are set forth at 40 CFR part 68. The regulations require, among other things, that owners and operators of stationary sources with more than a threshold quantity of a regulated substance in a process submit a risk management plan (RMP) by June 21, 1999, to a central location specified by EPA. A RMP must include, in general, an offsite consequence analysis (OCA), a prevention program, and an emergency response program.

It should be noted that the Chemical Safety Information, Site Security and Fuels Regulatory Relief Act, Public Law No. 106–40, which was enacted on August 5, 1999, excludes from coverage by the Federal Chemical Accident Prevention provisions any regulated flammable substance when used as fuel or held for sale as fuel by a retail facility. In its May 28, 1999 (64 FR 29167) rule amendments, EPA provided a stay of effectiveness from the risk management program regulation for these facilities until December 21, 1999. EPA amended its regulations on March 13, 2000 (65 FR 13243) to conform with this legislation. Public Law 106–40 also limits, until at least August 5, 2000, public access to the OCA portions of risk management plans submitted by covered facilities. A final rule concerning distribution of OCA information was published on August 4, 2000 (65 FR 48107) and codified in 40 CFR chapter IV.

In its January 6, 1999 (64 FR 963) amendments to the rule, EPA added mandatory and voluntary RMP data elements, specified the use of the North American Industry Classification System (NAICS), listed the applicable processes by NAICS code, required the five year accident history to include the weight percent of a toxic substance involved in a release and the NAICS code for the process involved a release, required an owner or operator to certify compliance with the regulation, established specific procedures for confidential business information and made technical clarifications to the regulation. In addition, EPA amended the procedure to calculate worst-case release scenarios for flammable substances in its regulations on May 26, 1999 (64 FR 28695) so that worst-case release scenarios for liquified or refrigerated flammable substances can be calculated in the same manner as liquified or refrigerated toxic substances.

The RMPs will be available to state and local governments and to the public. These regulations encourage sources to reduce the probability of accidentally releasing substances that have the potential to cause harm to public health and the environment. Further, the regulations stimulate dialog between industry and the public on ways to improve accident prevention and emergency response practices.

Section 112(l) of the CAA and 40 CFR sections 63.91, 63.93 and 63.95, authorize EPA, in part, to approve of State rules and programs to be implemented and enforced in place of the certain CAA requirements, including the chemical accident prevention provisions set forth at 40 CFR part 68. EPA promulgated the program approval regulations on November 26, 1993 (58 FR 62262) and subsequently amended these regulations on September 14, 2000 (65 FR 55810). An approvable State program must contain, among other criteria, the following elements: a demonstration of the state's authority and resources to implement and enforce regulations that are at least as stringent as the CAA section 112(r) regulations including an auditing strategy at least as stringent as the EPA regulation; a requirement that subject sources submit an RMP; procedures for reviewing RMPs; and procedures to provide technical assistance to subject sources, including small businesses.

II. DNREC's Accidental Release Prevention Program

On June 7, 1999, DNREC requested EPA's approval of its Accidental Release Prevention Program to be implemented and enforced in place of the chemical

accident prevention provisions set forth at 40 CFR part 68. On August 9, 1999, DNREC provided supplemental information for its request.

The Delaware Extremely Hazardous Substances Risk Management Act (Chapter 77, Title 7 of the Delaware Code), as amended, became effective July 1, 1999. This amended law provides authority to DNREC to develop regulations and implement and enforce a risk management program. On January 11, 1999, DNREC's Accidental Release Prevention Regulation, as amended, became effective. This regulation adopts the Federal requirements found in 40 CFR part 68, last revised January 6, 1998, with some adjustments and substitutions. Specifically, DNREC has:

1. Modified the scope of the regulation, as described in 40 CFR section 68.1;

2. Removed the definition of ''designated agency'', added a definition for ''Department'', and replaced all references in the Federal regulation to ''implementing agency'' with ''Department'';

3. Removed irrelevant provisions in the Federal regulation, including 40 CFR sections 68.2, 68.215(c), and 68.120;

4. Modified 40 CFR section 68.215(d) by replacing the terms ''implementing agency'' and ''air permitting authority'' with ''the Department''; and

5. Replaced 40 CFR section 68.220 with a more stringent auditing program that requires that all risk management plans be reviewed by DNREC within 6 months of receipt.

In addition, DNREC's regulation specifies a risk management program inspection protocol and a procedure for resolving findings of noncompliance. DNREC's regulation includes additional requirements for sources not regulated by the Federal program. These provisions are located in section 6 of DNREC's Accidental Release Prevention Regulation. DNREC is not seeking Federal approval of the requirements in section 6 of its Accidental Release Prevention Regulation.

DNREC's regulation was adopted prior to the changes that EPA made to its regulation on January 6, 1999, May 26, 1999, May 28, 1999 and March 13, 2000 (see description in Background section, above). Most of these changes are not included in the Delaware regulation. These changes, described in Section III. of this rulemaking, do not impact the stringency of DNREC's regulation and, thus, do not alter EPA's decision to approve of DNREC's rules.

III. EPA's Analysis of DNREC's Accidental Release Prevention Program

The following paragraphs describe, in detail, the differences between the Federal regulation and DNREC's regulation. The scope of the Federal program, outlined in 40 CFR section 68. 1, has been incorporated into section 1 ''Statement of Authority'', section 2 ''Purpose'' and section 3 ''Policy and General Duty'' of DNREC's Accidental Release Prevention Regulation. These sections of DNREC's regulation:

1. Cite DNREC's legislative and regulatory authority to implement the regulation and seek delegation of the Federal program;

2. Describe the intent of the regulation with the overall goal of preventing catastrophic releases of regulated substances and protecting the public; and

3. Outline the general duty of owners and operators of stationary sources to identify hazards, to design, operate and maintain safe facilities and to minimize the consequences of accidental releases.

These provisions are no less stringent than the corresponding Federal requirements.

DNREC has removed the definition of the term ''designated agency'' used in the Federal regulation, added the definition of ''Department'', and defined the term ''implementing agency'' used in the Federal regulation as ''Department''. The term ''designated agency'' in the Federal regulation refers to the state, local or Federal agency which is delegated authority by the state air permitting agency to verify that sources permitted under 40 CFR part 70 or 71 and subject to the Federal or state accidental release prevention requirements have submitted an RMP and have certified compliance with the requirements. In addition, the designated agency is tasked with ensuring that these sources are in compliance with the Federal or state accidental release prevention requirements. Because Delaware's air permitting authority, DNREC, is not delegating this authority to any other state, local or Federal agency, the ''designated agency'' term was removed from its regulation. DNREC will be responsible for implementing the aforementioned tasks which are described in detail in section 5.215(c) of DNREC's regulation. The term ''Department'' in DNREC's regulation has been defined as ''the Department of Natural Resources and Environmental Control''. The definition of ''implementing agency'' used in the Federal regulation has been replaced in DNREC's regulation with ''Department'' since, on the effective date of this rulemaking, DNREC will be the state agency delegated the authority to implement an accidental release prevention program.

In addition, DNREC has defined several terms which are not used in the Federal regulation. These terms are only used in section 6 of DNREC's regulation. DNREC is not seeking Federal approval of section 6 of its regulation. DNREC has removed irrelevant sections of the Federal regulation from its regulation. Specifically, the ''stayed provisions'' of 40 CFR section 68.2 were removed from the DNREC regulation because the time limit of this stay has expired. DNREC has removed the permitting provisions of 40 CFR section 68.215(c), requiring the state permitting authority to reopen or reissue permits that do not contain the applicable accidental release prevention requirements, because all permits issued pursuant to Delaware's permitting program (approved under 40 CFR part 70) contain language incorporating the accidental release prevention requirements. Regardless, in accordance with the program approval requirements of 40 CFR section 63.95(b), DNREC is not required to have permitting provisions comparable to the provisions of 40 CFR section 68.215(c).

DNREC removed the auditing requirements of 40 CFR section 68.220 and replaced these requirements with sections 7 and 8 of its regulation. Specifically, section 8(a) of DNREC's regulation requires DNREC to audit all RMPs within six months of the date that they are received by DNREC or posted by EPA on its website. This provision is clearly more stringent than the Federal regulation, 40 CFR sections 68.220(a), (b) and (c), which requires the implementing agency to ''periodically audit RMPS'' according to specific criteria.

The Federal regulation specifically exempts stationary sources with a Star or Merit ranking under the Occupational Safety and Health Administration's (OSHA's) voluntary protection program from auditing where DNREC's regulation does not. Sections 8(b), (c), and (d) of DNREC's regulation grant DNREC access to the regulated stationary sources for auditing and outline the procedures for DNREC to notify the stationary source of its deficiencies in the program as a result of an audit and for the stationary source to respond to such deficiencies. Section 8(e) and (f) of DNREC's regulation outline the process that DNREC will use to issue a final determination of the audit and sets forth the provisions for identifying violations at a stationary source as a result of an audit. Sections

8(b), (c), (d), (e) and (f) of DNREC's regulation are equivalent to 40 CFR sections 68.220(d), (e), (f), (g) and (h).

Section 8(g) of DNREC's regulation grants the public access to the preliminary determinations, responses and final determinations made as a result of an audit, however, in accordance with section 14(a) of DNREC's regulation, confidential business information and the identification of persons interviewed during an inspection can be withheld from the public. This provision is equivalent to 40 CFR section 68.220(i) and 40 CFR section 68.210(a), which requires that preliminary determinations, responses and final determinations made as a result of an audit and RMP information be available to the public consistent with 42 U.S.C. 7414(c). In addition to these provisions, under 40 CFR section 68.151, owners and operators of stationary sources required to submit an RMP can assert a claim of confidential business information under 40 CFR section 2.301. Section 8(h) of DNREC's regulation, outlining DNREC's right to exercise its enforcement investigation and information gathering authorities, is equivalent to 40 CFR section 68.220.

EPA has, therefore, determinated that in accordance with the program approval requirements of 40 CFR section 63.95(b)(4), DNREC's auditing strategy is no less stringent than the corresponding Federal requirement.

Section 7 of DNREC's regulation provides a detailed description of DNREC's inspection procedures. There is no similar provision in the Federal regulation, however, this information provides the description necessary to fulfill DNREC's requirement to demonstrate its authority to implement and enforce the regulation, as required by 40 CFR section 63.95(b)(1)(i) and (4).

DNREC removed the provisions to petition EPA to modify the list of regulated substances identified in 40 CFR section 68.130, as described in 40 CFR section 68.120, from its regulations since DNREC does not have the authority to adopt future regulatory amendments or revisions. DNREC retained the provisions outlined in 40 CFR sections 68.150 through 68.190 in sections 5.150 through 5.190 of its regulation. However, DNREC added the following language to section 5.150: ''Note: The data elements of the Plan are required to be submitted to EPA. The data elements of the plan are based upon 40 CFR 68.150 through 68.190 dated July 1, 1997 reprinted here under Sections 5.150 through 5.190. It is the responsibility of the owner or operator to meet the existing EPA risk management plan data submittal requirements at the time of submission.'' These provisions are required by 40 CFR section 63.95(b)(1)(ii).

DNREC removed Tables 2 and 4 found in 40 CFR part 68 from its regulation. These tables present information identical to that presented in Tables 1 and 3 of 40 CFR part 68. DNREC has retained Tables 1 and 3 and has renamed them Tables 1 and 2, respectively. Appendix A of 40 CFR part 68 is Table 3 of DNREC's regulation.

As stated earlier, DNREC's regulation does not include all of the modifications that EPA made to its regulation on January 6, 1999, May 26, 1999, May 28, 1999 and March 13, 2000. DNREC made changes to its regulation in an attempt to conform with the January 6, 1999 amendments, based upon EPA's proposed amendments of April 17, 1998 (63 FR 19216). DNREC's changes included the addition of the definition of NAICS in section 5.3 and the requirements in sections 5.10(b)(1) and 5.79(a). These provisions are identical to the amendments made in EPA's regulation 40 CFR sections 68.3, 68.10(b)(1) and 68.79(a), respectively. Section 5.42(b) of DNREC's regulation does not conform with EPA's amendments in 40 CFR sections 68.42(b)(3) and (4) which added requirements to the five year accident history. Sections 5.160(b), 5.165(b), 5.170(b), 5.175(b) and 5.180(b) of DNREC's regulation do not conform with the provisions in 40 CFR sections 68.160(b)(1), (7), (12), (14)–(18), 68.165(b)(2), 68.170(b), 68.175(b) and 68.180(b) of EPA's amended regulation which require the RMP to contain the method for obtaining and describing the location of longitude and latitude of the facility, the Title V permit number, certain optional data elements, and the weight percentage of toxic substance in a liquid mixture used in the offsite consequence analysis. In addition, DNREC did not include the provisions corresponding to 40 CFR sections 68.150(e), 68.151, and 68.152 related to the procedures for claiming confidential business information.

However, regardless of the differences between DNREC's regulation and the January 6, 1999 amendments to EPA's regulation, section 5.150 of DNREC's regulation requires affected sources to submit RMPs which meet the existing EPA risk management plan data submittal requirements at the time of submission (see the description of section 5.150 of DNREC's regulation provided in Section II. of this document). Therefore, DNREC's regulation, when taken as a whole with respect to these provisions, is no less stringent than EPA's regulation.

The May 26, 1999 amendments include changes to the procedures in calculating the worst-case scenario releases for liquified and refrigerated flammable gases. Because these amendments allow for a less conservative approach for calculating worst-case scenario releases than the previous provisions, DNREC's current regulation is no less stringent than EPA's regulation. EPA's May 28, 1999 amendment, which provided a stay of effectiveness until December 21, 1999, is no longer applicable. EPA's March 13, 2000 amendment to its regulation revised the list of regulated flammable substances to exclude those substances when used as a fuel or held for sale as a fuel at a retail facility. DNREC's current regulation, which does not incorporate these provisions, is no less stringent than EPA's regulation. In fact, because DNREC will regulate sources which use flammable substances as a fuel or hold flammable substances for sale as a fuel at a retail facility, DNREC's regulation will cover a larger universe of sources than the Federal regulation.

DNREC's regulation includes additional requirements for sources not regulated by the Federal program. These provisions are located in section 6 of DNREC's Accidental Release Prevention Regulation. DNREC is not seeking Federal approval of the requirements in section 6 of DNREC's Accidental Release Prevention Regulation. EPA has separated these portions of DNREC's regulation from this approval, per the requirements of 40 CFR section 63.91(a)(3) and (f). Consequently, in accordance with 40 CFR section 63.91(c)(1)(iii), upon approval, section 6 of DNREC's Accidental Release Prevention Regulation will remain enforceable only by the State.

DNREC's regulation conforms to EPA's regulation regarding the distribution of off-site consequence analysis information, dated August 4, 2000 (65 FR 48107) and codified in 40 CFR chapter IV, because it requires that disclosure of classified information be controlled by applicable laws, regulations or executive orders, per section 5.120 of DNREC's regulation.

Based upon DNREC's program approval request and its pertinent laws and regulations, EPA has determined that such an approval is appropriate in that DNREC has satisfied the criteria of 40 CFR sections 63.91, 63.93 and 63.95. The DNREC program has adequate and effective authorities, resources, and procedures in place for implementation and enforcement of sources subject to the CAA section 112(r)(7) requirements.

DNREC has the primary authority and responsibility to carry out all elements of the CAA section 112(r)(7) program for all sources covered in Delaware, including on-site inspections, record keeping reviews, audits and enforcement.

DNREC's program to implement 112(r) of the CAA, has the authority and resources to educate subject sources through outreach programs; provide technical assistance; to review all risk management plans; to coordinate its efforts with other agencies and programs including the State Emergency Response Commission, the Local Emergency Planning Committees, and DNREC's air permitting program; and to adequately enforce its 112(r) program.

Upon approval, DNREC's program will be administered by its Accidental Release Prevention Group. Although DNREC has primary authority and responsibility to implement and enforce the CAA section 112(r)(7) requirements, nothing shall preclude, limit, or interfere with the authority of EPA to exercise its enforcement, investigatory, and information gathering authorities concerning this part of the Act.

IV. Final Action

EPA is approving DNREC's Accidental Release Prevention Regulation sections 1 through 5 and sections 7 thorough 14, as amended, effective January 11, 1999, as equivalent to the CAA section 112(r)(7) requirements set forth in Chapter 40 of the Code of Federal Regulations (CFR) part 68 for affected sources in the State of Delaware. Accordingly, EPA is revising 40 CFR sections 63.14 and 63.99 to reflect the Federal enforceability of DNREC's regulation. DNREC's regulation adopts the federal requirements found in 40 CFR part 68, last revised January 6, 1998, with some adjustments and substitutions. EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comment. The adjustments and substitutions made in the DNREC regulation are primarily non-substantive. The three substantive changes from the Federal regulation relate to auditing of the RMPs, calculating worst-case scenarios for flammable substances and the applicability of the DNREC regulations to flammable substances when used as a fuel or held for sale at retail facilities. These three substantive changes are clearly more stringent than EPA's regulation. DNREC is required to audit all RMPs within six months of submittal. EPA's regulations do not have such a requirement. DNREC requires facilities to estimate worst-case scenarios for liquified or refrigerated flammable substances in the same manner used for gaseous flammable substances (i.e., assuming the entire quantity of a liquified or refrigerated flammable substance vaporizes resulting in a vapor cloud explosion). EPA's regulation allow facilities to calculate worst-case scenarios for liquified or refrigerated flammable substances in the same manner used for liquified or refrigerated toxic substances which results in a less conservative estimate than DNREC's approach. Finally, because DNREC's regulation did not include EPA's exclusion of flammable substances used as a fuel or held for sale at retail facilities, DNREC will regulate a larger universe of facilities. Although EPA does not anticipate adverse comments on these changes, in the ''Proposed Rules'' section of today's **Federal Register**, EPA is publishing a separate document that will serve as the proposal to approve the program approval request if adverse comments are filed. This rule will be effective on August 7, 2001 without further notice unless EPA receives adverse comment by July 9, 2001. If EPA receives adverse comment, EPA will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. EPA will address all public comments in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time.

V. Administrative Requirements

A. General Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies 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.*). Because this rule approves 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 rule also 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), nor will it 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), because it merely approves 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 rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant. In reviewing requests for rule approval under Clean Air Act section 112, 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 requests for rule approval under Clean Air Act section 112 for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a request for rule approval under Clean Air Act section 112, to use VCS in place of a request for rule approval under Clean Air Act section 112 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. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive order. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

B. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

C. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by August 7, 2001. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action, pertaining to the approval of Delaware's accidental release prevention program (Clean Air Act Section 112(r)), may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects 40 CFR Part 63

Environmental protection, Administrative practice and procedure, Air pollution control, Hazardous substances, Incorporation by reference, Intergovernmental relations.

Dated: May 16, 2001.

Thomas C. Voltaggio,

Acting Regional Administrator, Region III.

40 CFR part 63 is amended as follows:

PART 63—[AMENDED]

1. The authority citation for part 63 continues to read as follows:

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

2. Section 63.14 is amended by adding paragraph (d)(3) to read as follows:

§ 63.14 Incorporation by Reference.

* * * * *

(d) * * *

(3)(i) Letter of June 7, 1999 to the U.S. Environmental Protection Agency Region 3 from the Delaware Department of Natural Resources and Environmental Control requesting formal full delegation to take over primary responsibility for implementation and enforcement of the Chemical Accident Prevention Program under Section 112(r) of the Clean Air Act Amendments of 1990.

(ii) Delaware Department of Natural Resources and Environmental Control, Division of Air and Waste Management, Accidental Release Prevention Regulation, sections 1 through 5 and sections 7 through 14, effective January 11, 1999, IBR approved for § 63.99(a)(8)(i) of subpart E of this part.

Subpart E—Approval of State Programs and Delegation of Federal Authorities

3. Section 63.99 is amended by adding paragraph (a)(8) to read as follows:

§ 63.99 Delegated Federal Authorities

(a) * * *

(8) Delaware

(i) Affected sources must comply with the Delaware Department of Natural Resources and Environmental Control, Division of Air and Waste Management, Accidental Release Prevention Regulation, sections 1–5 and sections 7–14, January 11, 1999 (incorporated by reference as specified in § 63.14). The material incorporated in the Delaware Department of Natural Resources and Environmental Control, Division of Air and Waste Management, Accidental Release Prevention Regulation, sections 1–5 and sections 7–14 pertains to owners and operators of stationary sources in the State of Delaware that have more than a threshold quantity of a regulated substance in a process, as described in section 5.10 of Delaware's regulation, and has been approved under the procedures in §§ 63.93 and 63.95 to be implemented and enforced in place of 40 CFR part 68–Chemical Accident Prevention Provisions.

(ii) [Reserved]

[FR Doc. 01–14079 Filed 6–7–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301127; FRL–6780–9]

RIN 2070–AB78

Methyl Anthranilate; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the methyl anthranilate on corn and sunflower when applied/used as a bird repellent. Bird Shield Repellent Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996, requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of methyl anthranilate on corn and sunflower and reasses the existing tolerance exemption for methyl anthranilate.

DATES: This regulation is effective June 8, 2001. Objections and requests for hearings, identified by docket control number [OPP–301127], must be received by EPA, on or before August 7, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit IX. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301127 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Jim Downing, c/o Product Manager (PM) 91, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703–308–9071; and e-mail address: downing.jim@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301127. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of January 24, 2000 (65 FR 3693) (FRL–6485–5), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), as amended by the Food Quality Protection Act (FQPA) (Public Law 104–170) announcing the filing of pesticide tolerance petitions (PP 9F5056 and 9F5055) by Bird Shield Repellent Corporation, P.O. Box 785, Pullman, WA 99163. This notice included a summary of the petitions prepared by the petitioner Bird Shield Repellent Corporation. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.1143 be amended by establishing an exemption from the requirement of a tolerance for residues of methyl anthranilate on corn and sunflower.

III. Risk Assessment

New section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(c)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Additionally, section 408(b)(2)(D) requires that the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

IV. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Methyl anthranilate is naturally occurring in certain foods, such as concord grapes. It is also synthetically produced and used as a flavoring agent (21 CFR 182.60) in beverages, ice cream, candy, baked goods, gelatins, puddings, and chewing gum. It is also exempt from the requirement of a tolerance in or on blueberries, cherries, and grapes (40 CFR 180.1143). A discussion of the rationale supporting that exemption may be found in the proposed rule, as well as in the April 26, 1995 final rule. In addition, methyl anthranilate is classified as generally recognized as safe (GRAS) by FDA (21 CFR 182.60).

Methyl anthranilate, because of volatility, rapidly decomposes into non-toxic components leaving no significant residue relative to levels found in food on corn and sunflower to which it is applied. The residue studies showed that the residues of methyl anthranilate found on corn and sunflower were less than those found naturally in grapes. Moreover, it has been determined that even if ingested, the chemical rapidly metabolizes in the intestines and byproducts are excreted. In addition to this information, the Agency has determined that all toxicology data requirements have been satisfied and it has conducted a review of these studies. Summaries of these studies are presented below. For a more detailed discussion of these studies, see the Data Review Records located in the information docket referred to above.

Mammalian toxicity. Methyl anthranilate exhibits little or no mammalian toxicity. As mentioned before, it metabolizes in the intestine when consumed. The LD_{50} values for methyl anthranilate were estimated to

be greater than 5,000 milligram/kilogram (mg/kg) in an acute oral toxicity study in rats (Toxicity Category IV). Methyl anthranilate was found to cause moderate irritation in a rabbit skin irritation assay after continuous exposure of the compound for 4 hours (Toxicity Category III) and corneal effects that cleared in 8 to 21 days in a rabbit eye irritation assay (Toxicity Category II). Since the mammalian toxicity is low and considering the diluted formulation that is used, no hypersensitivity studies were necessary.

Guideline	Study	MRID No.	Toxicity Category
870.1100	Acute Oral Toxicity -rat	447403-01	IV
870.1200	Acute Dermal Toxicity	447403-02	III
870.1300	Acute Inhalation Toxicity - rat	447403-03	III
870.2400	Acute (Primary) Eye Irritation - rabbits	440703-02	II
870.2500	Acute (Primary Dermal) Skin Irritation	440703-01	III
870.2600	Hypersensitivity (skin sensitization)	NA	Waived

Appropriate labeling (protective eyewear) was used to mitigate these moderately acute toxicological risks. Due to the low toxicity, metabolism, rapid degradation and long history of dietary exposure to this naturally occurring biochemical, chronic and subchronic data were waived. No other toxic endpoints were identified and therefore no reference dose and no observable effect level were established.

V. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

1. *Food*. Methyl anthranilate residues, when used as a bird repellent, are already exempt from the requirement of a tolerance on blueberries, cherries and grapes, based upon a ''worst case'' maximum concentration on cherries of 35 ppm (60 FR 9816, February 22, 1995) and the fact that natural levels of 33 ppm occur in commonly consumed foods, such as grapes, and that use of methyl anthranilate as a flavoring agent results in residues of approximately 30 ppm in baked goods and up to 400 ppm in gum. For corn and sunflowers, methyl anthranilate, applied at a rate of only 0.2862 pounds per acre, results in residues of less than 33 ppm on these crops, even when taking into account the 4.5-fold and 14-fold maximum theoretical concentration factors for processed commodities. Because methyl anthranilate is a volatile compound, which rapidly degrades when exposed to ultraviolet light (sunlight), and warm temperatures in the environment, further reduction in residues is expected. The dietary exposure is not anticipated to be increased significantly in a typical human diet by the use of this biochemical pesticide on sunflowers and corn. Further, since methyl anthranilate has shown no mammalian toxicity and is rapidly metabolized in human intestines and liver, no dietary risk from these additional uses of this biochemical pesticide are anticipated.

2. *Drinking water exposure*. Methyl anthranilate is very unlikely to be found in drinking water, given the extremely low application rate and rapid environmental and microbial degradation (MRID 431194–01).

B. Other Non-Dietary, Non-Occupational Exposure

The primary non-dietary, non-occupational sources of exposure the Agency considered include exposure through use in lawns (turf), and on cherries, blueberries and grapes grown around the home or structures. Methyl anthranilate products are registered for use on residential turf (lawns) but not for any indoor uses. Limited exposure would result from use on home lawns, because of the rapid degradation of methyl anthranilate under sunlight. Even though methyl anthranilate products can be used on household (gardens) grown cherries, blueberries and grapes, the use is expected to be infrequent and very low, because of the limited quantities needed to control the targeted species during any growing season. In addition, methyl anthranilate rapidly degrades, thus limited exposure is anticipated. Use of methyl anthranilate around structures would not significantly increase the exposure, because of the limited use anticipated around the home. Home applicators could be exposed to methyl anthranilate, but this would be in a limited manner due to the infrequent use around the home. The Agency expects little risk from this exposure due to the low toxicity (LD_{50} of >5,000 mg/kg oral toxicity in rats; dermal LD_{50} of >2,000 thru 5,000 mg/kg; inhalation LD_{50} of >0.5 thru 2.0 mg/liter) of this natural constituent of certain plants (i.e., grapes).

VI. Cumulative Effects

Methyl anthranilate does not exhibit a toxic mode of action to the target species (birds) or any mammals to which limit dose were tested. Thus, because there is no indication of mammalian toxicity to this substance, no cumulative effects with other related compounds is expected.

VII. Determination of Safety for U.S. Population, Infants and Children

Methyl anthranilate has been demonstrated by the results of acute toxicity testing in mammals to cause no adverse effects when dosed orally and via inhalation at the limit dose of each study. Further, significant methyl anthranilate residues relative to levels found in foods have not been detected on treated corn and sunflower. Considering the low toxicity and the lack of significant residues of this naturally occurring biochemical, combined with its metabolism in the intestines if ingested, EPA has concluded that there is reasonable certainty that no harm will result from aggregate exposure to the U.S. population, or any significant subpopulation, including infants and children, to residues of methyl anthranilate. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. EPA did not use a 10x safety factor for children in its

analysis because of the low toxicity of methyl anthranilate and the lack of significant residue relative to levels found in food when applied to corn and sunflower.

VIII. Other Considerations

A. Endocrine Disruptors

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) ''may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, to other such endocrine effects as the Administrator may designate.'' Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Programs (EDSP).

When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disruptor Screening Program have been developed, methyl anthranilate may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption. Based on the weight of the evidence of available data, no endocrine system-related effects have been identified.

B. Analytical Method(s)

This action is establishing an exemption from the requirement of a tolerance for the reasons described above. As previously noted, methyl anthranilate exhibits rather low toxicity. For this reason and because no significant residues have been detected on treated corn and sunflower (in other words, residues beyond that of methyl anthranilate found naturally in grapes are unlikely), no analytical method for enforcement purposes is required.

C. Codex Maximum Residue Level

The Agency is not aware of any international tolerances, exemptions from tolerance or Maximum Residue Levels (MRLs) issued for methyl anthranilate. Furthermore, the Agency is not aware of any issues regarding Codex Maximum Residue Levels.

IX. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301127 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before August 7, 2001.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit IX.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket number OPP–301127, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of

electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

X. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism*(64 FR 43255, August 10, 1999). Executive Order 13132 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.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XI. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 25, 2001.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

2. Section 180.1143 is revised to read as follows:

§ 180.1143 Methyl anthranilate; exemption from the requirement of a tolerance.

Methyl anthranilate, a biochemical pesticide, is exempt from the requirement of a tolerance when used in accordance with good agricultural practices on the following raw agricultural commodities: Blueberry, cherry, corn, grape, and sunflower.

[FR Doc. 01–14487 Filed 6–7–01; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 01–1293]

Radio Broadcasting Services; Various Locations

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, on its own motion, editorially amends the Table of FM Allotments to specify the actual classes of channels allotted to various communities. The changes in channel classifications have been authorized in response to applications filed by licensees and permittees operating on these channels. This action is taken pursuant to *Revision of Section 73.3573(a)(1) of the Commission's Rules Concerning the Lower Classification of an FM Allotment,* 4 FCC Rcd 2413 (1989), and the *Amendment of the Commission's Rules to permit FM Channel and Class Modifications [Upgrades] by Applications,* 8 FCC Rcd 4735 (1993).

DATES: Effective June 8, 2001.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, adopted May 16, 2001, and released May 25, 2001. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center, 445 12th Street, SW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, Inc., 1231 20th Street, NW., Washington, DC 20036, (202) 857–3800, facsimile (202) 857–3805.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

PART 73—RADIO BROADCAST SERVICES

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

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

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Alabama, is amended by removing Channel 286C and adding Channel 286C3 at Albertville.

3. Section 73.202(b), the Table of FM Allotments under Arizona, is amended by removing Channel 255C and adding Channel 255A at Leupp.

4. Section 73.202(b), the Table of FM Allotments under Delaware, is amended by removing Channel 250A and adding Channel 251A at Selbyville.

5. Section 73.202(b), the Table of FM Allotments under Florida, is amended by removing Channel 272A and adding Channel 274A at Blountstown and by removing Channel 274A and adding Channel 274C3 at Blountstown.[1]

6. Section 73.202(b), the Table of FM Allotments under Georgia, is amended by removing Channel 300C3 and adding Channel 300C2 at Valdosta.

7. Section 73.202(b), the Table of FM Allotments under Michigan, is amended by removing Channel 264A and adding Channel 264C1 at Crystal Falls.

8. Section 73.202(b), the Table of FM Allotments under Nebraska, is amended by removing Channel 292C2 and adding Channel 292C1 at Lincoln.

9. Section 73.202(b), the Table of FM Allotments under Nevada, is amended by removing Channel 262A and adding Channel 261C at Beatty.

10. Section 73.202(b), the Table of FM Allotments under New Mexico, is amended by removing Channel 272C3 and adding Channel 272C1 at Clovis.

11. Section 73.202(b), the Table of FM Allotments under Vermont, is amended by removing Channel 233C3 and adding Channel 233A at Rutland.

12. Section 73.202(b), the Table of FM Allotments under Garapan, Saipan, is amended by adding Channel 250C1 at Garapan, Saipan.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 01–14524 Filed 6–7–01; 8:45 am]

BILLING CODE 6712–01–U

[1] On April 22, 1999, the authorization for Channel 272A, Blountstown, Florida, was amended by a one-step application to specify Channel 274A in lieu of Channel 272A. However, that change was not published in the **Federal Register** and the FM Table of Allotments was not corrected to reflect the channel change. We take this opportunity to correct the FM Table of Allotments with respect to Blountstown.

Proposed Rules

Federal Register
Vol. 66, No. 111
Friday, June 8, 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 COMMERCE

National Oceanic and Atmospheric Administration

15 CFR Part 922

Initiation of Review of Management Plan for the Florida Keys National Marine Sanctuary; Notice of Scoping Meetings

AGENCY: Marine Sanctuaries Division (MSD), National Ocean Service (NOS), National Oceanic and Atmospheric Administration, Department of Commerce (DOC).

ACTION: Initiation of review of management plan; Notice of scoping meetings.

SUMMARY: In accordance with section 304(e) of the National Marine Sanctuaries Act, as amended, (NMSA) (16 U.S.C. 1431 et seq.), the Marine Sanctuaries Division of the National Oceanic and Atmospheric Administration (NOAA) is initiating a review of the Florida Keys National Marine Sanctuary (FKNMS or Sanctuary) Management Plan, to evaluate substantive progress toward implementing the goals for the Sanctuary, and to make revisions to the plan and regulations as necessary to fulfill the purposes and policies of the NMSA.

NOAA will conduct public scoping meetings to gather information and comments from individuals, organizations, and government agencies on the scope, types and significance of issues related to the Sanctuary's management plan and regulations.

DATES: Written comments should be received by July 20, 2001.

The scoping meeting dates are:

1. Thursday, June 21, 2001, 7:00 p.m. in Marathon.

2. Friday, June 22, 2001, 7:00 p.m. in Key Largo.

3. Tuesday, June 26, 2001, 7:00 p.m. in Key West.

ADDRESSES: Mail written comments to the Florida Keys National Marine Sanctuary (Management Plan Review), Post Office Box 500368, Marathon, FL 33050. Comments will be available for public review at the same address.

The scoping meeting locations are:

1. Marathon—Marathon Garden Club, 5270 Overseas Highway, Marathon, FL.

2. Key Largo—Key Largo Library, Tradewinds Shopping Center, 101485 Overseas Highway, Key Largo, FL.

3. Key West—Holiday Inn Beachside, 3841 N. Roosevelt Blvd., Key West, FL.

FOR FURTHER INFORMATION CONTACT: Billy D. Causey, Sanctuary Superintendent, (305) 743–2437×26.

SUPPLEMENTARY INFORMATION: The Florida Keys National Marine Sanctuary was designated by the Florida Keys National Marine Sanctuary and Protection Act (FKNMSPA) P.L. 101–605. The Sanctuary includes 2900 square nautical miles of coastal and ocean waters, and the submerged lands thereunder, surrounding the Florida Keys. The 2.5 million-acre Sanctuary contains one of North America's most diverse assemblages of terrestrial, estuarine, and marine fauna and flora, including, in addition to the Florida reef tract, thousands of patch reefs, one of the largest sea grass communities covering 1.4 million acres, mangrove fringed shorelines, mangrove islands, and various hardbottom habitats. These diverse habitats provide shelter and food for thousands of species of marine plants and animals, including more than 50 species of animals identified under federal or state law, as endangered or threatened. The present Management Plan for the Sanctuary was completed in 1996.

The proposed revised Management Plan will likely involve changes to existing management policies of the Sanctuary, to address current issues and challenges, and to better protect and manage the Sanctuary's resources and qualities. NOAA anticipates completion of the revised Management Plan by June 30, 2002, and concomitant documents, including any revised regulations, will require approximately six to twelve additional months.

This timeline will allow NOAA to prepare a revised plan to be submitted to the Governor of the State of Florida for review and approval in July 2002. The State of Florida is a co-trustee in the management of the Sanctuary and NOAA has determined that at the conclusion of the five-year review of the Sanctuary, it will re-propose the management plan and regulations for the Governor's review, similar to the forty-five day review period required under section 304(b) of the National Marine Sanctuary Act at the time a national marine sanctuary is being designated (16 U.S.C. 1434(b)).

Authority: 16 U.S.C. section 1431 et seq.

(Federal Domestic Assistance Catalog Number 11.429 Marine Sanctuary Program)

Dated: June 4, 2001.

Ted I. Lillestolen,

Deputy Assistant Administrator for Ocean Services and Coastal Zone Management.

[FR Doc. 01–14428 Filed 6–7–01; 8:45 am]

BILLING CODE 3510–08–M

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

37 CFR Parts 1 and 2

[Docket No. 991105297–1125–03]

RIN 0651–AB01

Revision of Patent and Trademark Fees for Fiscal Year 2002; Correction

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice of proposed rulemaking; correction.

SUMMARY: The United States Patent and Trademark Office published a proposed rule in the **Federal Register** of May 9, 2001, revising certain patent fee amounts and a trademark fee amount for fiscal year 2002, changing the maintenance fee correspondence address, and amending a fee to reflect current business practice. This document corrects one error in that proposed rule.

FOR FURTHER INFORMATION CONTACT: Matthew Lee by e-mail at *matthew.lee@uspto.gov,* by telephone at (703) 305–8051, or by fax at (703) 305–8007.

SUPPLEMENTARY INFORMATION: The United States Patent and Trademark Office published a proposed rule entitled ''Revision of Patent and Trademark Fees for Fiscal Year 2002'' in the **Federal Register** of May 9, 2001 (66 FR 23642). The proposed rule contains an error in the Other Considerations section. The paragraph that references

an appendix comparing existing and proposed fee amounts should have been omitted. The appendix was referenced for informational purposes only. This document corrects the error in the Other Considerations section.

In rule FR Doc. 01–11591, published on May 9, 2001 (66 FR 23642), make the following correction. On page 23643, in the third column, remove the third paragraph from the Other Considerations section.

Dated: May 31, 2001.

Nicholas P. Godici,

Acting Under Secretary of Commerce for Intellectual Property and Acting Director of the United States Patent and Trademark Office.

[FR Doc. 01–14510 Filed 6–7–01; 8:45 am]

BILLING CODE 3510–16–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[RI–022a; A–1–FRL–6990–7]

Approval and Promulgation of Air Quality Implementation Plans; Rhode Island; Post-1996 Rate-of-Progress Emission Reduction Plans

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of Rhode Island. This revision establishes a post-1996 rate-of-progress (ROP) plan for the Providence serious ozone nonattainment area. In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

DATES: Written comments must be received on or before July 9, 2001.

ADDRESSES: Comments may be mailed to David Conroy, Unit Manager, Air Quality Planning, Office of Ecosystem Protection (mail code CAQ), U.S. Environmental Protection Agency, EPA—New England, One Congress Street, Suite 1100, Boston, MA 02114–2023. Copies of the State submittal and EPA's technical support document are available for public inspection during normal business hours, by appointment at the Office of Ecosystem Protection, U.S. Environmental Protection Agency, EPA—New England, One Congress Street, 11th floor, Boston, MA and at the Office of Air Resources, Department of Environmental Management, 235 Promenade Street, Providence, RI 02908–5767.

FOR FURTHER INFORMATION CONTACT: Robert McConnell, (617) 918–1046.

SUPPLEMENTARY INFORMATION: For additional information, see the direct final rule which is located in the Rules Section of this **Federal Register**.

Dated: May 21, 2001.

Ira W. Leighton,

Acting Regional Administrator, EPA—New England.

[FR Doc. 01–13942 Filed 6–7–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 095–0237b; FRL–6987–4]

Revisions to the Arizona and California State Implementation Plans, Maricopa County Environmental Services Department, Placer County Air Pollution Control District and South Coast Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve revisions to the Maricopa County Environmental Services Department (MCESD) portion of the Arizona State Implementation Plan (SIP), and the Placer County Air Pollution Control District (PCAPCD) and South Coast Air Quality Management District (SCAQMD) portions of the California SIP. These revisions concern volatile organic compound (VOC) emissions from Pharmaceutical, Cosmetic and Vitamin Manufacturing Operations, Fiberboard Manufacturing, and Hydrogen Plant Process Vents. We are proposing to approve local rules to regulate these emission sources under the Clean Air Act as amended in 1990 (CAA or the Act).

DATE: Any comments on this proposal must arrive by July 9, 2001.

ADDRESSES: Mail comments to Andy Steckel, Rulemaking Office Chief (AIR–4), U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

You can inspect copies of the submitted SIP revisions and EPA's technical support documents (TSDs) at our Region IX office during normal business hours. You may also see copies of the submitted SIP revisions at the following locations:

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 1001 ''I'' Street, Sacramento, CA 95814

Maricopa County Environmental Services Department, 1001 N. Central Avenue, Suite 201, Phoenix, Arizona, 85004–1942

Placer County APCD, DeWitt Center, 11464 ''B'' Ave., Auburn, CA 95603–2603

South Coast AQMD, 21865 E. Copley Dr., Diamond Bar, CA 91765–4182

FOR FURTHER INFORMATION CONTACT: Ed Addison, Rulemaking Office (Air-4), U.S. Environmental Protection Agency, Region IX, (415) 744–1160.

SUPPLEMENTARY INFORMATION: This proposal addresses the following local rules: MCESD 349—Pharmaceutical, Cosmetic and Vitamin Manufacturing Operations, PCAPCD 229—Fiberboard Manufacturing, and SCAQMD 1189—Hydrogen Plant Process Vents. In the Rules and Regulations section of this **Federal Register**, we are approving these local rules in a direct final action without prior proposal because we believe these SIP revisions are not controversial. If we receive adverse comments, however, we will publish a timely withdrawal of the direct final rule and address the comments in subsequent action based on this proposed rule. We do not plan to open a second comment period, so anyone interested in commenting should do so at this time. If we do not receive adverse comments, no further activity is planned. For further information, please see the direct final action.

Dated: April 27, 2001.

Mike Schulz,

Acting Regional Administrator, Region IX.

[FR Doc. 01–14248 Filed 6–7–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[DE001–1000; FRL–6988–2]

Approval of Section 112(l) Authority for Hazardous Air Pollutants; Chemical Accident Prevention Provisions and Risk Management Plans; Delaware; Approval of Accidental Release Prevention Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve the Delaware Department of Natural Resources and Environmental Control's (DNREC's) request to implement and enforce its accidental release prevention program in place of similar Federal requirements. In the Final Rules section of this **Federal Register**, EPA is approving the State's request for rule approval as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

DATES: Written comments must be received on or before July 9, 2001.

ADDRESSES: Written comments on this action should be sent concurrently to: Makeba A. Morris, Chief, Permits and Technical Assessment Branch, Mail Code 3AP11, Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, PA 19103–2029 and Robert A. Barrish, Delaware Department of Natural Resources and Environmental Control, Division of Air and Waste Management, 715 Grantham Lane, New Castle, DE 19720. 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; the Air and Radiation Docket and Information Center, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460; and Delaware Department of Natural Resources & Environmental Control, Division of Air and Waste Management, 715 Grantham Lane, New Castle, DE 19720.

FOR FURTHER INFORMATION CONTACT: Dianne J. Walker, 215–814–3297, at the EPA Region III address above, or by e-mail at *walker.dianne@epa.gov.*

SUPPLEMENTARY INFORMATION: For further information on this action, pertaining to the proposed approval of Delaware's accidental release prevention program (Clean Air Act section 112(r)), please see the information provided in the direct final action, with the same title, that is located in the ''Rules and Regulations'' section of this **Federal Register** publication.

Dated: May 16, 2001.

Thomas C. Voltaggio,

Acting Regional Administrator, Region III.

[FR Doc. 01–14080 Filed 6–7–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 86

[FRL–6992–7]

RIN 2060–AG13

Control of Air Pollution From Motor Vehicles and New Motor Vehicle Engines; Revisions to Regulations Requiring Availability of Information for use of On-Board Diagnostic Systems and Emission-Related Repairs on 1994 and Later ModelYear Light-Duty Vehicles and Light-Duty Trucks and 2005 and Later Model Year Heavy-Duty Vehicles and Engines Weighing 14,000 Pounds Gross Vehicle Weight or Less

AGENCY: Environmental Protection Agency.

ACTION: Notice of proposed rulemaking.

SUMMARY: Today's action proposes modifications to EPA's Service Information regulations for light-duty vehicles and trucks, including requiring vehicle manufacturers to; make full text emissions-related service information and training information available via the World Wide Web; provide equipment and tool companies with information that allows them to develop equipment with pass-through reprogramming capabilities; make available enhanced diagnostic information to aftermarket scan tool manufacturers; make available manufacturer-specific diagnostic tools for sale to interested parties; and make available additional OBD technical information that manufacturers must provide. In addition, today's proposal requests comment on extending the availability of emission-related service information to heavy-duty engines and vehicles weighing 14,000 pounds or less beginning in the 2005 model year.

DATES: Comments must be received on or before August 7, 2001. A public hearing will be held on July 25, 2001. Requests to present oral testimony must be received on or before July 2, 2001.

ADDRESSES: Comments must be submitted to Holly Pugliese, Certification and Compliance Division, U.S. Environmental Protection Agency, 2000 Traverwood, Ann Arbor, Michigan 48105.

The public hearing will be held at the Holiday Inn North Campus, 3600 Plymouth Road, Ann Arbor, MI. The hearing will begin at 10:00 a.m. and continue until all testimony has been presented.

Materials relevant to this rulemaking are contained in EPA Air Docket No. A–2000–49. The docket is located at The Air Docket, 401 M. Street, SW., Washington, DC 20460, and may be viewed in room M1500 between 8:00 a.m. and 5:30 p.m., Monday through Friday. The telephone number is (202) 260–7548 and the facsimile number is (202) 260–4400. A reasonable fee may be charged by EPA for copying docket material.

FOR FURTHER INFORMATION CONTACT: Holly Pugliese, Certification and Compliance Division, U.S. Environmental Protection Agency, 2000 Traverwood, Ann Arbor, Michigan 48105, Telephone 734–214–4288, Internet e-mail ''pugliese.holly@epa.gov,'' or Christine Mikolajczyk, 734–214–4403, Internet e-mail ''mikolajczyk. christine@ epamail.epa.gov.''

SUPPLEMENTARY INFORMATION:

Regulated Entities

Entities potentially regulated by this action are those which manufacturer new motor vehicles and engines. Regulated categories include:

Category	NAICS Codes (1)	SIC Codes (2)	Examples of potentially regulated entities
Industry	336111 336112 336120	3711	Motor Vehicle Manufacturers.

(1) North American Industry Classification System (NAICS).
(2) Standard Industrial Classification (SIC) system code.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your product is regulated by this action, you should carefully examine the applicability criteria in § 86.099–17 of title 40 of the Code of Federal Regulations. If you have questions regarding the applicability of this action to a particular product, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

Obtaining Rulemaking Documents Through the Internet

The preamble, regulatory language and regulatory support document are also available electronically from the EPA Internet Web site. This service is free of charge, except for any cost you already incur for Internet connectivity. The official EPA version is made available on the day of publication on the primary Web site listed below. The EPA Office of Transportation and Air Quality also publishes these notices on the secondary Web site listed below.

(1) http://www.epa.gov/docs/fedrgstr/EPA–AIR/ (either select desired date or use Search feature)
(2) http://www.epa.gov/OTAQ/ (look in ''What's New'' or under the specific rulemaking topic)

Please note that due to differences between the software used to develop the document and the software into which the document may be downloaded, changes in format, page length, etc. may occur.

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I. What Is the Important Background Information for This Proposal?

Section 202(m)(5) of the CAA directs EPA to promulgate regulations requiring vehicle manufacturers to provide to:

> Any person engaged in the repairing or servicing of motor vehicles or motor vehicle engines, and the Administrator for use by any such persons, * * * any and all information needed to make use of the [vehicle's] emission control diagnostic system * * * and such other information including instructions for making emission-related diagnoses and repairs.

Such requirements are subject to the requirements of section 208(c) regarding protection of trade secrets; however, no such information may be withheld under section 208(c) if that information is provided (directly or indirectly) by the manufacturer to its franchised dealers or other persons engaged in the repair, diagnosing or servicing of motor vehicles.

On August 9, 1995, EPA published a final rulemaking (60 FR 40474) which set forth the Agency's service information regulations. These regulations, in part, required each Original Equipment Manufacturer (OEM) to do the following: (1) List all of its emission-related service and repair information on a Web site called FedWorld (including the cost of each item and where it could be purchased); (2) either provide enhanced information to equipment and tool companies or make its OEM-specific diagnostic tool available for purchase by aftermarket technicians, and (3) make reprogramming capability available to independent service and repair professionals if its franchised dealerships had such capability. These requirements were intended to ensure that aftermarket service and repair facilities have access to the same emission-related service information, in the same or similar manner, as that provided by vehicle manufacturers to their franchised dealerships.

In order to meet Congress' intent that consumers have freedom of choice in where to have their vehicles serviced, it is essential for independent technicians to have access to timely and accurate emission-related service and repair information. Industry estimates indicate that independent technicians perform up to 80% of all vehicle service and repairs. Further, independent technicians perform more repairs on older vehicles (which are more likely than newer vehicles to have higher emissions) than technicians in franchised dealerships. These conclusions are the result of statistics issued from the Motor and Equipment Manufacturers Association (Automotive Industry Status Report, 1999. EPA Air Docket A–2000–49, item II–F–05) that (1) the level of excess emissions increases as a vehicle's mileage increases, and (2) the percentage of non-dealer repairs increased and dealer repairs decreased as a vehicle's mileage increased and warranty coverage is no longer an issue.

In addition, OEM comments submitted during the comment period for the prior service information proposal (56 FR 48278, September 24, 1991) spoke to the integral role aftermarket technicians play in servicing the approximately 200 million vehicles in use. Many OEMs indicated that the number of service bays in their franchised dealerships are inadequate to service their fleets of vehicles and that

they depend on aftermarket technicians to provide service for their customers' vehicles, especially for those vehicles out of warranty. This further highlights the need for independent technicians to have access to timely and appropriate emission-related repair and service information.

Since 1995, the Agency has gained experience in the implementation of the service information requirements. Additionally, changing technology has made it necessary to revisit the current requirements to take advantage of advanced technology.

II. What Are the Details of This Proposal?

A. How Would Vehicle Manufacturers Disseminate Information Under This Proposed Rulemaking?

In the prior service information proposal (56 FR 48272, September 24, 1991), we proposed the dissemination of the required information by electronic format. However, after extensive comments from the automotive industry and our concerns at that time about the capability of the World Wide Web to handle the information and its limited use by the general public, we elected to use NTIS' FedWorld as the means of making information available. Rather than being a full text data base, the FedWorld data base is best characterized as a card catalog of required information, i.e., it lists the title, price, and purchasing instructions for each item.

As we have implemented the 1995 requirements, a variety of issues have been raised about the effectiveness of the information distribution requirements. First, several issues have been raised related to the effectiveness of FedWorld in making the required information available in an efficient and cost-effective manner. Input from both OEMs and aftermarket technicians indicates that it is often difficult to find specific items in the FedWorld data base. This is due to various factors, including the lack of common terminology among OEMs for the same or similar items and the failure of OEMs to provide descriptions of each item, e.g., documents are often listed by part number with no indication of what they contain. Additionally, EPA has been made aware that the information listed in FedWorld often was not available to be shipped from an OEM's designated distributor within one business day of an order being placed, as required by the regulations. OEMs have also complained about the administrative costs they were charged by NTIS and the lack of technicians accessing the data base.

EPA agrees that there appears to be a limited number of technicians accessing the FedWorld database. We believe this is due to a variety of factors, including the following: (1) A lack of awareness about its existence; (2) the model years applicable to the information listed are just now coming out of the original manufacturer warranty; and (3) the inability to receive the information in a timely manner. Based on recent communications to the Agency, it appears that technicians are beginning to use FedWorld as the models contained in the database are appearing in larger numbers at aftermarket repair facilities. However, the database is still cumbersome to search and does not result in the information being provided in a timely manner. Finally, over the past year, several OEMs have sought the Agency's opinion as to whether they could opt-out of the FedWorld requirement if they made available the required information on their own Internet sites.

As a result of these requests and the issues cited above, we concluded that changes to the existing regulations are necessary to ensure that emission-related service and repair information is available in a timely manner to all persons who service and repair motor vehicles.

Therefore, today's rulemaking proposes that within 6 months of publication of the Final Rule, each OEM shall launch individual World Wide Web Internet sites and up-load on its Web site the full text of all emission-related service and repair documents,[1] in English, for all OBD equipped 1996 and later model year vehicles. We are aware that OEMs may be at different points in their Web site development. We are also aware that some OEM information for 1996 through 2000 model years may not be readily converted for use on the World Wide Web and the cost of doing so may be prohibitive. Therefore, EPA requests comment on the need for a short phase-in period for making available full-text service information as required in this proposal for 1996 through 2000 model year vehicles. Additionally, we are aware that service information for the 1994 and 1995 model years poses even greater technological challenges for conversion to full-text for use on the World Wide Web. For example, several OEMs have indicated to us that their service manuals and technical service bulletins for some of these model years are no longer available to them in electronic format. As a result, large volumes of information would need to be electronically scanned and converted for Web-based access. Therefore, we will propose alternative requirements for these two model years. For a discussion of service information requirements for 1994 and 1995 model years, please see section II(A)(2). OEMs will not be required to simultaneously maintain their indexes on the FedWorld database.

OEMs may choose to have a third party (e.g., FedWorld, an information intermediary, or another entity) establish and maintain their full-text Web sites. However, OEMs would remain responsible for ensuring accuracy and completeness of information as well as compliance with the regulations.

1. Required Information

In the original Service Information requirements finalized in August of 1995 (60 FR 40475), we required manufacturers to make available ''any and all'' information needed by the aftermarket to make use of the OBD system and such other information, including instructions for making emission-related repairs, excluding trade secrets. The 1995 regulations defined emission-related information as including, but not limited to, any information regarding any system, component or part of a vehicle that controls emissions and any system, component and/or part associated with the powertrain system, including, but not limited to, the engine, the fuel system and ignition system. The existing regulations also require that information must be provided for any system, component or part that is likely to affect emissions, such as transmission systems.

Specifically, EPA required an index of emissions-related documents available for ordering to be up-loaded on the FedWorld database. The required information included, but was not limited to, manuals, technical service bulletins (TSBs), diagrams, charts, training materials (instructor manuals), and videos.

While we believe that the definition of ''emissions-related'' as described above is fairly comprehensive, we have received input from aftermarket technicians suggesting that there is additional information needed by the aftermarket to diagnose and complete emissions-related repairs that is not readily available across all

[1] This requirement does not apply to indirect information. Indirect information means any information that is not specifically contained in the service literature, but is contained in items such as tools or equipment provided to franchised dealerships (or others).

manufacturers. To address these concerns we are providing additional clarification and examples of the types of information that we believe is consistent with the statutory intent to provide ''any and all'' information needed to make use of the OBD system. These examples, which include pages from several OEM service manuals and a generic logic flow diagram for a repair procedure, can be found in EPA Air Docket A–2000–49 items II–F–02, and II–F–04. To the extent that manufacturers do not already make this information available to their dealerships, we are proposing that this information be developed for both their dealerships and aftermarket service providers. We also believe that the level of information being sought by the aftermarket and proposed in today's action is not proprietary and should therefore be included in the scope of the required information. This belief is based in part upon the increasing number of manufacturers who are voluntarily providing a wider scope of OBD information to aftermarket service providers without any expressed concerns to EPA regarding the release of proprietary information. To further ensure manufacturers that we do not intend to require proprietary information, we have provided specific examples of the increased level of information that is currently being made available by some manufacturers that we believe should be consistently required from all manufacturers to ensure the diagnosis and repair of OBD equipped vehicles.

We are proposing that manufacturers make available in full-text on their respective Web sites OBD system operational information which describes functional characteristics of the OBD system and emission-related components necessary to accurately diagnose and repair emissions-related problems. In particular, aftermarket and dealership service providers have indicated that OBD system operational information such as generic drive cycles, component operating ranges and system logic flow diagrams are valuable pieces of information needed for accurate diagnosis and repair of emissions-related problems. We also believe that this type of information will be needed for use in Inspection and Maintenance (I/M) programs. Currently some I/M programs have voluntarily incorporated checks of the OBD system into their programs. Additionally, within the next one to two years, EPA will require a check of the OBD system in Inspection and Maintenance programs. EPA has been working with the voluntary I/M programs and they have expressed the need for information such as generic drive cycles to assist them in successfully implementing OBD checks into their programs.

As an example of the type of general OBD information that EPA believes is required to make emission-related repairs, and thus is proposing to require OEMs to make available, the most recent Advanced Engine Performance Specialist Test (L1) Preparation Guide developed by the organization Automotive Service Excellence (ASE) includes a reference booklet that has been placed in EPA Air Docket A–2000–49, item II–F–01. The ASE L1 Preparation Guide provides generic examples of various operating parameters for OBD components and sensors (e.g. a properly functioning engine coolant temperature sensor will show values ranging from −40 °F to 248°F). This information is provided for those taking the test as an example of a diagnostic procedure a technician would utilize when servicing an emissions-related problem. We believe that the ASE L1 Preparation Guide is an effective example of the types of information we believe should be more readily available for all OEMs. To further analyze the availability of this level of service information, we conducted a literature search of a variety of service manuals from a cross-section of manufacturers. We looked at service manuals ranging from model years 1996–2000 for randomly chosen diagnostic trouble code PX300 (random misfire). A search of the service manuals was conducted to evaluate if information such as component operating ranges, logic flow diagrams, or generic drive cycles was available to assist technicians in trouble-shooting this particular code. Our research indicated that this type of information is not consistently made available by all manufacturers. Our analysis is contained in EPA Air Docket A–2000–49, item II–B–01, ''Technical Memorandum from Shannon Elliot to Holly Pugliese and Arvon Mitcham, March 10, 2000''.

We are aware of at least one manufacturer who makes this information available only via their manufacturer-specific diagnostic scan tool. For manufacturers who currently utilize this approach, we propose that this information also be included in full-text on their respective Web site(s). For manufacturers who make this information available in publications other than service manuals (e.g., training materials) that are not otherwise subject to the proposed full-text requirements, we propose that this information be readily accessible in full text on manufacturer Web sites as well. For all manufacturers, this information should be formatted and appear in a clear, consistent, and readily accessible manner (e.g., tables or logic flow diagrams). Although the information should be as vehicle specific as possible, we understand that a manufacturer's system may be consistent across vehicle lines and, therefore, the information may be consolidated to make it as generic as is appropriate.

Additionally, vehicle systems are evolving in such a way that there is an increased likelihood of all vehicle systems, including the anti-theft system, affecting the electronic control unit (ECU). Therefore, we believe it is necessary and appropriate to ensure that information reflecting and affecting these inter-relationships is also provided to the aftermarket.

With today's action, we propose that the full-text documents to be up-loaded and available for viewing on OEM Web sites include, but not be limited to, the following items:

(a) Manuals, technical service bulletins (TSBs), diagrams, charts, training materials (see Section IIB for further detail) and videos.

(b) OBD system operational information that describes functional characteristics of the OBD system and emission-related components. OBD system operational information includes, but is not limited to, OBD generic drive cycle information, component operating ranges, and system logic flow diagrams. OEMs are not required to provide algorithms, look-up tables, or any values associated with look-up tables.

In addition, it is proposed that OEMs provide emission-related diagnostic procedures on their respective Web sites and that access to these procedures not require connection to the vehicle to access this information.

(c) Documents such as component and subsystem manuals provided to OEMs or franchised dealerships by suppliers or other parties that have agreements with OEMs. We understand that OEMs are increasingly using third party contractors and suppliers to design and develop parts and other vehicle subsystems. We believe that this information is critical for the diagnosis and service of emissions-related problems and needs to be made available to aftermarket service providers. Thus, the fact that information is not provided directly by an OEM to its franchised dealerships should not preclude the OEM from making non-propriety service and repair

information available to the aftermarket. EPA believes that it is appropriate for this information to be made available on OEM Web sites but also requests comment on alternative mechanisms for making this information available to the aftermarket.

(d) Any information on other systems that can directly effect the emission system within a multiplexed system (including how information is sent between emission-related system modules and other modules on a multiplexed bus),

(e) Any information regarding any system, component, or part of a vehicle monitored by the OBD system that could in a failure mode cause the OBD system to illuminate the malfunction indicator light (MIL).

(f) Any other information relevant to the diagnosis and completion of an emissions-related repair. This information includes, but is not limited to, information needed to start the vehicle when the vehicle is equipped with an anti-theft or similar system that disables the engine. This information also includes any manufacturer-specific emissions-related diagnostic trouble codes (DTCs) and any related service bulletins, trouble shooting guides, and/or repair procedures associated with these manufacturer-specific DTCs.

With regard to anti-theft systems, it appears that some OEMs have incorporated systems into their vehicles which, when the ECU is replaced or reprogrammed as part of an emissions-related repair, prevent the vehicles from being started without the use of an OEM-specific tool and codes. Additionally, some OEMs have incorporated anti-theft systems into their vehicles that disable the engine when the vehicle is brought in for service. In both of these instances, an aftermarket service provider would not be able to complete the repair for the customer without otherwise having to take the vehicle to a dealership to complete the repair. We believe that an emissions-related repair cannot be considered complete if the owner is not able to drive the vehicle away from the repair shop. Therefore, we are proposing that OEMs make this information directly available to the aftermarket.

EPA appreciates that vehicle manufacturers spend considerable resources to prevent vehicle theft and we do not want to jeopardize this security by allowing illegal disablement of the vehicle security system. Given the sensitive nature of the anti-theft system information, we believe it is reasonable to allow manufacturers some additional lead-time to incorporate additional appropriate security measures as needed by each OEM. EPA requests comment on this issue.

Information for making emission-related repairs does not include information used to design and manufacture parts, but may include manufacturer changes to internal calibrations. However, a manufacturer need only provide such information to the extent it has provided such information to its dealerships.

Finally, we believe that manufacturers are accountable for the accuracy of their service information, for both their dealerships and the aftermarket repair industry. Moving toward Internet-based delivery of service information should increase the ability of OEMs to more quickly respond to errors in their service information and provide updates to the required information for all interested parties in a timely manner.

2. Pre-1996 Model Years

The primary focus of this proposal is on service information for vehicles equipped with complete OBD systems , i.e. 1996 and newer model year vehicles. However, we believe that it is important for aftermarket service providers to have access to service information for older models as well, particularly since the aftermarket services a majority of older vehicles. To address this need, EPA is proposing that OEMs either continue to maintain their databases of information on FedWorld or transfer information from FedWorld onto their Web sites and continue to make information available for sale as it currently is in FedWorld for 1994 and 1995 model year vehicles. Alternatively, OEMs could elect to provide full text information on their Web site for vehicles for model years 1994 and 1995.

3. Other Media

Currently, OEMs can choose to simultaneously provide information through a variety of media, such as print or CDs. However, EPA will not propose to require OEMs to maintain multi-media formats with this rule. Some manufacturers have expressed an interest in moving away from print and other media in the future and are concerned about having to maintain multiple media formats to meet the EPA requirements. We believe that it is reasonable for manufacturers who wish to do so to provide service information to the aftermarket via the Internet only and are not proposing to require manufacturers to make available information in multiple media formats.

However, we are also sensitive to the fact that a majority of repairs performed by the aftermarket are on older vehicles. Additionally, the useful lives of vehicles continue to increase. Thus, aftermarket service providers need access to service information for a wide range of model years. In Section II(A)(5), we discuss our proposal that OEMs maintain the required information in full-text available on their Web 2001model years to address this issue. We are requesting comment on this proposed length of time and are also requesting comment on the mechanisms that would be used by the aftermarket to obtain information that is no longer available in full-text format from OEM Web sites.

4. Small Volume Provisions

Because of the small U.S. sales volumes of some OEMs and the relatively small demand for the service information for these manufacturers, EPA believes it is appropriate to propose some flexibility for small volume manufacturers. It is proposed that OEMs with annual sales of less than five thousand vehicles be given 12 months after the effective date of the final rule to comply with the Web site requirements. We also propose that OEMs be exempt from the Internet requirements if they modify or manufacture less than one thousand vehicles annually, provided they present to the Administrator and obtain approval for an alternative method by which emission-related information can be obtained.

5. Timeliness and Maintenance of Information

We believe that for information to be effective, it must be provided in a timely manner. For aftermarket technicians this means having access to needed information when the vehicle is brought in for service. In the past, OEMs have argued that the aftermarket service industry seldom perform emission-related service during the first two or three years of ownership (during the 24,000 or 36,000 mile warranty period), and therefore don't need to have immediate access to new model service information. However, we believe that aftermarket service providers have, at least, a limited need for service information for new vehicles. Dealership service may not always be convenient for a customer and there are customers who prefer aftermarket service even though a vehicle is still under warranty. Further, EPA believes that it does not place undue burden on the OEMs to provide information that is already being made available to the dealerships. To ensure that aftermarket technicians have the required information when needed, we propose that OEMs upload the required information on their Web site within

three months of model introduction. After this three month period, we propose that the required information for each model be available and updated on the OEM Web site at the same time it is available by any means to their dealers.

EPA is also proposing that, beginning with the 1996 model year, manufacturers maintain the required information in full text for at least 15 years after model introduction. After this fifteen-year period, we propose that manufacturers can archive the required service information, but that it must be made available upon request, in a format of the manufacturer's choice (e.g., CD–ROM). We are proposing this requirement to account for the increasing useful life of vehicles and the fact that the aftermarket services a majority of older vehicles as discussed above. However, we also believe it is not necessary to over-burden OEM Web servers with service information that is still needed by the aftermarket, but not on as regular a basis as service information for newer models. Therefore, we believe it is appropriate to allow some flexibility for the distribution of service information for older vehicles. We request comment on the proposed length of time that manufacturers will be required to maintain full text information on their Web sites.

6. Accessibility and Performance Requirements

(a) Accessibility Requirements. We propose that each OEM Web site allow end-users to search its database of emission-related service information by various topics. These topics include, but are not limited to, model, model year, key words and phrases, diagnostic procedures, scheduled maintenance, and vehicle identification number (VIN). Additionally, we propose that manufacturers must provide information to allow for readily identifying the latest calibration. Further, while the VIN may be offered as one means of conducting a search, OEMs may not require the use of a VIN to initially access the data base. We further propose that the use of proprietary hardware, software, viewers, browsers and formats for accessing information be prohibited. In other words, manufacturers must develop their service information, and provide access to it, in such a way that it can be viewed using software such as Adobe Acrobat Reader that is readily available to Internet users. The manufacturer's Home Page must be accessible to anyone and contain instructions on how to access the information. Instructions should include, but not be limited to, minimum hardware and non-proprietary software needed by the end-user and associated costs for accessing and purchasing information.

Finally, we propose that OEMs not limit the modem speed by which aftermarket service providers can access OEM Web sites. In other words, OEMs may not limit access to modem speeds of 28k or 56k. As more and more computer users invest in digital subscriber lines (DSL) and cable modems to access the Internet, we are concerned that limiting access at these relatively slower speeds will impact the ability to access information from OEM Web sites in a timely manner.

Feedback from aftermarket service providers has indicated that there are three primary ways to generally categorize the aftermarket. First, many aftermarket shops service a wide variety of makes, models, and model years and are likely to rely on consolidated information such as Mitchell or All Data and do not generally need access to manufacturer-specific information on a daily basis. There are also aftermarket shops who specialize by categories such as European or Asian makes and models. There are also shops that further specialize by a specific manufacturer. Additionally, other parties such as Inspection/Maintenance lanes and do-it-yourself mechanics may be interested in accessing OEM Web sites. Because of the potential for a wide variety of OEM Web site usage, we are proposing that manufacturers develop a three-tiered approach for the access to and cost structure of their Web-based service information to provide maximum flexibility and access to aftermarket service providers. We propose that these options include, but not be limited to short-term, mid-term, and long-term access to the required information.

(1) Short-Term Access. We propose that manufacturers provide short term access for a set price. Under this scenario, manufacturers would set up a short time frame of approximately 24 hours whereby an aftermarket service provider would be able to access that OEM's Web site, search for the piece of information they need, and purchase, download and/or print it for a set fee. EPA believes that a reasonable fee for short term access can be as little as $0, but should be no greater than $20.

(2) Mid-term Access. We are proposing that manufacturers provide mid term access for a set price. Under this scenario, aftermarket service providers would be able to access to the OEM Web site for a 30 day time frame and purchase, download and/or print information under this option for a set fee. EPA believes that a reasonable fee for mid term access can be as little as $0, but no greater than $300.

(3) Long-term Access. We are proposing that manufacturers provide long term access for a set price. Under this scenario, aftermarket service providers would have access to the OEM Web site for a 365 day time frame, including the ability to purchase, download and/or print the information for a set fee. EPA believes that a reasonable fee for long term access can be as little as $0, but no greater than $2500.

We believe that establishing this tiered approach will serve as a reference point for manufacturers to develop and implement access to their Web sites that allow maximum flexibility for aftermarket service providers, and others who engage in the service and diagnosis of vehicles given the varying needs for access to manufacturer specific information. Additionally, EPA is significantly concerned that some OEMs will develop pricing structures for access to their sites in such a way that will prevent the purchase of information. Because of this concern and to help reduce the possibility that inappropriate pricing will occur, we believe that it is appropriate for EPA to establish specific pricing parameters that each manufacturer must follow when determining access fees for the three tiers described above. In determining the pricing parameters described above, we took into consideration feedback we have received thus far from some aftermarket service providers on what they believe the appropriate pricing parameters are for each of the three tiers. We also took into consideration other factors such as the current cost to the aftermarket for purchasing information from OEMs and the potential costs to OEMs for developing, implementing, and maintaining OEM Web sites. We have not received specific feedback from a majority of manufacturers on their intended pricing structures, mainly due to the fact that most manufacturers are still in the development stages of their sites and are not in a position to comment on the issue at this time. We understand that the cost of service information is a significant issue for both the OEMs and aftermarket service providers. To this extent, we request comment on this proposed tiered structure, the pricing parameters established by EPA for each of the tiers, and what other factors should be considered by EPA when evaluating whether manufacturers are making their information available via the Internet at

a reasonable cost. For a more complete discussion of cost for all of the provisions contained in today's proposal, see Section II(F).

(b) Performance Requirements. The availability of service information also relies heavily on the ability of OEM Web sites to perform in such a way that service information can be delivered via the Internet to potentially thousands of users at any given time without significant delay. This is particularly important given the complexity of the service information being transmitted (e.g., wiring diagrams, electrical circuit diagrams, etc). The transmission of information via the Internet depends on a complex array of server, database, network, and other Web-based infrastructures that impact a Web site's ability to transmit at maximum efficiency. While manufacturers cannot be held accountable for issues such as end-user hardware and software or the type of connectivity utilized by the end-user, (e.g., standard modem, cable modem, or digital subscriber line), we believe it is necessary for manufacturers to measure the parameters that are within their control.

To this end, we are proposing that manufacturers submit to the Administrator on an annual basis a report that provides detailed, monthly measurements of the OEM's Web site. Each OEM report is to be submitted to the Administrator beginning one year after the required launch date of manufacturers' Web sites (i.e., one year and 6 months after the final rule is issued), or upon request by the Administrator. The parameters to be measured include, but are not limited to, the following:

(1) Total successful requests (measured in number of files including graphic interchange formats (GIFs) and joint photographic expert group (JPEG) images, i.e. electronic images such as wiring or other diagrams or pictures). This is defined as the total successful request counts of all the files which have been requested, including pages, graphics, etc.

(2) Average successful requests per day (measured in number of files). This is defined as reports of the average successful requests per day of all files which have been requested, including pages, graphics, etc.

(3) Total successful requests for pages [report on number of pages (including graphic interchange formats (GIFs) and joint photographic expert group (JPEG) images, i.e. electronic images such as wiring or other diagrams or pictures). This is defined as the total successful requests counts all the documents that were returned or where the document was requested but was not needed because it had not been recently modified and the user could use a cached copy.

(4) Total failed requests (measured in number of files). This is defined as the total failed request counts of all the files which were requested but failed requests because they could not be found or were read-protected. This includes pages, graphics, etc.

(5) Total redirected requests (measured in number of files). This is defined as redirected requests that indicate that the user was directed to a different file instead.

(6) Number of distinct files requested (measured in number of files). This is defined as the number of different file types that were requested (i.e., html, pdf, txt).

(7) Number of distinct hosts served (measured in number of files). This is defined as reports on the number of different computers where requests have come from.

(8) Corrupt logfile lines (measured in number of lines). This is defined as the lines in the logfile that were unreadable by the computer.

(9) Total data transferred (measured in bytes). This is defined as the total amount of data transferred from one place to another.

(10) Average data transferred per day (measured in bytes). This is defined as the average amount of data transferred per day from one place to another.

(11) Daily Summary (measured in number of files/pages by day of week). This is defined as the total number of requests in each day of the week, over the time period given at the very top of the report.

(12) Daily Report (measured in number of files/pages by day of month). This is defined as how many requests there were in each day of a specific month.

(13) Hourly Summary (measured in number of files/pages by hour of day). This is defined as the total number of requests for each hour of the day, over a specific time period.

(14) Request Report (measured in number of files/pages by individual URL). This is defined as which files were downloaded.

(15) Referrer Report (measured in number of files/pages by individual referring URL). This is defined as which pages linked to your files.

(16) Browser Summary (measured in number of files/pages by browser type, i.e., Netscape, Internet Explorer). This is defined as the versions of browsers by vendor.

(17) Browser Report (measured in number of files/pages by browser type, i.e., Mozilla 4.0). This is defined as a list of the detailed versions of browsers used.

This list will be periodically reviewed by the Administrator to address changes in technology and any potential compliance issues.

Manufacturers would have the option of conducting their own performance measurements or contracting with companies who specialize in Internet performance measurement (e.g. Keynote Systems, Inc.). However, we intend to work with OEMs to develop a standard format that all manufacturers would use to submit the required information to the Administrator and issue the required format via a manufacturer guidance letter.

We believe that manufacturers are likely to evaluate at least some aspects of the performance of their Web sites regardless of any requirement do so. As a result, we believe that this requirement places minimal burden on OEMs to meet the proposed requirements for performance evaluation. The proposed requirements to assess Web site performance serve to outline a consistent level of information to be provided to the Administrator to assist in evaluating compliance with Internet-based access to service information.

7. Hyperlinking

To facilitate the search for emission-related information on the Internet, we propose that OEMs allow direct simple hyperlinking to their Web sites from government Web sites and from all automotive-related Web sites, such as aftermarket service providers, educational institutions, and automotive associations. For example, an association such as the Service Technician's Society (STS) may want to have a section of their Web site that will allow an aftermarket technician to access a complete listing of all the OEM Service Information Web sites. Hyperlinking will allow individuals to connect directly to the OEM Web home page of their choice directly from the STS Web site.

8. Administrator Access to OEM Web Sites

The Administrator shall have access to each OEM Web site at no charge to the Agency. The Administrator shall have access to to the site, reports, records and other information as provided by sections 114 and 208 of the Clean Air Act and other provisions of law.

B. What Provisions Are Proposed for Service Information for Third Party Information Providers?

Currently, many aftermarket service and repair facilities depend on consolidated service information purchased from third party providers such and Mitchell and All-Data. These companies primarily consolidate and repackage OEM service manuals and technical service bulletins (TSBs) for purchase by the aftermarket. Currently, OEMs often provide their service manuals and TSBs to these third parties in hardcopy. Given the trend in the electronic exchange of information, we believe that it is reasonable for OEMs to provide information electronically to third party providers. While we are proposing to require that OEMs provide full-text access to their information via the Internet for aftermarket service providers and that this is the same information needed by third party information intermediaries, we do not believe that it is a practical option for these third party information providers to download this information directly from the OEM Web sites. There are numerous manufacturers with tens of thousands of pages of service information. For third parties to access service information directly from the each OEM Web site could result in unreasonably long Internet connectivity times for third party service providers. More importantly, we are concerned that third party access directly from the OEM Web sites could impact the overall performance of those sites given the large volumes of information that would be accessed by third party information providers. We believe that this could impede the ability of aftermarket service providers to access the relatively smaller bits of information they need to diagnose and repair vehicles. Finally, manufacturers will already have developed this information in electronic format for uploading onto their individual Web sites and we are not proposing to require manufacturers to develop special formats to meet this proposed requirement. Because of these factors, we believe it does not place undue burden on OEMs to provide the information required by this regulation in electronic formats directly to third party service information providers, rather than utilizing individual OEM Web sites to access the required information. To this end, we propose that OEMs provide information directly to third party information intermediaries with all emission-related information in electronic format in English that utilizes nonproprietary software. In the alternate, OEMs may provide access to third party information intermediaries to a Web site other than the Web site provided for aftermarket service providers to meet this proposed provision if they choose. OEMs are not responsible for the accuracy of the information distributed by third parties. However, it is proposed that where OEMs charge information intermediaries for information, whether through licensing agreements or other arrangements, OEMs be responsible for inaccuracies contained in the information they provide to third party consolidators. We propose that manufacturers begin providing their information electronically directly to third party service providers with whom they license this material beginning with the 2002 model year.

We propose this requirement because, in spite of recent trends of moving toward electronic access to information, we believe that there is likely to be a market for third party service information providers, particularly for aftermarket service providers who service numerous makes, models, and model years. This proposed requirement does not apply to the 1996 through 2001 model years because service information for these model years has already been supplied by manufacturers to third party service providers.

C. What Requirements Are Proposed for the Availability of Training Information?

In our 1995 Final Rule on Service Information, manufacturers were required to make available to the aftermarket ''any and all'' information needed to make use of the OBD system, including any instructions, for emission-related repairs. All training materials (including notices of OEM sponsored classroom training) were also to be made available for purchase from FedWorld at the same time this information was made available to dealerships. OEMs supported a provision that would require them to make available the training material they provided to their dealerships, but indicated they could not offer classroom training to the aftermarket because of limited classroom space and other resource limitations. Likewise, the aftermarket indicated that sending their technicians to offsite training would also be very resource intensive in terms of training cost, loss of technician work time, and potential loss of business. EPA agreed that it would be overly burdensome to require manufacturers to open their classrooms and instead finalized provisions that required the availability of training information through the medium of their choice (e.g. printed manuals, videotapes, CDs, etc.) and made available for purchase from FedWorld.

Since that time, EPA has been in discussions with the aftermarket indicate that complex OBD technology requires an even greater access to OEM-specific training than is available to the aftermarket today. A recent survey conducted by the Service Technicians Society, (EPA Air-2000–49, item II–F–03) indicates that one of the greatest concerns of the aftermarket remains the availability of OEM-specific training and repair information. Aftermarket service providers generally believe that OEM-specific training provides a more comprehensive level of critical information that is necessary to perform some of the most complex emission-related repairs as compared to some of the generic training that is currently available to the aftermarket.

Additionally, we have become aware that several of the larger manufacturers are revising the mechanisms used to deliver training to their franchised dealerships. In particular, some manufacturers are moving toward consolidating their training facilities and beginning to offer training courses to the dealerships via satellite and the World Wide Web. Computer and satellite technologies are also becoming more accessible and affordable for aftermarket service providers and the general public. We believe that these trends, which are likely to continue, provide an opportunity for aftermarket technicians to have access to OEM-specific training that may be delivered via the Internet and satellite without placing burden on OEMs to provide training directly to the aftermarket. In other words, we believe that technology is evolving in such a way that will allow aftermarket shops to receive OEM training directly from Internet sources or via satellite downlinks right on their own personal computers and/or from satellite transmissions.

In today's action, we propose to expand the training information availability requirements to include any training courses offered by OEMs to their franchised dealerships via satellite, Internet, Extranet, or other means that contain, in whole or part, emission-related information. To achieve this, we are proposing two provisions: (1) availability of OEM training material for purchase from OEM Web sites, and (2) availability of OEM Internet and satellite training materials for third party re-packaging and re-distribution.

1. OEM Training Material for Purchase on OEM Web Sites

We are proposing that OEMs make available for purchase on their Web sites the following items: training manuals, training videos, and interactive, multimedia CD's or similar training tools available to franchised dealerships. Additionally, we are proposing that OEMs who transmit emissions-related training via satellite or the Internet must tape these transmissions and make them available for purchase on their Web sites within 30 days after the first transmission to franchised dealerships. It is proposed that all of the items included in this provision be shipped within 24 hours of the order being placed and are to be made available at a reasonable price as described in Section II(F). We also request comment on a provision that would require OEMs to tape the emissions-related class room training provided to dealerships and making those tapes available for sale on OEM Web sites.

We propose that these requirements apply for 1996 and later model year vehicles starting 6 months following the effective date of the Final Rule. For subsequent model years, it is proposed that the required information be made available for purchase within three months of model introduction, and then be made available at the same time it is made available to franchised dealerships.

2. Third Party Access to OEM Training Material

OEMs have expressed that the current state of Internet and satellite technologies and aftermarket demand for direct access via satellite or the Internet do not support a need for providing direct access of these training courses to the aftermarket in these formats. We recognize that there is some uncertainty with the technology as it exists today, but we believe, contrary to arguments made by OEMs, that computer hardware and software technology is evolving in such a way that advanced technologies such as cable modems, digital subscriber lines (DSL) and streaming video will become increasingly prevalent and affordable within the next 2–5 years. Additionally, the equipment needed to access satellite transmissions is also becoming increasingly affordable. We believe it is realistic that access to training for the aftermarket and other information directly on the Internet or via satellite is an attainable goal and will go a long way to meeting some of the concerns of the aftermarket on their ability to acquire training, OEM or otherwise. OEMs have also argued that it is unreasonable that OEMs be burdened with providing training directly to aftermarket service providers. While we recognize that advances in Internet and satellite technology will reduce some of the administrative issues that OEMs would face in delivering training to the aftermarket, it may still be a burden for OEMs themselves to deliver automotive training courses (e.g., Chrysler's OBDII Student Workbook and General Motors' OBDII manuals) to the aftermarket. Therefore, we are also proposing that OEMs make available to entities who develop or deliver training all emissions-related training courses transmitted via satellite or Internet training courses offered to franchised dealerships. This type of training information can then be repackaged and made available for transmission to the aftermarket by third party training providers at a later date or as market forces demand. OEMs may not charge unreasonable up-front fees to third party training providers for this access, but they may require a royalty, percentage or other arranged fee based on a per-use or enrollment/subscription basis.

While we are not requiring third party training entities to deliver training to the aftermarket in any format, there is a large market of third party training providers who currently provide both generic and some OEM-specific training to the automotive aftermarket in a variety of formats including training manuals, CDs and class room training. We are also specifically aware of several training providers who have developed, or in are in the process of developing, Web-based training programs for aftermarket service providers. To this end, we believe that requiring direct access to OEM Internet and satellite transmissions for third party training providers is simply expanding upon the training delivery mechanisms that can be utilized to deliver training to the aftermarket. To the extent that OEMs expand their usage of the Internet and/or satellite technology to deliver OEM-specific training to their franchised dealerships, we believe this proposed provision will increase the availability of OEM-specific training to aftermarket service providers.

EPA proposes that this requirement be effective for 1996 and later model year vehicles starting 6 months following the effective date of the Final Rule.

D. What Requirements Are Proposed for Reprogramming?

Under the existing service information regulations, if their franchised dealerships have the ability to reprogram the electronic control unit (ECU), OEMs are required to provide reprogramming capability to the aftermarket. The existing regulations allow OEMs to meet this requirement by providing information to equipment and tool companies that allows them to incorporate reprogramming into their tools or by making available to the aftermarket the manufacturer-specific reprogramming system or tool that performs reprogramming events. All but one manufacturer has satisfied this requirement through the latter option.

As a result, aftermarket shops that want to provide reprogramming services to their customers and that service multiple makes of vehicles have been faced with costly and time consuming barriers to performing reprogramming services for their customers. Because manufacturers have opted to meet the current requirement by making their OEM-specific reprogramming tools available for sale, an aftermarket service provider who wishes to perform reprogramming events has to purchase a different reprogramming tool or system for each vehicle manufacturer. This has imposed significant costs on aftermarket shops. Several manufacturers incorporate reprogramming capabilities into their manufacturer specific diagnostic scan tool. An aftermarket technician who otherwise uses a generic diagnostic scan tool, which ranges in cost from approximately $300 to $3000, to perform most diagnoses and repair would need to purchase multiple manufacturer-specific diagnostic scan tools or systems, which generally range in cost from $1600 to several thousand dollars each, not including the cost of purchasing the re-calibration or re-programming event itself or the software and software updates needed to use the diagnostic scan tool. For example, an aftermarket shop who wanted to perform reprogramming events just for Ford, GM and Chrysler would have to purchase 3 separate OEM-specific diagnostic tools that would cost a total of approximately $6000 to $10,000. Additionally, EPA is aware of at least three larger manufacturers who intend to move toward reprogrammable OBD computers within the next few model years. This trend underscores the need to work with manufacturers and aftermarket scan tool companies to develop cost effective reprogramming alternatives for aftermarket repair facilities. As a point of comparison, we estimate that diagnostic scan tools capable of reprogramming multiple makes and models will cost approximately $1500 to $2500.

Aftermarket shops who want to perform this advanced diagnostic

service for their customers short of investing in multiple manufacturer-specific diagnostic scan tools must then rely on a dealership to perform this service. This option can impose significant burden on aftermarket service providers and consumers in several ways. First, the service provider must purchase the service from the dealership with dealer mark-up, which could result in potentially higher cost for the consumer who chooses to have service performed by aftermarket shops. Second, having to bring a vehicle in need of a reprogramming event to a dealership can add significant additional time needed to complete an emissions-related repair. There is no guarantee that the dealership will be willing to perform this service for the aftermarket in a timely fashion and we have received complaints from aftermarket service providers indicating that they have had to wait days, or even weeks, to have reprogramming service provided by a dealership. We believe that these factors place the aftermarket in a non-competitive position in the marketplace for performing reprogramming services, which ultimately impacts a consumer's freedom of choice for who services their vehicle.

At the time the 1995 regulations were being developed, OEMs expressed concern that making reprogramming capabilities widely available to the aftermarket would result in a significant increase in tampering or misuse of calibrations and re-calibrations. Though neither EPA nor the OEMs could substantiate how much of a problem this would be, we believed a cautious approach regarding misuse of this new technology was appropriate at that time. We therefore finalized a provision that allowed manufacturers the options described above.

Since that time, neither EPA nor the manufacturers have been made aware of significant instances of the misuse of the information needed to develop aftermarket scan tools with reprogramming capabilities, or misuse of the actual calibrations or re-calibrations themselves. We are also not aware of any confidentiality issues encountered by the one manufacturer who makes their information available to the aftermarket scan tool company that develops their aftermarket reprogramming tool. Further, we are not aware of any confidentiality issues regarding the information that manufacturers do provide to aftermarket scan tool companies to develop generic aftermarket diagnostic tools. We are aware that individual manufacturers currently have confidentiality agreements in place with individual aftermarket scan tool companies to protect any information provided to scan tool companies by OEMs and that information can be labeled as confidential business information by the OEM. Under these confidentiality agreements, OEMs have recourse to revoke or pursue other legal remedies for violations of these agreements. We are not aware of any such instances and believe that requirements proposed today will not impact the ability of OEMs to retain control of any information they label as confidential. Additionally, none of the information required by aftermarket scan tool companies to incorporate reprogramming capabilities into aftermarket scan tools reveals calibration or re-calibration specifications. Finally, technology known as pass-through reprogramming has evolved in such a way that allow for increased protection of calibrations and re-calibrations that the OEMs make available for the completion of reprogramming events. The manufacturer calibration software remains resident and accessible through the manufacturers Web site as opposed to the current CD–ROM distribution to the aftermarket. This allows the OEM more control of distribution and better tracking of distribution. In addition, the pass-through device does not have hardware interface or additional ports for software re-direction similar to an OEM or aftermarket scan tool which are currently used to transfer data between the PC and the vehicle ECU. An aftermarket diagnostic scan tool with pass-through reprogramming capability that can reprogram multiple manufacturers is expected to cost approximately $1500–$2500.

Taking into consideration all of these factors, we believe that it is necessary to propose changes for access to reprogramming capabilities in this proposed rulemaking. In order to make reprogramming capabilities available to the aftermarket for the broadest range of model years possible, we are proposing a two-tiered approach. First, for MY1994 through MY2002 OBD equipped vehicles with reprogramming capability, we are proposing that manufacturers make available all emissions-related reprogramming information to aftermarket tool and equipment companies in a similar manner to the information that manufacturers currently make available for enhanced diagnostics. This would include the following information necessary for programming the Electronic Control Unit (ECU):

(a) the physical hardware requirements including communication network specifications for reprogramming events or tools (e.g., system voltage requirements, cable terminals/pins, connections such as RS232 or USB, wires, etc.),

(b) ECU data communication including message format and data encoding (e.g., serial data protocols, transmission speed or baud rate, bit timing requirements, etc.),

(c) information on the application physical interface (API) or layers (descriptions for procedures such as connection, initialization, performing and verifying programming/download, and termination),

(d) vehicle application information or any other related service information (which interfaces or combination of interfaces are used on each vehicle system for each make/model year) such as special pins and voltages for reprogramming events or additional vehicle connectors that require enablement and specifications for the enablement. This is not a new information requirement for the vehicle manufacturers. This is the same information that is currently used to produce the same diagnostic functionality in dealership scan tool equipment. See EPA Air Docket #A–2000–49, item II–F–06 for complete New Product Information Guidelines (NPIG) developed by the Equipment and Tool Institute.

We believe that the information being proposed does not require manufacturers to make any hardware or software changes. Rather, manufacturers must only make the information available to aftermarket tool and equipment companies. We are proposing that this information be made available within 6 months of publication of the Final Rule. After that, this information shall be released when it is first provided to franchised dealerships.

Second, for MY2003 and later OBD equipped vehicles with reprogramming capabilities, we are proposing that manufacturers comply with SAE Standardized Practice J2534 for ''pass-through reprogramming.'' Pass-through reprogramming is a process that allows the programming or reprogramming of a vehicle's computer without revealing proprietary information to the end user. EPA has seen multiple demonstrations of this technology and is aware that several large manufacturers use this process for dealership reprogramming. In light of the success of pass-through reprogramming and the cost burden associated with the purchase of multiple tools under the existing regulations, we

believe that the aftermarket should not be required to use OEM-specific tools for emission-related reprogramming. Additionally, SAE J2534 was developed with extensive cooperation between the OEMs and aftermarket tool and equipment companies. We believe that this standardized practice addresses a vast majority of the technological issues raised by both parties and will ultimately provide a cost-effective means for aftermarket reprogramming while still protecting the proprietary information of the OEMs. This SAE Standard Practice is proposed to be Incorporated by Reference in Section II(G). SAE J2534 is currently undergoing final review and approval. A draft of J2534 is available for inspection in EPA Air Docket A–2000–49. While it has not been finalized in time for this proposal, we believe it will finalized in time for the final rule. Upon final approval of this standard, EPA will issue a notice of document availability at which time the finalized version will be placed in EPA Air Docket A–2000–49 for inspection. The final version of J2534 will also be available directly from the Society of Automotive Engineers (SAE).

We are aware that some manufacturers use manufacturer specific diagnostic link connectors for reprogramming that are placed in locations other than those which are currently required by SAE Standard Practice J1962. To standardize reprogramming capability for the aftermarket, we also propose that manufacturers must comply with SAE Standard Practice J1962, ''Diagnostic Link Connector'' for the purposes of pass-through reprogramming, beginning with the 2003 model year. J1962 has already been approved for Incorporation by Reference in EPA's On-Board Diagnostic regulations (58 FR 9468). EPA requests comment on the lead-time necessary for manufacturers to comply with this proposed requirement.

We also propose that manufacturers make available the necessary OEM software applications needed to initiate pass-through reprogramming events to the aftermarket at a reasonable cost. Initiation software can be described as the transport method used to transmit the OEM calibrations from storage to the pass-through device. In other words, the initiation software serves as a mechanism to transmit calibrations from where they are stored (Internet, BBS, or CD–ROM) to the ECU.

Manufacturers must also make available the necessary calibrations or reprogramming events via CD–ROM, diskette, or the Internet. We also propose that this be stand-alone software that can be run on a standard PC and must use a WIN–32 operating system. In other words, EPA expects that manufacturers will not simply bundle the pass-through reprogramming software with other OEM software, re-package this OEM-specific software as an aftermarket version and charge a price that is not reasonable for the aftermarket.

Finally, we propose that manufacturers continue to make reprogramming services available to aftermarket service providers in a timely manner and a reasonable cost via their dealerships. We propose this provision to ensure wide-spread availability of reprogramming capability for aftermarket service providers.

E. What Requirements Are Proposed for the Availability of Enhanced Information for Scan Tools and OEM-Specific Diagnostic Scan Tools?

The service information regulation published August 9, 1995 (60 FR 40474) required OEMs to make certain generic service information available to tool manufacturers. Enhanced service information was also required to be made available. However, OEMs had the option of either making their OEM enhanced diagnostic tools available for sale to independent technicians at a reasonable cost or making available to aftermarket tool and equipment companies the information needed to develop and manufacture enhanced aftermarket diagnostic tools. This requirement did not achieve the CAA directive to make available all information needed to make use of the emission control diagnostic system to any person engaged in repairing or servicing of motor vehicles or motor vehicle engines for several reasons.

First, because many manufacturers opted not to provide enhanced information to the equipment and tool companies, the aftermarket tools that are manufactured and sold often do not provide the comprehensive information needed by aftermarket technicians to perform more advanced emissions-related repairs. We believe that aftermarket shops who service numerous makes and models are placed at a competitive disadvantage regarding the level of service they can provide for their customers. Second, aftermarket service providers who wish to perform more advanced diagnoses and repairs must purchase an enhanced diagnostic tool for the majority of OEMs in order to be able to perform advanced OBD diagnoses. OEM-specific diagnostic scan tools range in cost from $1600 to approximately $5000. We are also aware of at least one OEM who makes their OEM-specific diagnostic tool available for sale for approximately $20,000. With the average cost of approximately $3000, aftermarket shops who want to be reasonably equipped to provide advanced diagnostic and repair services for the 6 or 7 largest manufacturers would have to invest tens of thousands of dollars in diagnostic equipment on top of the several thousands of dollars per year that aftermarket shops must invest each year for service information. On the other hand, OEM dealerships generally serve just one manufacturer and can make relatively smaller investments in tools and equipment. We believe that this is cost prohibitive and creates a substantial competitive disadvantage for independent shops who generally run much smaller businesses than OEM dealerships. We also believe that the large investments that need to be made in OEM-specific tools prevents independent shops from performing services that dealers are able to perform, placing them at a competitive disadvantage in the level of services they can provide, ultimately making it difficult for some aftermarket service providers to even stay in business.

Ultimately, we believe that the option most manufacturers have chosen under the existing requirements results in customers being denied freedom to choose where to have their vehicles serviced. To eliminate these inequities and to ensure that all aftermarket service providers have access to the diagnostic tools essential for the diagnosis and repair of OBD systems, we propose two requirements. First, we propose that manufacturers provide generic and enhanced information as described below to aftermarket tool and equipment companies to develop aftermarket diagnostic scan tools. Second, we propose that OEMs make available for sale their manufacturer-specific diagnostic scan tools at a fair and reasonable price.

(1) Description of Enhanced Diagnostic Information. We propose to require an increased level of enhanced information to be made available to aftermarket tool and equipment companies to develop more functional aftermarket diagnostic scan tools.

We propose that within 30 days of publication of the final rule OEMs make available to companies who develop aftermarket scan tools all generic and enhanced service information for MY 1996 and later needed to manufacture diagnostic tools that can be used by aftermarket technicians to diagnose, service and repair emission-related components and systems. Enhanced information is defined as information that is necessary to implement an on-

board diagnostic service interface. In general it encompasses information that describes each of the various diagnostic communication interfaces (communication protocol, message, timing and any information which identifies which interface is applicable to each particular my/model/engine combination). This information must cover both generic and enhanced information. Enhanced information includes, but is not limited to:

(a) All serial data stream information

(b) Bi-directional controls (e.g., operation of actuators, initiation of self-checks, etc.) Including any safety precautions necessary prior to invoking the controls.

(c) descriptions of non-proprietary logic and performance limits and specifications used in the OEM specific tools to perform diagnostic routines or sub-routines (E.g., injector or cylinder balance tests, etc.)

(d) the physical hardware requirements for reprogramming events or tools (e.g. system voltage requirements, cable terminals/pins, connections such as RS232 or USB, wires, etc.);

(e) Electronic Control Unit (ECU) data communication (e.g. serial data protocols, transmission speed or baud rate, bit timing requirements, etc);

(f) information on the application physical interface (API) or layers (i.e., processing algorithms or software design descriptions for procedures such as connection, initialization, performing and verifying programming/download, and termination);

(g) vehicle application information or any other related service information such as special pins and voltages for reprogramming events or additional vehicle connectors that require enablement and specifications for the enablement;

In addition, we propose that manufacturers provide information that describes which interfaces or combination of interfaces, from each of the categories in the sections above are used on each vehicle. This may be organized by application, system or a combination of both provided the information identifies which interfaces are used on each vehicle's system/model/model year. Manufacturers may use the New Product Information Guideline (NPIG) created by the Equipment and Tool Institute (ETI) to meet this requirement or provide a substitute matrix approved by the Administrator. The NPIG is a standard format already used by a majority of manufacturers when submitting information to ETI. An example of the NPIG is available in EPA Air Docket A–2000–49, item II–F–06. OEMs are not required to release the underlying computer codes that make up calibrations and recalibrations.

(2) Distribution of Enhanced Diagnostic Information. Currently, all but one of the manufacturers who make available scan tool information use the Equipment and Tool Institute (ETI) as the primary distribution mechanism for scan tool information. In particular, ETI maintains the ''TEK-NET Library'', which is administered through a secure Web site that ETI has developed to gather and re-distribute diagnostic scan tool information to its member companies as agreed through licensing and other contractual arrangements. This arrangement has been developed independently between the OEMs, ETI, and ETI member companies (e.g. Snap-On, SPX, etc) and has been in use for several years. However, since the 1995 regulations were finalized, we have become aware of several instances where manufacturers have submitted the information required by the regulations to ETI and/or their member companies in either unmanageable formats (e.g. reams of paper) or in languages other than English. These inconsistencies can affect the ability of aftermarket scan tool companies to provide timely updates and/or introduce new products to aftermarket service providers. Because aftermarket service providers rely heavily on the diagnostic scan tools they purchase from ETI member companies to diagnose and repair emissions-related problems, we believe it is imperative that the required information be provided to ETI and/or their member companies in a timely and manageable manner. Therefore, we propose that the required information be provided to aftermarket tool and equipment companies in English via the Internet to a secure Web site as arranged through necessary licensing, contractual, and confidentiality agreements between the OEMs, ETI, and/or their member companies. We propose that this information be uploaded in electronic format using common document formats such as MicroSoft Excel, Adobe Acrobat, MicroSoft Word, etc as preferred by the manufacturer. At this time, we believe that ETI's TEK–NET library meets the intent of this proposed requirement and we encourage manufacturers to continue the on-going, cooperative relationship. We also propose that the Administrator have free unrestricted access to this Web site in order to assist EPA in the verification that all required information is being made available as required by these regulations.

Finally, ETI must provide information to aftermarket scan tool companies who are not members of ETI involved in the manufacture and sale of scan tool type devices for use on vehicles sold in the United States if the non-members have arranged for the appropriate licensing, contractual and confidentiality agreements with the OEMs and ETI.

(3) Availability of Manufacturer-Specific Diagnostic Scan Tools.

The current regulations give manufacturers the option of either making information available to aftermarket diagnostic tool companies so that they can develop generic aftermarket diagnostic scan tools or making available for sale their OEM-specific diagnostic scan tools. As discussed above, a majority of manufacturers already make their OEM-specific tools available for sale rather than making available information available for the development of generic aftermarket tools. While we are proposing to require that all OEMs provide an increased level of information for the development of more sophisticated generic aftermarket scan tools, we believe there will continue to be a demand for OEM-specific tools as well. For example, we are aware that many aftermarket shops specialize in European or Asian models or exclusively in one manufacturer such as BMW or Mercedes-Benz. These aftermarket shops are likely to make the investment in manufacturer-specific diagnostic tools even though they are priced higher than generic diagnostic tools in order to provide more specialized services for their customers. In order to ensure that OEM-specific tools continue to be available to aftermarket service providers, we propose that vehicle manufacturers make available for sale their own manufacturer-specific diagnostic tools. OEMs may elect to develop different versions of one or more of their diagnostic tools, but emission-related service information must be made available to the aftermarket. In addition to making their diagnostic tools available for sale, OEMs must provide support for those tools or have a third party do so. If a third party does so, the OEM is responsible for availability and accuracy. We propose that OEMs make their OEM-specific tools available for sale to the aftermarket at a reasonable cost. With a few exceptions, we believe that most manufacturers who currently make their OEM-specific tools available meet the intent of reasonable cost. We expect that the cost of OEM-specific

tools should not change significantly as a result of this proposed provision.

(4) Decontenting of OEM-specific Tools. Some OEM-specific diagnostic tools contain information that is not emission-related. If OEMs decide to delete the non-emission related information (''decontent'') from the tool before offering it for sale to the aftermarket, we expect that the cost of the tool will be adjusted to reflect its decreased value. It is proposed that the emission-related information in the tool be identical to that contained in the tool offered to the dealers. In such cases, it is proposed that OEMs obtain approval from the Administrator following demonstration that the emission-related functions of the dealer tool and the decontented tool are the same.

(5) Availability of Special Tools. Some manufacturers currently require the use of a special tool to extinguish the MIL. It is our understanding that these tools are not always available to the aftermarket. To address this issue, EPA is proposing that OEMs be precluded from using such systems beginning with model year 2002. For model years 1994–2001, today's rulemaking proposes that OEMs who require such tools to extinguish the MIL make the necessary information available to equipment and tool companies to design a comparable generic tool. It is proposed that this information be made available no later than 3 months following the effective date of the Final Rule.

F. What Are the Cost Provisions Proposed for Service Information?

As discussed in the 1995 Service Information regulations, we believe that cost is an integral factor influencing the availability of service information. At that time, we were concerned that manufacturers could have priced their service information and OEM-specific diagnostic scan tools in such a way that would preclude their purchase and subsequent use, therefore rendering the information and/or tools unavailable. While we believe that a majority of manufacturers have made a good faith attempt to meet the ''reasonable cost'' provisions finalized in 1995, we believe it is necessary to revisit the issue of cost of service information and diagnostic scan tools and the Agency's position on this issue. Additionally, full-text access to information via the Internet introduces additional parameters that must be evaluated in order to ensure that the information required by these regulations can be considered available. As a result, we are proposing revisions to the regulations governing ''reasonable cost'' to reflect the proposed move from FedWorld to the World Wide Web.

The 1995 regulations establish parameters for OEMs on what factors should be considered by manufacturers when developing the pricing structures for the required information. We also received substantive comments from OEMs and aftermarket service providers on what those factors should be and incorporated many of them into the 1995 final rule. As a result, we required manufacturers to make emission-related service information available at a reasonable cost. Reasonable cost was described as a fair and reasonable price taking into consideration factors such as the cost to the manufacturer of preparing and/or providing the information, the type of information, the format in which it is provided, the price charged by other manufacturers for similar information, the differences that exist among manufacturers (e.g. the size of the manufacturer), the quantity of material contained in a publication, the detail of the information, the cost of the information prior to finalization of the 1995 rule, volume discounts and inflation. One of the factors that was finalized as a reference point for evaluating the cost of service information allows OEMs to recover the costs incurred for preparing and/or providing the information. Since manufacturers will be moving to the World Wide Web as a primary means of distribution for their information, we propose that one of the factors to be considered in determining whether the price charged for the access to the information on the World Wide Web is reasonable is the cost incurred by OEMs for developing their Web sites. Section II(6)(a) also discusses some of the feedback we have received from the aftermarket on what some aftermarket service providers consider as reasonable costs for access to information on OEM Web sites. We solicit comment on the general pricing structure as it is discussed in this section.

While we have discussed some specific aspects of the cost of service information for Web access to the required information, we expect that all of the information and diagnostic scan tools covered by this proposal to be made available at a reasonable cost in such a manner that ensures its availability. Manufacturers who develop pricing structures for the required information in a manner that renders it unavailable to the aftermarket will be considered in violation of the regulations and subject to fines of $25,000 per day per violation.

G. Which Reference Materials Are Proposed for Incorporation by Reference?

Also being proposed is the adoption of SAE Recommended Practice J1930, ''Electrical/Electronic Systems Diagnostic Terms, Definitions, Abbreviations, and Acronyms.'' This standardized procedure was proposed in the September 1991 (56 FR 48272) proposal, but was not finalized due to a variety of issues on the standardization of the electronic format of service information. It is proposed that manufacturers comply with J1930 beginning with the 2003 model year. EPA believes that most manufacturers have already adopted J1930 in the development of their service information. However, the Agency believes that it is important for all manufacturers to adopt J1930 definitions and terminology given the increasing complexity and volume of service information. Therefore, the Agency is proposing to require that all manufacturers comply with J1930 beginning with the 2003 model year.

Today's action also proposes the incorporation of SAE Recommended Practice J2284, ''High Speed CAN (HSC) for Vehicle Applications at 500 KBPS.'' This recommended practice was finalized in February of 1999 and defines a level of standardization in the implementation of a 500 KBPS vehicle communication network using the Controller Area Network (CAN) protocol. It is proposed that manufacturers comply with J2284 beginning with the 2003 model year. EPA also believes that most manufacturers are moving toward the adoption of J2284 with model year 2003 and that there will be little objection from the manufacturers on this requirement.

As discussed above in section II(D), we are also proposing to Incorporate by Reference SAE Recommended Practice J2534 and SAE Recommended Practice J1962. All of these items with the exception of J2534 are available for inspection in EPA Air Docket A–2000–49. SAE J2534 will be made available for inspection in the docket once it has been finalized. A draft of SAE J2534 has been placed in EPA Air Docket A–2000–49 for inspection. All SAE recommended practices can be obtained from the Society of Automotive Engineers, Inc., 400 Commonwealth Drive, Warrendale, PA 15096–0001, or at www.sae.org.

H. What Are the Proposed Requirements for Heavy-duty Service Information?

Section 202(m)(5) of the Clean Air Act applies service information availability requirements to all motor vehicles equipped with emission-control diagnostic systems, including heavy-duty vehicles and engines. We are proposing that all of the requirements proposed today apply to manufacturers of all heavy-duty vehicles and engines weighing 14,000 pounds gross vehicle weight (GVW) and lower beginning in model year 2005, which is the first year that such engines and vehicles are subject to OBD requirements. Today's proposal applies only to engines and vehicles subject to the OBD requirements during the phase-in of those requirements. EPA is proposing the same requirements for these engines and vehicles as it is proposing for light-duty vehicles and trucks. However, we recognize that certain aspects of these proposed regulations may need to be reviewed to ensure that they accurately reflect how the aftermarket service industry can be best assured of receiving the information necessary to make use of the OBD system and to make emissions-related diagnosis and repairs. We request comment on the appropriateness of the proposed requirements for this sector.

I. Are Formats for Service Information Proposed?

The Agency is not proposing any requirements that specify the format that manufacturers must use to organize or display the required information on their Web sites. In particular, we are not requiring manufacturers to comply with SAE Standardized Practice J2008 ''Recommended Organization of Service Information''. In the August 1995 final rule, the Agency could not finalize the incorporation of J2008 because the standard had not yet been finalized. At that time, the Agency was optimistic that J2008 would be finalized in time to allow manufacturers to adopt it voluntarily or give EPA the option of incorporating it into the service information requirements. However, J2008 was not finalized until October of 1998. By that time, several large OEMs were well into the development of their Web sites and some manufacturers were already conducting pilots within their dealerships. While the Agency is supportive of providing information in formats that are user-friendly and readily accessible to the end-user, we are reluctant to implement requirements that would require manufacturers to redesign existing service information that has already been developed. The Agency has put forth minimum performance requirements that we believe will allow us to monitor manufacturer Web site performance while allowing manufacturers maximum flexibility and creativity in the development of their service information for access on the Internet. Finally, we believe that the learning curve for aftermarket service industry will level off relatively quickly given the ever increasing dependence on computers and the Internet to conduct business. EPA requests comment on the need for J2008 or another format for service information.

III. What Is the Cost of This Proposal?

This proposed rulemaking alters existing provisions by revising the current service information regulations. The provisions proposed in today's rulemaking require OEMs to make available information and tools that have already been developed for use by their dealerships. Therefore, EPA believes that the changes proposed today put little or no new additional requirements on OEMs beyond administrative costs for providing access to existing information and tools, which are recoverable to the OEM as discussed above in IIF.

IV. What Are the Opportunities for Public Participation?

A. Comments and the Public Docket

EPA welcomes comments on all aspects of this proposed rulemaking. Commenters are especially encouraged to give suggestions for changing any aspects of the proposal. All comments, with the exception of proprietary information should be addressed to the EPA Air Docket Section, Docket No. A–2000–49 (see **ADDRESSES**).

Commenters who wish to submit proprietary information for consideration should clearly separate such information from other comments by 1) labeling proprietary information ''Confidential Business Information'' and 2) sending proprietary information directly to the contact person listed (see **FURTHER INFORMATION CONTACT**) and not to the public docket. This will help insure that proprietary information is not inadvertently placed in the docket. If a commenter wants EPA to use a submission labeled as confidential business information as part of the basis for the final rule, then a nonconfidential version of the document, which summarizes the key data or information, should be sent to the docket.

Information covered by a claim of confidentiality will be disclosed by EPA only to the extent allowed and by the procedures set forth in 40 CFR Part 2. If no claim of confidentiality accompanies the submission when EPA receives it, the submission may be made available to the public without notifying the commenters.

B. Public Hearing

Anyone wishing to present testimony about this proposal at the public hearing (see **DATES**) should, if possible, notify the contact person (see **FOR FURTHER INFORMATION CONTACT**) at least seven days prior to the day of the hearing. The contact person should be given an estimate of the time required for the presentation of testimony and notification of any need for audio/visual equipment. Testimony will be scheduled on a first come, first serve basis. A sign-up sheet will be available at the registration table the morning of the hearing for scheduling those who have not notified the contact earlier. This testimony will be scheduled on a first come, first serve basis to follow the previously scheduled testimony.

EPA requests that approximately 50 copies of the statement or material to be presented be brought to the hearing for distribution to the audience. In addition, EPA would find it helpful to receive an advanced copy of any statement or material to be presented at the hearing at least one week before the scheduled hearing date. This is to give EPA staff adequate time to review such material before the hearing. Such advanced copies should be submitted to the contact person listed.

The official records of the hearing will be kept open for 30 days following the hearing to allow submission of rebuttal and supplementary testimony. All such submittals should be directed to the Air Docket Section, Docket No. A–2000–49 (see **ADDRESSES**). The hearing will be conducted informally, and technical rules of evidence will not apply. A written transcript of the hearing will be placed in the above docket for review. Anyone desiring to purchase a copy of the transcript should make individual arrangements with the court reporter recording the proceedings.

V. What Are the Administrative Requirements for This Proposal?

A. Administrative Designation and Regulatory Analysis

Under Executive Order 12866 (58 FR 51735 October 4, 1993), EPA must determine whether the regulatory action is ''significant'' and therefore subject to Office of Management and Budget (OMB) review and the requirements of this Executive Order. The Order defines

a ''significant regulatory action'' as one that is likely to result in a rule that may:

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

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

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

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

EPA has determined that this rule is not a ''significant regulatory action'' under the terms of Executive Order 12866 and is therefore not subject to OMB review.

B. Impact on Small Entities

The Regulatory Flexibility Act, 5 U.S.C. 601–612, generally requires federal agencies 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 businesses, small not-for-profit enterprises, and small governmental jurisdictions. This proposed rule would not have a significant impact on a substantial number of small entities because the regulated entities impacted by this rulemaking would not be considered small entities.

Therefore, I certify that this action will not have a significant economic impact on a substantial number of small entities.

C. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* An Information Collection Request (ICR) document has been prepared by EPA (ICR No. 0783.41) and a copy may be obtained from Sandy Farmer by mail at Collection Strategies Division; U.S. Environmental Protection Agency (2822); 1200 Pennsylvania Ave., NW., Washington, DC 20460, by email at farmer.sandy@epamail.epa.gov, or by calling (202) 260–2740. A copy may also be downloaded off the internet at *http://www.epa.gov/icr.*

EPA is proposing that manufacturers subject to the proposed requirements for Web based delivery of service information be required to submit to the Administrator on an annual basis an electronic report that contains measurements of the various performance parameters as outlined in Section II(A)(6) of this preamble. The information proposed to be collected will allow the Agency to assess compliance with the regulations.

It is estimated that the cost of collecting this information will be $250 per month, or $3000 per year for each of the approximately 45 manufacturers subject to this proposed information collection requirements. Initial start-up costs are expected to be approximately $1000 with approximately $100–$200 per year for maintenance. The 400 burden hours are estimated to cost $11,628.

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

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

Comments are requested on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques. Send comments on the ICR to the Director, Collection Strategies Division; U.S. Environmental Protection Agency (2822); 1200 Pennsylvania Ave., NW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th St., NW., Washington, DC 20503, marked ''Attention: Desk Officer for EPA.'' Include the ICR number in any correspondence. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after June 8, 2001, a comment to OMB is best assured of having its full effect if OMB receives it by July 9, 2001. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

D. 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 action on state, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. Before promulgation an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted.

Before we establish any regulatory requirement that may significantly or uniquely affect small governments, including tribal governments, we must develop, 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 our regulatory proposals with significant federal intergovernmental mandates. The plan must also provide for informing, educating, and advising small governments on compliance with the regulatory requirements.

EPA believes this proposed rule contains no federal mandates for state, local, or tribal governments. Nor does this rule have federal mandates that may result in the expenditures of $100 million or more in any year by the private sector as defined by the provisions of Title II of the UMRA. Nothing in the proposed rule would

significantly or uniquely affect small governments.

E. 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.''

This proposed rule will impose no direct compliance costs on states. Thus, Executive Order 13132 does not apply to this rule.

In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed rule from State and local officials.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 6, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.''

This proposed rule does not have tribal implications. It will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. The requirements proposed by this action impact private sector businesses, particularly the automotive and engine manufacturing industries. Thus, Executive Order 13175 does not apply to this rule.

G. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, 12(d) (15 U.S.C. 272), directs the EPA to use voluntary consensus standards (VCS) 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 requires EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This proposed rule incorporates by reference technical standards adopted by the Society of Automotive Engineers (SAE). We believe these standards are well accepted by industry.

EPA welcomes comments on this aspect of the proposed rulemaking and, specifically, invites the public to identify potentially applicable voluntary consensus standards and to explain why such standards should be used in this regulation.

H. Executive Order 13045: Children's Health Protection

Executive Order 13045: ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997) applies to any rule that: (1) is determined to be economically significant as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

EPA believes this proposed rule is not subject to the Executive Order because it is not an economically significant regulatory action as defined by Executive Order 12866.

List of Subjects in 40 CFR Part 86

Environmental protection, Administrative practice and procedure, Air pollution control, Gasoline, Incorporation by reference, Motor vehicles, Motor vehicle pollution, Reporting and recordkeeping requirements.

Dated: May 30, 2001.

Christine Todd Whitman,

Administrator.

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

PART 86—CONTROL OF AIR POLLUTION FROM NEW AND IN-USE MOTOR VEHICLES AND NEW AND IN-USE MOTOR VEHICLE ENGINES: CERTIFICATION AND TEST PROCEDURES

1. The authority citation for part 86 continues to read as follows.

Authority: 42 U.S.C. 7401–7671q.

2. Section 86.094–38 is proposed to be amended by adding paragraph (g)(21) to read as follows:

§ 86.094–38 Maintenance instructions.

* * * * *

(g) * * *

(21) In lieu of meeting the requirements of paragraphs (g)(5) through (g)(9) of this section, manufacturers may upload the required information in full text on its manufacturer-specific Web site as required in § 86.096–38(g)(3). In the alternative, manufacturers may upload an index of the required information on its Web site consistent with paragraphs (g)(5), (g)(6), and (g)(9) of this section.

3. Section 86.096–38 is proposed to be added to subpart A to read as follows:

§ 86.096–38 Maintenance instructions.

(a)–(f) [Reserved]

(g) Emission control diagnostic service information.

(1) Manufacturers are subject to the provisions of this paragraph (g) beginning in the 1996 model year for manufacturers of light-duty vehicles and light-duty trucks, and beginning in the 2005 model year for manufacturers of heavy-duty vehicles and heavy-duty engines weighing 14,000 pounds gross vehicle weight (GVW) and less that are subject to the OBD requirements of this part.

(2) *General requirements.* (i) Manufacturers shall furnish or cause to be furnished to any person engaged in the repairing or servicing of motor vehicles or motor vehicle engines, or the Administrator upon request, any and all information needed to make use of the on-board diagnostic system and such other information, including instructions for making emission-related diagnosis and repairs, including but not limited to service manuals, technical service bulletins, recall service information, data stream information, bi-directional control information, and

training information, unless such information is protected by section 208(c) as a trade secret. No such information may be withheld under section 208(c) of the Act if that information is provided (directly or indirectly) by the manufacturer to franchised dealers or other persons engaged in the repair, diagnosing, or servicing of motor vehicles or motor vehicle engines.

(ii) *Definitions.* The following definitions apply for this paragraph (g).

(A) Aftermarket service provider means any individual or business engaged in the diagnosis, service, and repair of a motor vehicle or engine who is not directly affiliated with a manufacturer or manufacturer franchised dealership.

(B) Bi-directional control means the capability of a diagnostic tool to send messages on the data bus that temporarily overrides the module's control over a sensor or actuator and gives control to the diagnostic tool operator. Bi-directional controls do not create permanent changes to engine or component calibrations.

(C) Data stream information means information (i.e., messages and parameters) originated within the vehicle by a module or intelligent sensors (i.e., a sensor that contains and is controlled by its own module) and transmitted between a network of modules and/or intelligent sensors connected in parallel with either one or two communication wires. The information is broadcast over the communication wires for use by other modules (e.g., chassis, transmission, etc.) to conduct normal vehicle operation or for use by diagnostic tools. Data stream information does not include engine calibration related information.

(D) Emissions-related information means any information related to the diagnosis, service, and repair of emissions-related components.

(E) Emissions-related training information means any information related training or instruction for the purpose of the diagnosis, service, and repair of emissions-related components. Emissions-related information includes, but is not limited to:

(*1*) Manuals, including subsystem and component manuals, technical service bulletins (TSBs), recall service information, diagrams, charts, and training materials;

(*2*) OBD system operational information that describes functional characteristics of the OBD system and emission-related components. OBD system operational information includes, but is not limited to, OBD generic drive cycle information, component operating ranges, and system logic flow diagrams. Algorithms, look-up tables, or any values associated with look-up tables are not required to be made available;

(*3*) Emission-related diagnostic procedures. Manufacturers who utilize their manufacturer-specific scan tool to provide emissions-related diagnostic procedures cannot require connection to the vehicle to access this information. Additionally, manufacturers shall also make any emissions-related diagnostic procedures incorporated into their manufacturer-specific scan tools available to aftermarket service providers on their respective manufacturer Web sites;

(*4*) Any information on other systems that can directly effect the emission system within a multiplexed system (including how information is sent between emission-related system modules and other modules on a multiplexed bus);

(*5*) Any information regarding any system, component, or part of a vehicle monitored by the OBD system that could in a failure mode cause the OBD system to illuminate the malfunction indicator light (MIL);

(*6*) Information needed to start the vehicle when the vehicle is equipped with an anti-theft system or other systems that disables the engine and prevents it from starting after the completion of an emissions-related repair; and

(*7*) Manufacturer-specific emissions-related diagnostic trouble codes (DTCs) and any related service bulletins, trouble shooting guides, and/or repair procedures associated with these manufacturer-specific DTCs.

(F) Enhanced service and repair information means information which is specific for an original equipment manufacturer's brand of tools and equipment.

(G) Generic service and repair information means information which is not specific for an original equipment manufacturer's brand of tools and equipment.

(H) Indirect information means any information that is not specifically contained in the service literature, but is contained in items such as tools or equipment provided to franchised dealers (or others).

(I) Intermediary means any individual or entity, other than an original equipment manufacturer, which provides service or equipment to aftermarket service providers.

(J) Manufacturer franchised dealership means any service provider with which an manufacturer has a direct business relationship.

(K) Third party information provider means any individual or entity, other than an original equipment manufacturer, who consolidates manufacturer service information and makes this information available to aftermarket service providers.

(L) Third party training provider means any individual or entity, other than an original equipment manufacturer who develops and/or delivers instructional and educational material for automotive training courses.

(3) *Information dissemination.* By [date six months after the effective date of the final rule], each manufacturer shall provide or cause to be provided a manufacturer-specific World Wide Web site available to the persons specified in paragraph (g)(2)(i) of this section and to any other interested parties containing in the information specified in paragraph (g)(2)(i) of this section for 1996 and later model year vehicles which have been offered for sale; this requirement does not apply to indirect information, including the information specified in paragraphs (g)(11) through (g)(15) of this section. Each manufacturer Web site shall:

(i) Provide access in full-text to all of the information specified in paragraph (g)(5) of this section.

(ii) Be updated at the same time as dealership World Wide Web sites, but in no instance less than 14 days after new information or changes to existing information have been changed or updated on the manufacturer's dealership site.

(iii) Provide users with a description of the minimum computer hardware and software needed by the user to access that manufacturer's information (e.g., computer processor speed and operating system software). This description shall appear when users first log-on to the home page of the manufacturer's Web site.

(iv) Provide Short-Term (≤24 hours), Mid-Term (30 day period), and Long-Term (365 day period) Web site subscription options to any person specified in paragraph (g)(1) of this section at a fair and reasonable cost as specified in paragraph (g)(6) of this section for each of the options. Reasonable cost shall not exceed $20 for short-term access, $300 for mid-term access, and $2500 for long-term access in year 2001 dollars.

(v) Allow the user to search the manufacturer Web site by various topics including but not limited to model, model year, key words or phrases, vehicle identification number (VIN),

etc., while allowing ready identification of the latest vehicle calibration.

(vi) Provide accessibility using common, readily available software and shall not require the use of proprietary software, hardware, viewers, or browsers. manufacturers shall also provide hyperlinks to any plug-ins, viewers or browsers (e.g. Adobe Acrobat or Netscape) needed to access the manufacturer Web site.

(vii) Allow simple hyper-linking to the manufacturer Web site from Government Web sites and automotive-related Web sites.

(viii) Allow access to the manufacturer Web sites with no limits on the modem speed by which aftermarket service providers or other interested parties can connect to the manufacturer Web site.

(4) *Small volume provisions for information dissemination.* (i) Manufacturers with annual sales of less than 5,000 vehicles shall have until [12 months after the effective date of the final rule] to launch their individual Web sites as required by paragraph (g)(2) of this section.

(ii) Manufacturers with annual sales of less than 1,000 vehicles may, in lieu of meeting the requirement of paragraph (g)(3) of this section, request the Administrator to approve an alternative method by which the required emissions-related information can be obtained by the persons specified in paragraph (g)(1) of this section.

(5) *Required information.* All information relevant to the diagnosis and completion of emissions-related repairs shall be posted on manufacturer Web sites excluding indirect information specified in paragraphs (g)(11) through (g)(15) of this section. The required information includes, but is not limited to:

(i) Manuals, including subsystem and component manuals, technical service bulletins (TSBs), recall service information, diagrams, charts, and training materials;

(ii) OBD system operational information that describes functional characteristics of the OBD system and emission-related components; OBD system operational information includes, but is not limited to, OBD generic drive cycle information, component operating ranges, and system logic flow diagrams. Algorithms, look-up tables, or any values associated with look-up tables are not required to be made available;

(iii) Emission-related diagnostic procedures; manufacturers who utilize their manufacturer-specific scan tool to provide emissions-related diagnostic procedures cannot require connection to the vehicle to access this information and shall make such information available to aftermarket service providers on their respective manufacturer Web sites;

(iv) Any information on other systems that can directly effect the emission system within a multiplexed system (including how information is sent between emission-related system modules and other modules on a multiplexed bus);

(v) Any information regarding any system, component, or part of a vehicle monitored by the OBD system that could in a failure mode cause the OBD system to illuminate the malfunction indicator light (MIL); and

(vi) Information needed to start the vehicle when the vehicle is equipped with an anti-theft system or other systems that disables the engine and prevents it from starting after the completion of an emissions-related repair.

(6) *Cost of required information.* All information required to be made available by this section shall be made available at a fair and reasonable price to any person engaged in the repairing or servicing of motor vehicles or motor vehicle engines. In determining whether a price is fair and reasonable, consideration may be given to relevant factors, including, but not limited to, the cost to the manufacturer of preparing and/or providing the information, the type of information, the format in which it is provided, the price charged by other manufacturers for similar information, the differences that exist among manufacturers (e.g., the size of the manufacturer), the quantity of material contained in a publication, the level of detail of the information, the cost of the information prior to [effective date of this paragraph], volume discounts, and inflation.

(7) *Unavailable information.* Any information which is not provided at a fair and reasonable price shall be considered unavailable, in violation of this paragraph (g) and section 202(m)(5) of the Clean Air Act.

(8) *Third party information providers.* By [date 6 months after publication of the final rule], manufacturers shall, for model year 2002 and later vehicles and engines, provide the required emissions-related information as specified in paragraph (g)(5) of this section.

(i) Directly to third-party information providers as defined in paragraph (g)(2)(ii) of this section in electronic format such as diskette or CD-ROM using non-proprietary software, in English; or

(ii) Indirectly via a Web site other than that required by paragraph (g)(3) of this section for aftermarket service providers.

(9) *Required emissions-related training information.* By [date 6 months after publication of final rule], for emissions-related training information, manufacturers shall:

(i) Provide on the manufacturer Web site an index of all emissions-related training information available for purchase by aftermarket service providers for 1994 and newer vehicles. The index shall describe the title of the course or instructional session, the cost of the video tape or duplicate, and information on how to order the item(s) from the manufacturer Web site.

(ii) Video tape or otherwise duplicate any emissions-related training courses and instructional sessions that are made available to manufacturer dealerships via satellite or the World Wide Web and make these items available for purchase as described in paragraph (g)(3) of this section. Additionally, manufacturers shall tape or otherwise duplicate any emissions-related class-room training courses made available to manufacturer franchised dealerships and make those duplicates available for sale at a fair and reasonable price on the manufacturers Web site.

(iii) Provide access to third party training providers as defined in paragraph (g)(2)(ii) of this section all emission-related training courses transmitted via satellite or Internet offered to their franchised dealerships

(10) *Timeliness and maintenance of information dissemination.* Manufacturers must make the information required under paragraphs (g)(5) and (g)(8) of this section available to any person engaged in the repairing or servicing of motor vehicles or motor vehicle engines on their Web site within three months of model introduction. After this three month period, the information must be available and updated on the manufacturer Web site at the same time that the information is made available and updated to manufacturer franchised dealerships, except as otherwise specified in this section. Beginning with the 1996 model year, manufacturers must maintain the required information on their Web sites in full-text as defined in paragraph (g)(2)(ii) of this section for a minimum of 15 years after model introduction. Subsequent to this fifteen year period, manufacturers may archive the information in the manufacturer's format of choice and provide an index of the archived information on the manufacturer Web site and how it can be obtained by interested parties. Archived information must be made

available on demand and at a fair and reasonable price.

(11) *Reprogramming Information.* (i) For model years 1996 and later, manufacturers shall make available to the persons specified in paragraph (g)(1) of this section all emissions-related recalibration or reprogramming events (including driveability reprogramming events that may affect emissions) in the format of their choice at the same time they are made available to dealerships.

(ii) For model years 1996 and later manufacturers shall be responsible for ensuring that persons specified in paragraph (g)(1) of this section shall have access to reprogramming services via manufacturer dealerships at a fair and reasonable cost and in a timely manner.

(iii) For model years 1996 and later manufacturers shall provide persons specified in paragraph (g)(1) of this section with an efficient and cost-effective method for identifying whether the calibrations on vehicles are the latest to be issued.

(iv) For all 2003 and later OBD vehicles equipped with reprogramming capability, manufacturers shall comply with SAE J2534.

(v) For model years 2003 and later, manufacturers shall comply with SAE Standardized Practice J1962, ''Diagnostic Link Connector'' for the purposes of pass-through reprogramming.

(vi) For model years 2003 and later, manufacturers shall make available to aftermarket service providers the necessary manufacturer specific software applications needed to initiate pass-through reprogramming. This software shall be able to run on a standard personal computer that utilizes standard operating systems.

(vii) Compliance with SAE J2534 is not mandatory for model years prior to 2003, provided that the manufacturer makes available to aftermarket scan tool manufacturers by [date 6 months after the effective date of the final rule] the following information necessary for reprogramming the Electronic Control Unit (ECU):

(A) The physical hardware requirements for reprogramming events or tools (e.g. system voltage requirements, cable terminals/pins, connections such as RS232 or USB, wires, etc.).

(B) Electronic Control Unit (ECU) data communication (e.g. serial data protocols, transmission speed or baud rate, bit timing requirements, etc).

(C) Information on the application physical interface (API) or layers (descriptions for procedures such as connection, initialization, performing and verifying programming/download, and termination).

(D) Vehicle application information or any other related service information such as special pins and voltages for reprogramming events or additional vehicle connectors that require enablement and specifications for the enablement.

(12) *Generic and enhanced information for scan tools.* By [date 30 days after the effective date of the final rule], vehicle manufacturers shall make available to equipment and tool companies all generic and enhanced service information including bi-directional control and data stream information as defined in paragraph (g)(2)(ii) of this section. This requirement applies for 1996 and later model year vehicles.

(i) The information required by this paragraph shall be transmitted electronically to the aftermarket tool and equipment companies in English to a secure World Wide Web site. This site shall be agreed upon between manufacturers and aftermarket tool and equipment companies. The information required by this paragraph (g)(12) shall be provided using common document formats.

(ii) In addition to the generic and enhanced defined in paragraph (g)(2)(ii) of this section, vehicle manufacturers shall also make available the following information necessary for developing generic diagnostic scan tools:

(A) The physical hardware requirements for data communication (e.g. system voltage requirements, cable terminals/pins, connections such as RS232 or USB, wires, etc.)

(B) Electronic Control Unit (ECU) data communication (e.g. serial data protocols, transmission speed or baud rate, bit timing requirements, etc),

(C) Information on the application physical interface (API) or layers (i.e., processing algorithms or software design descriptions for procedures such as connection, initialization, performing and verifying programming/download, and termination),

(D) Vehicle application information or any other related service information such as special pins and voltages for reprogramming events or additional vehicle connectors that require enablement and specifications for the enablement.

(E) The necessary calibrations via CD–ROM, diskette, or the Internet.

(F) Information that describes which interfaces, or combinations of interfaces, from each of the categories as described in paragraphs (g)(12)(ii)(A) through (E) of this section.

(13) *Availability of vehicle manufacturer-specific scan tools.* Manufacturers shall make available for sale to the persons specified in paragraph (g)(2) of this section their own manufacturer-specific diagnostic tools at a fair and reasonable cost. Manufacturers who develop different versions of one or more of their diagnostic tools that are used in whole or in part for emission-related diagnosis and repair shall insure that all emission-related diagnosis and repair information is available for sale to the aftermarket at a fair and reasonable cost. Manufacturers shall provide technical support to aftermarket service providers for the tools described in this section, either themselves or through a third-party of their choice.

(14) *Changing content of manufacturer-specific scan tools.* Manufacturers who opt to remove non-emissions related content from their manufacturer-specific scan tools and sell them to the persons specified in paragraph (g)(2) of this section shall adjust the cost of the tool accordingly lower to reflect the decreased value of the scan tool. All emissions-related content that remains in the manufacturer-specific tool shall be identical to the information that is contained in the complete version of the manufacturer specific tool.

(15) *Special tools.* (i) Manufacturers who have developed special tools to extinguish the malfunction indicator light (MIL) for Model Years 1994 through 2001 shall make available the necessary information available to equipment and tool companies to design a comparable generic tool. This information shall be made available to equipment and tool companies no later than [date 90 days following the effective date of the Final Rule].

(ii) Manufacturers are prohibited from requiring special tools to extinguish the malfunction indicator light (MIL) beginning with Model Year 2002.

(16) *Reference materials.* Manufacturers shall conform with the following Society of Automotive Engineers (SAE) standards. Copies of these documents may be obtained from SAE 400 Commonwealth Drive, Warrendale, PA 15096–0001, or at www.sae.org. The following documents are Incorporated by Reference.

(i) For Web-based delivery of service information, vehicles manufacturers shall comply with SAE Recommended Practice J1930,''Electrical/Electronic Systems Diagnostic Terms, Definitions, Abbreviations, and Acronyms.'' (May 1988). This recommended practice standardizes various terms, abbreviations, and acronyms associated

with On-board diagnostics. Vehicle manufacturers shall comply with J1930 beginning with Model Year 2003.

(ii) For OBD vehicle communications, vehicle manufacturers shall comply with SAE Recommended Practice J2284, ''High Speed CAN (HSC) for Vehicle Applications at 500 KBPS.'' (February 1999). This recommended practice defines a level of standardization in the implementation of a 500 KBPS vehicle communication network using the Controller Area Network (CAN) protocol. Vehicle manufacturers shall comply with J2284 beginning with Model Year 2003.

(iii) For pass-through reprogamming capabilities, vehicle manufacturers shall comply with SAE Recommended Practice J1962 (FEB 98), ''Diagnostic Connector''. This recommended practice specifies the boundaries within the passenger compartment where vehicle manufacturers may place the OBD diagnostic link connector. Vehicle manufacturers shall comply with J1962 beginning with model year 2003.

(iv) For pass-through reprogramming capabilities, vehicle manufacturers shall comply with SAE Recommended Practice J2534 (DEC 00), ''Specifications for Pass-Through Reprogramming.'' This recommended practice provides technical specifications and information that vehicle manufacturers must supply to aftermarket tool and equipment companies to develop aftermarket pass-through reprogramming tools. Vehicle manufacturers shall comply with J2534 beginning with model year 2003.

(17) *Reporting Requirements.* Manufacturers shall provide to the Administrator reports on an annual basis and upon request of the Administrator, that describe the performance of their individual Web sites. These annual reports shall be submitted to the Administrator electronically utilizing non-proprietary software in the format as agreed to by the Administrator and the manufacturers. These annual reports shall include, at a minimum, monthly measurements of the following parameters:

(i) Total successful requests. This is measured in number of files (including graphic interchange formats (GIFs) and joint photographic expert group (JPEG) images, i.e. electronic images such as wiring or other diagrams or pictures). This is defined as the total successful requests counts all the files which have been requested, including pages, graphics, etc.

(ii) Average successful requests per day (measured in number of files). This is defined as reports of the average successful requests per day of all files which have been requested, including pages, graphics, etc.

(iii) Total successful requests for pages [report on number of pages (including graphic interchange formats (GIFs) and joint photographic expert group (JPEG) images, i.e. electronic images such as wiring or other diagrams or pictures). This is defined as the total successful requests counts all the documents that were returned or where the document was requested but was not needed because it had not been recently modified and the user could use a cached copy.

(iv) Total failed requests (measured in number of files). This is defined as the total failed requests counts all the files which were requested but failed requests because they could not be found or is read-protected. This includes pages, graphics, etc.

(v) Total redirected requests (measured in number of files). This is defined as redirected requests that indicate that the user was directed to a different file instead.

(vi) Number of distinct files requested (measured in number of files). This is defined as the number of different file types that were requested (i.e html, pdf, txt).

(vii) Number of distinct hosts served (measured in number of files). This is defined as reports on the number of different computers where requests have come from.

(viii) Corrupt logfile lines (measured in number of lines). This is defined as the lines in the logfile that were unreadable by the computer.

(ix) Total data transferred (measured in bytes). This is defined as the total amount of data transferred from one place to another.

(x) Average data transferred per day (measured in bytes). This is defined as the average amount of data transferred per day from one place to another.

(xi) Daily Summary (measured in number of files/pages by day of week). This is defined as the total number of requests in each day of the week, over the time period given at the very top of the report.

(xii) Daily Report (measured in number of files/pages by day of month). This is defined as how many requests there were in each day of a specific month.

(xiii) Hourly Summary (measured in number of files/pages by hour of day). This is defined as the total number of requests for each hour of the day, over a specific time period.

(xiv) Request Report (measured in number of files/pages by individual URL). This is defined as which files were downloaded.

(xv) Referrer Report (measured in number of files/pages by individual referring URL). This is defined as which pages linked to your files.

(xvi) Browser Summary (measured in number of files/pages by browser type, i.e., Netscape, Internet Explorer). This is defined as the versions of browsers by vendor.

(xvii) Browser Report (measured in number of files/pages by browser type, i.e., Mozilla 4.0). This is defined as a list of the detailed versions of browsers used.

(18) *Prohibited Acts, Liability and Remedies.* (i) It is a prohibited act for any person to fail to promptly provide or cause a failure to promptly provide information as required by this paragraph (g), or to otherwise fail to comply or cause a failure to comply with any provision of this paragraph (g).

(ii) Any person who fails or causes the failure to comply with any provision of this paragraph (g) is liable for a violation of that provision. A corporation is presumed liable for any violations of this subpart that are committed by any of its subsidiaries, affiliates or parents that are substantially owned by it or substantially under its control.

(iii) Any person who violates a provision of this paragraph (g) shall be subject to a civil penalty of not more than $27,500 per day for each violation. In addition, such person shall be liable for all other remedies set forth in Title II of the Clean Air Act, remedies pertaining to provisions of Title II of the Clean Air Act, or other applicable provisions of law.

4. Section. 86.1808–01 is proposed to be amended by revising paragraph (f) to read as follows:

§ 86.1808–01 Maintenance instructions.

* * * * *

(f) Emission control diagnostic service information.

(1) Manufacturers are subject to the provisions of this paragraph (f) beginning in the 2001 model year for manufacturers of light-duty vehicles and light-duty trucks, and beginning in the 2005 model year for manufacturers of heavy-duty vehicles and heavy-duty engines weighing 14,000 pounds gross vehicle weight (GVW) and less that are subject to the OBD requirements of this part.

(2) *General requirements.* (i) Manufacturers shall furnish or cause to be furnished to any person engaged in the repairing or servicing of motor vehicles or motor vehicle engines, or the Administrator upon request, any and all information needed to make use of the on-board diagnostic system and such other information, including

instructions for making emission-related diagnosis and repairs, including but not limited to service manuals, technical service bulletins, recall service information, data stream information, bi-directional control information, and training information, unless such information is protected by section 208(c) as a trade secret. No such information may be withheld under section 208(c) of the Act if that information is provided (directly or indirectly) by the manufacturer to franchised dealers or other persons engaged in the repair, diagnosing, or servicing of motor vehicles or motor vehicle engines.

(ii) *Definitions.* The following definitions apply for this paragraph (f):

(A) Aftermarket service provider means any individual or business engaged in the diagnosis, service, and repair of a motor vehicle or engine who is not directly affiliated with a manufacturer or manufacturer franchised dealership.

(B) Bi-directional control means the capability of a diagnostic tool to send messages on the data bus that temporarily overrides the module's control over a sensor or actuator and gives control to the diagnostic tool operator. Bi-directional controls do not create permanent changes to engine or component calibrations.

(C) Data stream information means information (i.e., messages and parameters) originated within the vehicle by a module or intelligent sensors (i.e., a sensor that contains and is controlled by its own module) and transmitted between a network of modules and/or intelligent sensors connected in parallel with either one or two communication wires. The information is broadcast over the communication wires for use by other modules (e.g., chassis, transmission, etc.) to conduct normal vehicle operation or for use by diagnostic tools. Data stream information does not include engine calibration related information.

(D) Emissions-related information means any information related to the diagnosis, service, and repair of emissions-related components.

(E) Emissions-related training information means any information related training or instruction for the purpose of the diagnosis, service, and repair of emissions-related components. Emissions-related information includes, but is not limited to:

(*1*) Manuals, including subsystem and component manuals, technical service bulletins (TSBs), recall service information, diagrams, charts, and training materials;

(*2*) OBD system operational information that describes functional characteristics of the OBD system and emission-related components. OBD system operational information includes, but is not limited to, OBD generic drive cycle information, component operating ranges, and system logic flow diagrams. Algorithms, look-up tables, or any values associated with look-up tables are not required to be made available;

(*3*) Emission-related diagnostic procedures. Manufacturers who utilize their manufacturer-specific scan tool to provide emissions-related diagnostic procedures cannot require connection to the vehicle to access this information. Additionally, manufacturers shall also make any emissions-related diagnostic procedures incorporated into their manufacturer-specific scan tools available to aftermarket service providers on their respective manufacturer Web sites;

(*4*) Any information on other systems that can directly effect the emission system within a multiplexed system (including how information is sent between emission-related system modules and other modules on a multiplexed bus);

(*5*) Any information regarding any system, component, or part of a vehicle monitored by the OBD system that could in a failure mode cause the OBD system to illuminate the malfunction indicator light (MIL);

(*6*) Information needed to start the vehicle when the vehicle is equipped with an anti-theft system or other systems that disables the engine and prevents it from starting after the completion of an emissions-related repair; and

(*7*) Manufacturer-specific emissions-related diagnostic trouble codes (DTCs) and any related service bulletins, trouble shooting guides, and/or repair procedures associated with these manufacturer-specific DTCs.

(F) Enhanced service and repair information means information which is specific for an original equipment manufacturer's brand of tools and equipment.

(G) Generic service and repair information means information which is not specific for an original equipment manufacturer's brand of tools and equipment.

(H) Indirect information means any information that is not specifically contained in the service literature, but is contained in items such as tools or equipment provided to franchised dealers (or others).

(I) Intermediary means any individual or entity, other than an original equipment manufacturer, which provides service or equipment to aftermarket service providers.

(J) Manufacturer franchised dealership means any service provider with which an manufacturer has a direct business relationship.

(K) Third party information provider means any individual or entity, other than an original equipment manufacturer, who consolidates manufacturer service information and makes this information available to aftermarket service providers.

(L) Third party training provider means any individual or entity, other than an original equipment manufacturer who develops and/or delivers instructional and educational material for automotive training courses.

(3) *Information dissemination.* By [date six months after the effective date of the final rule], each manufacturer shall provide or cause to be provided a manufacturer-specific World Wide Web site available to the persons specified in paragraph (f)(2)(i) of this section and to any other interested parties containing in the information specified in paragraph (f)(2)(i) of this section for 2001 and later model year vehicles which have been offered for sale; this requirement does not apply to indirect information, including the information specified in paragraphs (f)(11) through (f)(15) of this section. Each manufacturer Web site shall:

(i) Provide access in full-text to all of the information specified in paragraph (f)(5) of this section.

(ii) Be updated at the same time as dealership World Wide Web sites, but in no instance less than 14 days after new information or changes to existing information have been changed or updated on the manufacturer's dealership site.

(iii) Provide users with a description of the minimum computer hardware and software needed by the user to access that manufacturer's information (e.g., computer processor speed and operating system software). This description shall appear when users first log-on to the home page of the manufacturer's Web site.

(iv) Provide Short-Term(≤ 24 hours), Mid-Term (30 day period), and Long-Term (365 day period) Web site subscription options to any person specified in paragraph (f)(1) of this section at a fair and reasonable cost as specified in paragraph (f)(6) of this section for each of the options. Reasonable cost shall not exceed $20 for short-term access, $300 for mid-term access, and $2500 for long-term access in year 2001 dollars.

(v) Allow the user to search the manufacturer Web site by various topics including but not limited to model, model year, key words or phrases, vehicle identification number (VIN), etc., while allowing ready identification of the latest vehicle calibration.

(vi) Provide accessibility using common, readily available software and shall not require the use of proprietary software, hardware, viewers, or browsers. manufacturers shall also provide hyperlinks to any plug-ins, viewers or browsers (e.g. Adobe Acrobat or Netscape) needed to access the manufacturer Web site.

(vii) Allow simple hyper-linking to the manufacturer Web site from Government Web sites and automotive-related Web sites.

(viii) Allow access to the manufacturer Web sites with no limits on the modem speed by which aftermarket service providers or other interested parties can connect to the manufacturer Web site.

(4) *Small volume provisions for information dissemination.* (i) Manufacturers with annual sales of less than 5,000 vehicles shall have until [12 months after the effective date of the final rule] to launch their individual Web sites as required by paragraph (f)(2) of this section.

(ii) Manufacturers with annual sales of less than 1,000 vehicles may, in lieu of meeting the requirement of paragraph (f)(3) of this section, request the Administrator to approve an alternative method by which the required emissions-related information can be obtained by the persons specified in paragraph (f)(1) of this section.

(5) *Required information.* All information relevant to the diagnosis and completion of emissions-related repairs shall be posted on manufacturer Web sites excluding indirect information specified in paragraphs (f)(11) through (f)(15) of this section. The required information includes, but is not limited to:

(i) Manuals, including subsystem and component manuals, technical service bulletins (TSBs), recall service information, diagrams, charts, and training materials;

(ii) OBD system operational information that describes functional characteristics of the OBD system and emission-related components; OBD system operational information includes, but is not limited to, OBD generic drive cycle information, component operating ranges, and system logic flow diagrams. Algorithms, look-up tables, or any values associated with look-up tables are not required to be made available;

(iii) Emission-related diagnostic procedures; manufacturers who utilize their manufacturer-specific scan tool to provide emissions-related diagnostic procedures cannot require connection to the vehicle to access this information and shall make such information available to aftermarket service providers on their respective manufacturer Web sites;

(iv) Any information on other systems that can directly effect the emission system within a multiplexed system (including how information is sent between emission-related system modules and other modules on a multiplexed bus);

(v) Any information regarding any system, component, or part of a vehicle monitored by the OBD system that could in a failure mode cause the OBD system to illuminate the malfunction indicator light (MIL); and

(vi) Information needed to start the vehicle when the vehicle is equipped with an anti-theft system or other systems that disables the engine and prevents it from starting after the completion of an emissions-related repair.

(6) *Cost of required information.* All information required to be made available by this section shall be made available at a fair and reasonable price to any person engaged in the repairing or servicing of motor vehicles or motor vehicle engines. In determining whether a price is fair and reasonable, consideration may be given to relevant factors, including, but not limited to, the cost to the manufacturer of preparing and/or providing the information, the type of information, the format in which it is provided, the price charged by other manufacturers for similar information, the differences that exist among manufacturers (e.g., the size of the manufacturer), the quantity of material contained in a publication, the level of detail of the information, the cost of the information prior to [effective date of the final rule], volume discounts, and inflation.

(7) *Unavailable information.* Any information which is not provided at a fair and reasonable price shall be considered unavailable, in violation of this paragraph (f) and section 202(m)(5) of the Clean Air Act.

(8) *Third party information providers.* By [date 6 months after publication of the final rule], manufacturers shall, for model year 2002 and later vehicles and engines, provide the required emissions-related information as specified in paragraph (f)(5) of this section.

(i) Directly to third-party information providers as defined in paragraph (f)(2)(ii) of this section in electronic format such as diskette or CD–ROM using non-proprietary software, in English; or

(ii) Indirectly via a Web site other than that required by paragraph (f)(3) of this section for aftermarket service providers.

(9) *Required emissions-related training information.* By [date 6 months after publication of the final rule], for emissions-related training information, manufacturers shall:

(i) Provide on the manufacturer Web site an index of all emissions-related training information available for purchase by aftermarket service providers for 1994 and newer vehicles. The index shall describe the title of the course or instructional session, the cost of the video tape or duplicate, and information on how to order the item(s) from the manufacturer Web site.

(ii) Video tape or otherwise duplicate any emissions-related training courses and instructional sessions that are made available to manufacturer dealerships via satellite or the World Wide Web and make these items available for purchase as described in paragraph (f)(3) of this section. Additionally, manufacturers shall tape or otherwise duplicate any emissions-related class-room training courses made available to manufacturer franchised dealerships and make those duplicates available for sale at a fair and reasonable price on the manufacturers Web site.

(iii) Provide access to third party training providers as defined in paragraph (f)(2)(ii) of this section all emission-related training courses transmitted via satellite or Internet offered to their franchised dealerships

(10) *Timeliness and maintenance of information dissemination.* Manufacturers must make the information required under paragraphs (f)(5) and (f)(8) of this section available to any person engaged in the repairing or servicing of motor vehicles or motor vehicle engines on their Web site within three months of model introduction. After this three month period, the information must be available and updated on the manufacturer Web site at the same time that the information is made available and updated to manufacturer franchised dealerships, except as otherwise specified in this section. Beginning with the l996 model year, manufacturers must maintain the required information on their Web sites in full-text as defined in paragraph (f)(2)(ii) for a minimum of 15 years after model introduction. Subsequent to this fifteen year period, manufacturers may archive the information in the manufacturer's format of choice and provide an index of the archived

information on the manufacturer Web site and how it can be obtained by interested parties. Archived information must be made available on demand and at a fair and reasonable price.

(11) *Reprogramming Information.* (i) For model years 2001 and later, manufacturers shall make available to the persons specified in paragraph (f)(1) of this section all emissions-related recalibration or reprogramming events (including driveability reprogramming events that may affect emissions) in the format of their choice at the same time they are made available to dealerships.

(ii) For model years 2001 and later manufacturers shall be responsible for ensuring that persons specified in paragraph (f)(1) of this section shall have access to reprogramming services via manufacturer dealerships at a fair and reasonable cost and in a timely manner.

(iii) For model years 2001 and later manufacturers shall provide persons specified in paragraph (f)(1) of this section with an efficient and cost-effective method for identifying whether the calibrations on vehicles are the latest to be issued.

(iv) For all 2003 and later OBD vehicles equipped with reprogramming capability, manufacturers shall comply with SAE J2534.

(v) For model years 2003 and later, manufacturers shall comply with SAE Standardized Practice J1962, ''Diagnostic Link Connector'' for the purposes of pass-through reprogramming.

(vi) For model years 2003 and later, manufacturers shall make available to aftermarket service providers the necessary manufacturer specific software applications needed to initiate pass-through reprogramming. This software shall be able to run on a standard personal computer that utilizes standard operating systems.

(vii) Compliance with SAE J2534 is not mandatory for model years prior to 2003, provided that the manufacturer makes available to aftermarket scan tool manufacturers by [date 6 months after the effective date of the final rule] the following information necessary for reprogramming the Electronic Control Unit (ECU):

(A) The physical hardware requirements for reprogramming events or tools (e.g. system voltage requirements, cable terminals/pins, connections such as RS232 or USB, wires, etc.).

(B) Electronic Control Unit (ECU) data communication (e.g. serial data protocols, transmission speed or baud rate, bit timing requirements, etc).

(C) Information on the application physical interface (API) or layers (descriptions for procedures such as connection, initialization, performing and verifying programming/download, and termination).

(D) Vehicle application information or any other related service information such as special pins and voltages for reprogramming events or additional vehicle connectors that require enablement and specifications for the enablement.

(12) *Generic and enhanced information for scan tools.* By [date 30 days after the effective date of the final rule], vehicle manufacturers shall make available to equipment and tool companies all generic and enhanced service information including bi-directional control and data stream information as defined in paragraph (f)(2)(ii) of this section. This requirement applies for 2001 and later model year vehicles.

(i) The information required by this paragraph shall be transmitted electronically to the aftermarket tool and equipment companies in English to a secure World Wide Web site. This site shall be agreed upon between manufacturers and aftermarket tool and equipment companies. The information required by this paragraph (f)(12) shall be provided using common document formats.

(ii) In addition to the generic and enhanced defined in paragraph (f)(2)(ii) of this section, vehicle manufacturers shall also make available the following information necessary for developing generic diagnostic scan tools:

(A) The physical hardware requirements for data communication (e.g. system voltage requirements, cable terminals/pins, connections such as RS232 or USB, wires, etc.)

(B) Electronic Control Unit (ECU) data communication (e.g. serial data protocols, transmission speed or baud rate, bit timing requirements, etc),

(C) Information on the application physical interface (API) or layers (i.e., processing algorithms or software design descriptions for procedures such as connection, initialization, performing and verifying programming/download, and termination),

(D) Vehicle application information or any other related service information such as special pins and voltages for reprogramming events or additional vehicle connectors that require enablement and specifications for the enablement.

(E) The necessary calibrations via CD–ROM, diskette, or the Internet.

(F) Information that describes which interfaces, or combinations of interfaces, from each of the categories as described in paragraphs (f)(12)(ii)(A) through (E) of this section.

(13) *Availability of vehicle manufacturer-specific scan tools.* Manufacturers shall make available for sale to the persons specified in paragraph (f)(2) of this section their own manufacturer-specific diagnostic tools at a fair and reasonable cost. Manufacturers who develop different versions of one or more of their diagnostic tools that are used in whole or in part for emission-related diagnosis and repair shall insure that all emission-related diagnosis and repair information is available for sale to the aftermarket at a fair and reasonable cost. Manufacturers shall provide technical support to aftermarket service providers for the tools described in this section, either themselves or through a third-party of their choice.

(14) *Changing content of manufacturer-specific scan tools.* Manufacturers who opt to remove non-emissions related content from their manufacturer-specific scan tools and sell them to the persons specified in paragraph (f)(2) of this section shall adjust the cost of the tool accordingly lower to reflect the decreased value of the scan tool. All emissions-related content that remains in the manufacturer-specific tool shall be identical to the information that is contained in the complete version of the manufacturer specific tool.

(15) *Special tools.* (i) Manufacturers who have developed special tools to extinguish the malfunction indicator light (MIL) for Model Years 1994 through 2001 shall make available the necessary information available to equipment and tool companies to design a comparable generic tool. This information shall be made available to equipment and tool companies no later than [date 90 days following the effective date of the Final Rule].

(ii) Manufacturers are prohibited from requiring special tools to extinguish the malfunction indicator light (MIL) beginning with Model Year 2002.

(16) *Reference materials.* Manufacturers shall conform with the following Society of Automotive Engineers (SAE) standards. Copies of these documents may be obtained from SAE 400 Commonwealth Drive, Warrendale, PA 15096–0001, or at www.sae.org. The following documents are Incorporated by Reference.

(i) For Web-based delivery of service information, vehicles manufacturers shall comply with SAE Recommended Practice J1930,''Electrical/Electronic Systems Diagnostic Terms, Definitions, Abbreviations, and Acronyms.'' (May

1988). This recommended practice standardizes various terms, abbreviations, and acronyms associated with On-board diagnostics. Vehicle manufacturers shall comply with J1930 beginning with Model Year 2003.

(ii) For OBD vehicle communications, vehicle manufacturers shall comply with SAE Recommended Practice J2284, ''High Speed CAN (HSC) for Vehicle Applications at 500 KBPS.'' (February 1999). This recommended practice defines a level of standardization in the implementation of a 500 KBPS vehicle communication network using the Controller Area Network (CAN) protocol. Vehicle manufacturers shall comply with J2284 beginning with Model Year 2003.

(iii) For pass-through reprogramming capabilities, vehicle manufacturers shall comply with SAE Recommended Practice J1962 (FEB 98), ''Diagnostic Connector''. This recommended practice specifies the boundaries within the passenger compartment where vehicle manufacturers may place the OBD diagnostic link connector. Vehicle manufacturers shall comply with J1962 beginning with model year 2003.

(iv) For pass-through reprogramming capabilities, vehicle manufacturers shall comply with SAE Recommended Practice J2534 (DEC 00), ''Specifications for Pass-Through Reprogramming.'' This recommended practice provides technical specifications and information that vehicle manufacturers must supply to aftermarket tool and equipment companies to develop aftermarket pass-through reprogramming tools. Vehicle manufacturers shall comply with J2534 beginning with model year 2003.

(17) *Reporting Requirements.* Manufacturers shall provide to the Administrator reports on an annual basis and upon request of the Administrator, that describe the performance of their individual Web sites. These annual reports shall be submitted to the Administrator electronically utilizing non-proprietary software in the format as agreed to by the Administrator and the manufacturers. These annual reports shall include, at a minimum, monthly measurements of the following parameters:

(i) Total successful requests. This is measured in number of files (including graphic interchange formats (GIFs) and joint photographic expert group (JPEG) images, i.e. electronic images such as wiring or other diagrams or pictures). This is defined as the total successful requests counts all the files which have been requested, including pages, graphics, etc.

(ii) Average successful requests per day (measured in number of files). This is defined as reports of the average successful requests per day of all files which have been requested, including pages, graphics, etc.

(iii) Total successful requests for pages [report on number of pages (including graphic interchange formats (GIFs) and joint photographic expert group (JPEG) images, i.e. electronic images such as wiring or other diagrams or pictures). This is defined as the total successful requests counts all the documents that were returned or where the document was requested but was not needed because it had not been recently modified and the user could use a cached copy.

(iv) Total failed requests (measured in number of files). This is defined as the total failed requests counts all the files which were requested but failed requests because they could not be found or is read-protected. This includes pages, graphics, etc.

(v) Total redirected requests (measured in number of files). This is defined as redirected requests that indicate that the user was directed to a different file instead.

(vi) Number of distinct files requested (measured in number of files). This is defined as the number of different file types that were requested (i.e., html, pdf, txt).

(vii) Number of distinct hosts served (measured in number of files). This is defined as reports on the number of different computers where requests have come from.

(viii) Corrupt logfile lines (measured in number of lines). This is defined as the lines in the logfile that were unreadable by the computer.

(ix) Total data transferred (measured in bytes). This is defined as the total amount of data transferred from one place to another.

(x) Average data transferred per day (measured in bytes). This is defined as the average amount of data transferred per day from one place to another.

(xi) Daily Summary (measured in number of files/pages by day of week). This is defined as the total number of requests in each day of the week, over the time period given at the very top of the report.

(xii) Daily Report (measured in number of files/pages by day of month). This is defined as how many requests there were in each day of a specific month.

(xiii) Hourly Summary (measured in number of files/pages by hour of day). This is defined as the total number of requests for each hour of the day, over a specific time period.

(xiv) Request Report (measured in number of files/pages by individual URL). This is defined as which files were downloaded.

(xv) Referrer Report (measured in number of files/pages by individual referring URL). This is defined as which pages linked to your files.

(xvi) Browser Summary (measured in number of files/pages by browser type, i.e., Netscape, Internet Explorer). This is defined as the versions of browsers by vendor.

(xvii) Browser Report (measured in number of files/pages by browser type, i.e., Mozilla 4.0). This is defined as a list of the detailed versions of browsers used.

(18) *Prohibited Acts, Liability and Remedies.* (i) It is a prohibited act for any person to fail to promptly provide or cause a failure to promptly provide information as required by this paragraph (f) or to otherwise fail to comply or cause a failure to comply with any provision of this paragraph (f).

(ii) Any person who fails or causes the failure to comply with any provision of this subsection is liable for a violation of that provision. A corporation is presumed liable for any violations of this subpart that are committed by any of its subsidiaries, affiliates or parents that are substantially owned by it or substantially under its control.

(iii) Any person who violates a provision in this paragraph (f) shall be subject to a civil penalty of not more than $27,500 per day for each violation. In addition, such person shall be liable for all other remedies set forth in Title II of the Clean Air Act, remedies pertaining to provisions of Title II of the Clean Air Act, or other applicable provisions of law.

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AF96

Endangered and Threatened Wildlife and Plants; Proposed Establishment of Nonessential Experimental Population Status for 4 Fishes Into the Tellico River, From the Backwaters of Tellico Reservoir Upstream to Tellico River Mile 33, in Monroe County, Tennessee

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the Fish and Wildlife Service (Service), propose to reintroduce two federally listed endangered fishes—the duskytail darter (*Etheostoma percnurum*) and smoky madtom (*Noturus baileyi*)—and two federally listed threatened fishes—the yellowfin madtom (*Noturus flavipinnis*) and spotfin chub (=turquoise shiner) (*Cyprinella* (=*Hybopsis) monacha*)—into the Tellico River, between the backwaters of the Tellico Reservoir (approximately Tellico River mile (TRM) 19 (30.4 kilometers (km))) and TRM 33 (52.8 km), near the Tellico Ranger Station, in Monroe County, Tennessee. These populations would be established as nonessential experimental populations (NEPs) in accordance with section 10(j) of the Endangered Species Act of 1973, as amended (Act). This area is identified as the proposed NEP Area. We would manage these populations under provisions of this special rule.

DATES: Comments must be received by August 7, 2001.

ADDRESSES: Send comments and information concerning this proposal to the State Supervisor, Asheville Field Office, U.S. Fish and Wildlife Service, 160 Zillicoa Street, Asheville, North Carolina 28801. Comments and materials received will be available for public inspection, by appointment, during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Mr. Richard G. Biggins at 828/258–3939, ext. 228; facsimile 828/258–5330; or e-mail richard_biggins@fws.gov.

SUPPLEMENTARY INFORMATION:

Background

1. *Legislative:* Congress made significant changes to the Endangered Species Act of 1973, as amended (Act), with the addition of section 10(j), which provides for the designation of specific reintroduced populations of listed species as ''experimental populations.'' Previously, we had authority to reintroduce populations into unoccupied portions of a listed species' historical range when doing so would foster the conservation and recovery of the species. However, local citizens often opposed these reintroductions because they were concerned about the placement of restrictions and prohibitions on Federal and private activities. Under section 10(j), the Secretary of the Department of the Interior can designate reintroduced populations established outside the species' current range, but within its historical range, as ''experimental.''

Under the Act, species listed as endangered or threatened are afforded protection primarily through the prohibitions of section 9 and the requirements of section 7. Section 9 of the Act prohibits the take of a listed species. ''Take'' is defined by the Act as harass, harm, pursue, hunt, shoot, wound, trap, capture, or collect, or attempt to engage in any such conduct. Section 7 of the Act outlines the procedures for Federal interagency cooperation to conserve federally listed species and protect designated critical habitats. It mandates all Federal agencies to determine how to use their existing authorities to further the purposes of the Act to aid in recovering listed species. It also states that Federal agencies will, in consultation with the Service, insure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. Section 7 of the Act does not affect activities undertaken on private lands unless they are authorized, funded, or carried out by a Federal agency.

Section 10(j) is designed to increase our flexibility in managing an experimental population by allowing us to treat the population as threatened, regardless of the species' designation elsewhere in its range. Threatened designation gives us more discretion in developing and implementing management programs and special regulations for such a population and allows us to develop any regulations we consider necessary to provide for the conservation of a threatened species. In situations where we have experimental populations, most of the section 9 prohibitions that apply to threatened species no longer apply, and the special rule contains the prohibitions and exceptions necessary and appropriate to conserve that species. Regulations for NEPs may be developed to be more compatible with routine human activities in the reintroduction area.

Based on the best available information, we must determine whether experimental populations are ''essential,'' or ''nonessential,'' to the continued existence of the species. An experimental population that is essential to the survival of the species is treated as a threatened species. An experimental population that is nonessential to the survival of the species is also treated as a threatened species. However, for section 7 interagency cooperation purposes, if the NEP is located outside of a National Wildlife Refuge or National Park, it is treated as a species proposed for listing.

For the purposes of section 7 of the Act, in situations where there is a nonessential experimental population located within a National Wildlife Refuge or National Park (treated as threatened), section 7(a)(1) and the consultation requirements of section 7(a)(2) of the Act would apply. Section 7(a)(1) requires all Federal agencies to use their authorities to conserve listed species. Section 7(a)(2) requires that Federal agencies consult with the Service before authorizing, funding, or carrying out any activity that would likely jeopardize the continued existence of a listed species or adversely modify its critical habitats. When NEPs are located outside a National Wildlife Refuge or National Park, only two provisions of section 7 would apply; section 7(a)(1) and section 7(a)(4). In these instances, NEPs provide additional flexibility because Federal agencies are not required to consult with us under section 7(a)(2). Section 7(a)(4) requires Federal agencies to informally confer with the Service on actions that are likely to jeopardize the continued existence of a proposed species. However, since we determined that the NEP is not essential to the continued existence of the species, it is very unlikely that we would ever determine jeopardy for a project impacting a species within an NEP.

Individuals used to establish an experimental population may come from a donor population, provided their removal is not likely to jeopardize the continued existence of the species, and appropriate permits are issued in accordance with our regulations (50 CFR 17.22) prior to their removal.

2. *Biological:* Since the mid-1980s, Conservation Fisheries, Inc. (CFI), with support from us, the Tennessee Wildlife Resources Agency (TWRA), U.S. Forest Service (USFS), National Park Service, Tennessee Valley Authority (TVA), and Tennessee Aquarium (TA), has reintroduced the smoky madtom, duskytail darter, yellowfin madtom, and spotfin chub into Abrams Creek, within the Great Smoky Mountains National Park, Blount County, Tennessee. We have evidence that all four species are becoming reestablished in Abrams Creek (Rakes *et al.* 1998). Based on this success and CFI's intimate knowledge of the fishes' habitat needs, we contracted them to survey the Tellico River to determine if we could expand the recovery program for these fishes into the Tellico River.

CFI determined that the Tellico River appears to contain ideal habitat for the reintroduction of the four fishes, between the backwaters of the Tellico Reservoir (approximately Tellico River

mile (TRM) 19 (30.4 kilometers (km))) and TRM 33 (52.8 km), near the Tellico Ranger Station, in Monroe County, Tennessee (Rakes and Shute 1998). CFI concluded that the Tellico River's overall water quality and clarity, combined with substrate quality, were somewhat less optimal than Citico Creek, where three of the four species currently exist. However, they also concluded that the Tellico River contains as good or better habitat than that which exists in Abrams Creek, where reintroductions of all four species are apparently succeeding.

Rakes and Shute (1998) reported that there are no confirmed historical collection records for these fishes from the Tellico River. However, they believe that all four species probably occurred in the river historically. They based their conclusion on two facts—(1) That the Tellico River is a Little Tennessee tributary just downstream from the mouths of Abrams and Citico Creeks (all four fishes historically occurred in these creeks) and (2) that all three streams drain the same physiographic provinces (Blue Ridge and Ridge and Valley). Additionally, all four species historically had access to the Tellico River. Prior to the construction of reservoirs on the main stem of the Little Tennessee River, no physical barriers prevented the movement of these fishes among Abrams Creek, Citico Creek, and the Tellico River (Peggy Shute, TVA, personal communication, 1998).

3. *Recovery Efforts:* We listed the duskytail darter (*Etheostoma percnurum*) (Jenkins 1994) as an endangered species on April 27, 1993 (58 FR 25758), and completed the recovery plan for this species in March 1994 (Service 1994). Although likely once more widespread in the upper Tennessee and middle Cumberland River systems, the species was historically known from only six populations—Little River and Abrams Creek, Blount County, Tennessee; Citico Creek, Monroe County, Tennessee; Big South Fork Cumberland River, Scott County, Tennessee, and McCreary County, Kentucky; Copper Creek and the Clinch River (this is one population), Scott County, Virginia; and the South Fork Holston River, Sullivan County, Virginia (Service 1994). The South Fork Holston River population is apparently extirpated. The Little River, Copper Creek/Clinch River, and Big South Fork Cumberland River populations are extant but small. CFI has reintroduced the duskytail darter into Abrams Creek, where a population is apparently becoming reestablished (Rakes *et al.* 1998).

The downlisting criteria (reclassification from endangered to threatened status) in the Duskytail Darter Recovery Plan are: (1) Protect and enhance existing populations and reestablish a population so that at least three distinct viable duskytail darter populations exist, (2) complete studies of the species' biological and ecological requirements, (3) develop management strategies from these studies that are or are likely to be successful, and (4) ensure that no foreseeable threats exist which would likely threaten the continued existence of the three aforementioned viable populations. The delisting criteria in the recovery plan are: (1) Protect and enhance existing populations and reestablish populations so that at least five distinct viable duskytail darter populations exist, (2) complete studies of the species' biological and ecological requirements, (3) develop management strategies from these studies that are or are likely to be successful, and (4) ensure that no foreseeable threats exist which would likely threaten the continued existence of the five aforementioned viable populations.

We listed the smoky madtom (*Noturus baileyi*) (Taylor 1969) as an endangered species on October 26, 1984 (49 FR 43065), and finalized the recovery plan for this species in August 1985 (Service 1985). Although once probably more widespread in tributaries to the lower Little Tennessee River system, this species was historically collected from only two creeks—Abrams Creek, Blount County, Tennessee, and Citico Creek, Monroe County, Tennessee (Service 1985). The Citico Creek population is still extant. CFI has reintroduced smoky madtom into Abrams Creek, and a population is apparently becoming reestablished (Rakes *et al.* 1998).

The downlisting criteria in the Smoky Madtom Recovery Plan are: (1) Protect the existing Citico Creek population and reintroduce the species into Abrams Creek so that at least two distinct viable smoky madtom populations exist and (2) eliminate threats to the species by implementing management activities. The delisting criteria in the recovery plan are to: (1) Protect and enhance existing populations and reestablish populations so that at least four distinct viable smoky madtom populations (Abrams and Citico Creeks, plus two others) exist; (2) implement successful management plans for the populations in Abrams and Citico Creeks; and (3) protect all four populations and their habitat from present and foreseeable threats that could interfere with the survival of any of the populations.

We listed the yellowfin madtom (*Noturus flavipinnis*) (Taylor 1969) as a threatened species on September 9, 1977 (42 FR 45527), and finalized the recovery plan for this species in June 1983 (Service 1983a). This fish was probably once widely distributed in the Tennessee drainage, from the Chickamauga system upstream (Service 1983a). However, the yellowfin madtom was historically known from only six streams—South Chickamauga Creek, Catoosa County, Georgia; Hines Creek, a Clinch River tributary, Anderson County, Tennessee; North Fork Holston River, Smyth County, Virginia; Copper Creek, Scott and Russell Counties, Virginia; Powell River, Hancock County, Tennessee; and Citico Creek, Monroe County, Tennessee (Service 1983a). Although there are no historical yellowfin madtom records from Abrams Creek, Blount County, Tennessee, Lennon and Parker (1959) reported that the brindled madtom (the name given by early collectors for the yellowfin) was collected during a reclamation project of lower Abrams Creek in 1957. Based on this observation, Dinkins and Shute (1996) and others believe the species once occurred in the middle and lower reaches of Abrams Creek. Three small populations still persist—Citico Creek, Copper Creek, and the Powell River. CFI has reintroduced the species into Abrams Creek, and a population is apparently becoming reestablished (Rakes *et al.* 1998).

The delisting criteria in the Yellowfin Madtom Recovery Plan are to: (1) Protect and enhance existing populations and/or reestablish populations so viable populations exist in Copper Creek, Citico Creek, and the Powell River; (2) recreate and/or discover two additional viable populations; (3) ensure that noticeable improvements in coal-related problems and substrate quality exist in the Powell River; and (4) protect the species and its habitat in all five rivers from present and foreseeable threats that may adversely affect essential habitat or the survival of any of the populations.

We listed the spotfin chub (=turquoise shiner) (*Cyprinella* (=*Hybopsis*) *monacha*) (Cope 1868) as a threatened species on September 9, 1977 (42 FR 45527), and finalized the recovery plan for this species in November 1983 (Service 1983b). This once widespread species was historically known from 24 streams in the upper and middle Tennessee River system. It is now extant in only four rivers/river systems—the Buffalo River at the mouth of Grinders Creek, Lewis County, Tennessee; Little Tennessee River, Swain and Macon Counties, North Carolina; Emory River

system (Obed River, Clear Creek, and Daddys Creek) Cumberland and Morgan Counties, Tennessee; Holston River and its tributary, the North Fork Holston River, Hawkins and Sullivan Counties, Tennessee, and Scott and Washington Counties, Virginia (Service 1983b; P. Shute, TVA, personal communication, 1998). CFI has reintroduced the species into Abrams Creek, and there are indications that it may become reestablished (Rakes *et al.* 1998).

The delisting criteria in the Spotfin Chub Recovery Plan are to: (1) Protect and enhance existing populations and/or reestablish populations so that viable populations exist in the Buffalo River system, upper Little Tennessee River, Emory River system, and lower North Fork Holston River and (2) ensure, through reintroductions and/or the discovery of new populations, that two other viable populations exist.

The recovery criteria for all four of these fishes generally agree that, to reach recovery, we must: (1) Restore existing populations to viable levels, (2) reestablish viable populations in historical habitats, and (3) eliminate foreseeable threats that would likely threaten the continued existence of any viable populations. The number of secure, viable populations (existing and restored) that are needed to achieve recovery varies by species and depends on the extent of the species' probable historical range (i.e., species that were once widespread require a greater number of populations for recovery than species that were historically more restricted in distribution). However, the reestablishment of historical populations is a critical component to the recovery of all four species.

4. *Reintroduction Site:* In March 1998, the Executive Director of the TWRA stated that he supports the conclusions of Rakes and Shute (1998), and requested that we consider designating the Tellico River a NEP Area and reintroducing the four fishes. He further stated that (1) the Tellico River was the probable historical habitat of the duskytail darter, smoky madtom, yellowfin madtom, and spotfin chub; and (2) the Tellico River appeared to have almost ideal habitat for the reintroduction of all four fishes.

Dr. David Etnier, Department of Ecology and Evolutionary Biology, University of Tennessee, Knoxville, Tennessee, stated in April 1998, that he supports the reintroduction of the four species into the Tellico River. Dr. Etnier presented several reasons for his support: (1) The mouth of the Tellico River is approximately 10 miles (16 km) downstream of the mouth of Citico Creek, which historically supported all four species and currently supports all but the spotfin chub; (2) CFI's habitat analysis indicated that reintroductions of these fishes into the Tellico River have a greater potential for success than reintroductions into any other tributary of the Little Tennessee River system, except Abrams Creek, where apparently successful reintroductions are already occurring; (3) apparently, no fish collections were made from the Tellico River prior to the 1960s, so the extirpation of these fishes could have occurred prior to the 1960s due to siltation caused by heavy logging in the watershed around the turn of the century; and (4) none of these species displays any biological attributes that suggest they could become a problem if successfully established into the Tellico River.

We propose to reintroduce populations of the duskytail darter, smoky madtom, yellowfin madtom, and spotfin chub (=turquoise shiner) into the Tellico River, between the backwaters of the Tellico Reservoir (approximately Tellico River mile (TRM) 19 (30.4 kilometers (km))) and TRM 33 (52.8 km), near the Tellico Ranger Station, in Monroe County, Tennessee and to designate these populations as NEPs. This area is identified as the proposed NEP Area.

5. *Reintroduction Procedures:* At this time, we cannot determine the proposed dates for these reintroductions, the specific sites where the fish species will be released, and the actual number of individuals to be released. We will release primarily artificially propagated juveniles, but we could release some wild adult stock. Propagation and juvenile rearing technology is available for the spotfin chub and the duskytail darter. Limited numbers of smoky and yellowfin madtom juveniles can be reared using eggs and larvae taken from the wild. However, madtom artificial propagation technology, which is needed to produce large numbers of juvenile madtoms, will likely not be available for 2 to 3 years.

The parents of the juveniles reintroduced into the NEP Area will come from existing wild populations. The two madtoms and duskytail darters will come from a nearby Little Tennessee River tributary—Citico Creek, Monroe County, Tennessee. The spotfin chubs will come from upstream in the Little Tennessee River, Swain County, North Carolina. In some cases the parents will be returned to the wild population from which they were taken. However, in most cases the parents will be permanently relocated to propagation facilities.

Status of Reintroduced Populations

We determine that these proposed reintroduced fish populations are not essential to the continued existence of the species. Therefore, we believe it is appropriate to designate these populations as nonessential in accordance with section 10(j) of the Act. We will ensure, through our section 10 permit authority and the section 7 consultation process, that the use of animals from any donor population for these reintroductions is not likely to jeopardize the continued existence of the species. Therefore, if any of the reintroduced populations become established and are subsequently lost, it would not reduce the likelihood of the species' survival in the wild or jeopardize its continued existence. In fact, the anticipated success of these reintroductions will enhance the conservation and recovery potential of these species by extending their present ranges into currently unoccupied historic habitat. These species are not known to exist in the Tellico River or its tributaries at the present time.

Location of Reintroduced Populations

Sites for the proposed reintroduction of these four fish species into the Tellico River, Monroe County, Tennessee, are within the proposed NEP Area. This area is totally isolated from existing populations of these species by large reservoirs, and none of these fishes are known to occur or move through large reservoir habitat. Therefore, these reservoirs will act as barriers to the downstream expansion of these species into the main stem of the Little Tennessee River and its tributaries and ensure that these populations will remain geographically isolated.

Management

We do not believe these reintroductions will conflict with existing or proposed human activities or hinder public utilization of the NEP Area. Experimental population special rules contain all the prohibitions and exceptions regarding the taking of individual animals. These special rules are more compatible with routine human activities in the reintroduction area.

Based on the habitat requirements of these four fishes, we do not expect them to become established outside the NEP Area. However, if any of the four species move upstream or downstream or into tributaries outside of the designated NEP Area, we would presume that the animals had come from the reintroduced populations. The rule will be amended and the boundaries of the

NEP Area would be enlarged to include the entire range of the expanded population.

Preliminary Notification and Comment

On June 26, 1998, we mailed letters to 67 potentially affected congressional offices, Federal and State agencies, local governments, and interested parties that we were considering proposing NEP status for four fish species in the Tellico River. We received four written responses.

The U.S. Forest Service, which is significantly involved in reintroduction efforts for these fishes into Abrams Creek, supports proposed reintroductions into the Tellico River as NEPs and offered to cooperate with us and TWRA in the reintroductions.

The Tennessee Department of Environment and Conservation, Division of Natural Heritage, supports the reintroduction of the four fishes into the Tellico River. They believe that designating the reintroduced populations as NEPs is appropriate because it should enable Federal, State, and local authorities to continue to promote the conservation and recovery of these fishes.

The Tennessee Chapter of the American Fisheries Society supports the reintroduction of these fishes into the Tellico River under NEP status. They concluded that: (1) Although there is little information on the historical environmental conditions in the Tellico River, the river now supports a relatively healthy native fish community with respect to species diversity, species composition, fish abundance, and fish health; (2) the river appears to contain suitable habitat for the survival of all four species; (3) all four species probably historically occupied the river; and (4) designating reintroductions as NEPs greatly relaxes regulatory requirements and makes introduced populations more compatible with other resource use in the watershed.

The Southeast Aquatic Research Institute (SARI) fully supports these reintroductions.

Public Comments Solicited

We intend for any rule that is finally adopted to be as effective as possible. Therefore, we invite the public, concerned government agencies, the scientific community, industry, and other interested parties to submit comments or recommendations concerning any aspect of this proposed rule (see **ADDRESSES** section).

Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the rulemaking record, which we will honor to the extent allowable by law. In some circumstances, we would withhold from the rulemaking record a respondent's identity, as allowable by law. If you wish for us to withhold your name and/or address, you must state this request prominently at the beginning of your comment. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses available for public inspection in their entirety.

Public Hearings

You may request a public hearing on this proposal. Your request for a hearing must be made in writing and filed within 45 days of the date of publication of the proposal in the **Federal Register**. Such requests for a hearing must be addressed to the State Supervisor for the Fish and Wildlife Service in North Carolina (see **ADDRESSES** section).

Required Determinations

Regulatory Planning and Review

This rule is not a significant rule and is not subject to review by the Office of Management and Budget (OMB) under Executive Order 12866. This rule will not have an effect of $100 million or more on the economy. It will not adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. The area affected by this rule consists of a very limited and discrete geographic segment (only 14 river miles (22.4 km)) of the Tellico River in Monroe County, Tennessee. No significant impacts to existing human activities on the river as a result of this rule are expected.

This rule will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency. Designating reintroduced populations of federally listed species as NEPs significantly reduces the Act's regulatory requirements regarding the reintroduced listed species. Because of the substantial regulatory relief, we do not believe the reintroduction of these fishes will conflict with existing or proposed human activities or hinder public use of the Tellico River.

This rule does not alter the budgetary effects or entitlements, grants, user fees, or loan programs, or the rights and obligations of their recipients. Because there are no expected impacts or restrictions to existing human uses of the Tellico River as a result of this rule, no entitlements, grants, user fees, loan programs, or the rights and obligations of their recipients are expected to occur.

This rule does not raise novel legal or policy issues. We have previously promulgated section 10(j) rules for experimental populations of other listed threatened or endangered species in various localities since 1984. The rules are designed to reduce the regulatory burden that would otherwise exist when reintroducing listed species to the wild.

Regulatory Flexibility Act

The Department of the Interior certifies that this document will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Although most, if not all, of the identified entities are small businesses engaged in activities along the affected reach of the stream, this rule will have no economic effect in that it will operate to reduce or remove regulatory restrictions (see above for discussion of expected impacts).

Small Business Regulatory Enforcement Fairness Act (SBREFA)

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule does not have an annual effect on the economy of $100 million or more on local or State governments or private entities. This rule will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions. This rule 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. The intent of this special rule is to facilitate and continue the existing commercial activity, while providing for the conservation of species through reintroduction into suitable habitat.

Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than $100 million per year. The rule does not have a significant or unique effect on State, local or tribal governments or the private sector. The TWRA, which manages the fishes in the Tellico River, requested that we consider this reintroduction under an NEP designation. However, this rule will not require the TWRA to specifically manage for any of these reintroduced species. A statement

containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

Takings (Executive Order 12630)

In accordance with Executive Order 12630, the rule does not have significant takings implications. When reintroduced populations of federally listed species are designated as NEPs, the Act's regulatory requirements regarding the reintroduced listed species within the NEP are significantly reduced. Section 10(j) of the Act can provide regulatory relief with regard to the taking of reintroduced species within a NEP area. For example, this rule allows for the unavoidable and unintentional taking of these reintroduced fishes when such take is incidental to a legal activity (e.g., boating, wading, and fishing) and the activity is in accordance with State laws or regulations. Because of the substantial regulatory relief provided by NEP designations, we do not believe the reintroduction of these fishes will conflict with existing or proposed human activities or hinder public use of the Tellico River system. A takings implication assessment is not required.

Federalism (Executive Order 13732)

In accordance with Executive Order 13132, the rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment. This rule will not have substantial direct effects on the States, in the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have coordinated extensively with the State of Tennessee on the proposed reintroduction of fish to the Tellico River. We are undertaking this rulemaking at the request of the State wildlife agency (TWRA) in order to assist the State in restoring and recovering its native aquatic fauna. Achieving the recovery goals for these four fish species will contribute to the eventual delisting of these species and, thus, the return of these species to State management. We do not expect any intrusion on State policy or administration; roles or responsibilities of Federal or State governments will not change; and fiscal capacity will not be substantially directly affected. This special rule operates to maintain the existing relationship between the States and the Federal Government and is being undertaken at the request of a State agency. We have endeavored to cooperate with the TWRA in the preparation of this proposed rule.

Civil Justice Reform (Executive Order 12988)

In accordance with Executive Order 12988, the Department of the Interior has determined that this proposed rule does not unduly burden the judicial system and meets the applicable standards provided in sections (3)(a) and (3)(b)(2) of the order.

Paperwork Reduction Act

This rule does not require an information collection from 10 or more parties and a submission under the Paperwork Reduction Act is not required.

National Environmental Policy Act

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the National Environmental Policy Act is not required. We have determined that the issuance of a proposed rule for these NEPs is categorically excluded under our NEPA procedures (516 DM 6, Appendix 1.4 B (6)).

Clarity of This Regulation

Executive Order 12866 requires each agency to write regulations that are easy to understand. We invite your comments on how to make this rule easier to understand, including answers to questions such as the following: (1) Are the requirements in the rule clearly stated? (2) Does the rule contain technical language or jargon that interferes with its clarity? (3) Does the format of the rule (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce its clarity? (4) Would the rule be easier to understand if it were divided into more (but shorter) sections? (5) Is the description of the rule in the **SUPPLEMENTARY INFORMATION** section of the preamble helpful in understanding the rule? (6) What else could we do to make the rule easier to understand?

Send your comments concerning how we could make this rule easier to understand to: Office of Regulatory Affairs, Department of the Interior, Room 7229, 1849 C Street, NW., Washington, DC 20240 (e-mail: Exsec@ios.doi.gov).

Literature Cited

Dinkins, G.R., and P.W. Shute. 1996. Life history of *Noturus baileyi* and *N. flavipinnis* (Pisces: Ictaluridae), two rare madtom catfishes in Citico Creek, Monroe County, Tennessee. Bull. Alabama. Mus. Nat. His. 18:43–69.

Lennon, R.E., and P.S. Parker. 1959. The reclamation of Indian and Abrams Creeks, Great Smoky Mountains National Park. U.S. Fish and Wildlife Service Scientific Report 306. 22 pp.

Rakes, P.L., and J.R. Shute. 1998. Results of an assay of portions of the Tellico and Hiwassee Rivers for suitable habitat to support reintroductions of rare fish. January 23, 1998, unpublished report prepared by Conservation Fisheries, Inc., Knoxville, Tennessee, for U.S. Fish and Wildlife Service, Asheville, North Carolina. 14 pp.

Rakes, P.L., P.W. Shute, and J.R. Shute. 1998. Captive propagation and population monitoring of rare Southeastern fishes. Final Report for 1997. Field Season and Second Quarter Report for Fiscal Year 1998, prepared for Tennessee Wildlife Resources Agency, Contract No. FA–4–10792–5–00. 32 pp.

U.S. Fish and Wildlife Service. 1983a. Yellowfin Madtom Recovery Plan. Atlanta, GA. 33 pp.

_____1983b. Spotfin Chub Recovery Plan. Atlanta, GA. 46 pp.

_____1985. Smoky Madtom Recovery Plan. Atlanta, GA. 28 pp.

_____1994. Duskytail Darter Recovery Plan. Atlanta, GA. 25 pp.

Author

The principal author of this proposed rule is Richard G. Biggins (see **ADDRESSES** section).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations as follows:

PART 17—[AMENDED]

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

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500, unless otherwise noted.

2. In § 17.11(h), revise entries in the table under FISHES for ''Chub, spotfin''; ''Darter, duskytail''; ''Madtom, smoky''; and ''Madtom, yellowfin''; to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
*	*	*	* *		*		*
FISHES							
*	*	*	* *		*		*
Chub, spotfin (=turquoise shiner).	*Cyprinella* (=*Hybopsis*) *monacha*.	U.S.A. (AL, GA, NC, TN, VA).	Entire, except where listed as an experimental population.	T	28	17.95(e)	17.44(c)
Do	.....do	.....do	Tellico River, from the backwaters of the Tellico Reservoir (about Tellico River mile 19 (30.4 km)) upstream to Tellico River mile 33 (52.8 km), in Monroe County, TN.	XN		NA	17.84(m)
*	*	*	* *		*		*
Darter, duskytail	*Etheostoma percnurum*.	U.S.A. (TN, VA)	Entire, except where listed as an experimental population.	E	502	NA	NA
Do	.....do	.....do	Tellico River, from the backwaters of the Tellico Reservoir (about Tellico River mile 19 (30.4 km)) upstream to Tellico River mile 33 (52.8 km), in Monroe County, TN.	XN		NA	17.84(m)
*	*	*	* *		*		*
Madtom, smoky	*Noturus baileyi*	U.S.A. (TN)	Entire, except where listed as an experimental population.	E	163	17.95(e)	NA
Do	.....do	.....do	Tellico River, from the backwaters of the Tellico Reservoir (about Tellico River mile 19 (30.4 km)) upstream to Tellico River mile 33 (52.8 km), in Monroe County, TN.	XN		NA	17.84(m)
Madtom, yellowfin	*Noturus flavipinnis*	U.S.A. (TN, VA)	Entire, except where listed as an experimental population.	T	28,317	17.95(e)	17.44(c)
Do	.....do	.....do	N. Fork Holston River Watershed, VA, TN; S. Fork Holston R., upstream to Ft. Patrick Henry Dam, TN; Holston R. downstream to John Sevier Detention Lake Dam, TN; and all tributaries thereto.	XN	317	NA	17.84(e)
Do	.....do	.....do	Tellico River, from the backwaters of the Tellico Reservoir (about Tellico River mile 19 (30.4 km)) upstream to Tellico River mile 33 (52.8 km), in Monroe County, TN.	XN		NA	17.84(e)
*	*	*	* *		*		*

3. Revise § 17.84(e) to read as follows:

§ 17.84 Special rules—vertebrates.

* * * * *

(e) Yellowfin madtom (*Noturus flavipinnis*).

(1) Where is the yellowfin madtom designated as a nonessential experimental population (NEP)?

(i) The North Fork Holston River Watershed NEP Area is within the species' historic range and is defined as follows: The North Fork Holston River watershed, Washington, Smyth, and Scott Counties, Virginia; South Fork Holston River watershed upstream to Ft. Patrick Henry Dam, Sullivan County, Tennessee; and the Holston River from the confluence of the North and South Forks downstream to the John Sevier Detention Lake Dam, Hawkins County, Tennessee. This site is totally isolated from existing populations of this species by large Tennessee River tributaries and reservoirs. As the species is not known to inhabit reservoirs, and it is unlikely that the fish could move 100 river miles through these large reservoirs, the possibility of this population contacting extant wild populations is unlikely.

(ii) The Tellico River NEP Area is within the species' historic range and is defined as follows: The Tellico River, between the backwaters of the Tellico Reservoir (approximately Tellico River mile (TRM) 19 (30.4 kilometers (km))) and TRM 33 (52.8 km), near the Tellico Ranger Station, in Monroe County, Tennessee. This species is not currently known to exist in the Tellico River or its tributaries. Based on the habitat requirements of this species, we do not expect the fish to become established outside this NEP Area. However, if they do move upstream or downstream or into tributaries outside of the designated NEP Area, we will presume that the fish came from the reintroduced populations. We will amend this rule and enlarge the boundaries of the NEP Area to include the entire range of the expanded population.

(iii) We do not intend to change the NEP designations to ''essential experimental,'' ''threatened,'' or ''endangered'' within the NEP Areas. Additionally, we will not designate critical habitat for these NEPs, as provided by 16 U.S.C. 1539(j)(2)(C)(ii).

(2) What activities are not allowed in the NEP Area?

(i) Except as expressly allowed in this paragraph (e), all the prohibitions of § 17.31(a) and (b) apply to the fish identified in this paragraph.

(ii) Any manner of take not described under paragraph (e)(3) of this section is prohibited in the NEP Area. We may refer unauthorized take of these species to the appropriate authorities for prosecution.

(iii) You may not possess, sell, deliver, carry, transport, ship, import, or export by any means whatsoever any of the identified fish, or parts thereof, that are taken or possessed in violation of this paragraph or in violation of the applicable State fish and wildlife laws or regulations or the Act.

(iv) You may not attempt to commit, solicit another to commit, or cause to be committed any offense defined in this paragraph.

(3) What take is allowed in the NEP Area? Take of this species that is accidental and incidental to an otherwise lawful activity, such as fishing, boating, trapping, wading, or swimming, is allowed.

(4) How will the effectiveness of these reintroductions be monitored? We will prepare periodic progress reports and fully evaluate these reintroduction efforts after 5 and 10 years to determine whether to continue or terminate the reintroduction efforts.

* * * * *

4. Amend § 17.84 by adding paragraph (m) to read as follows:

§ 17.84 Special rules—vertebrates.

* * * * *

(m) Spotfin chub (=turquoise shiner) (*Cyprinella* (=*Hybopsis*) *monacha*), duskytail darter (*Etheostoma percnurum*), smoky madtom (*Noturus baileyi*).

(1) Where are these fish designated as nonessential experimental populations (NEPs)?

(i) The NEP Area for the three fishes is within the species' probable historic ranges and is defined as follows: The Tellico River, from the backwaters of the Tellico Reservoir (approximately Tellico River mile (TRM) 19 (30.4 kilometers (km))) to TRM 33 (52.8 km), near the Tellico Ranger Station, in Monroe County, Tennessee.

(ii) None of the fish named in this paragraph (m) are currently known to exist in the Tellico River or its tributaries. Based on the habitat requirements of these fish, we do not expect them to become established outside the NEP Area. However, if any of the species move upstream or downstream or into tributaries outside of the designated NEP Area, we will presume that the fish came from the reintroduced populations. We will amend this paragraph and enlarge the boundaries of the NEP Area to include the entire range of the expanded population.

(iii) We do not intend to change the NEP designations to ''essential experimental,'' ''threatened,'' or ''endangered'' within the NEP Area. Additionally, we will not designate critical habitat for these NEPs, as provided by 16 U.S.C. 1539(j)(2)(C)(ii).

(2) What activities are not allowed in the NEP Area?

(i) Except as expressly allowed in this paragraph, all the prohibitions of § 17.31(a) and (b) apply to the fish identified in this paragraph.

(ii) Any manner of take not described under paragraph (m)(3) of this section is prohibited in the NEP Area. We may refer unauthorized take of these species to the appropriate authorities for prosecution.

(iii) You may not possess, sell, deliver, carry, transport, ship, import, or export by any means whatsoever any of the identified fish, or parts thereof, that are taken or possessed in violation of this paragraph or in violation of the applicable State fish and wildlife laws or regulations or the Act.

(iv) You may not attempt to commit, solicit another to commit, or cause to be committed any offense defined in this paragraph.

(3) What take is allowed in the NEP Area? Take of these species that is accidental and incidental to an otherwise lawful activity, such as fishing, boating, trapping, wading, or swimming, is allowed.

(4) How will the effectiveness of these reintroductions be monitored? We will prepare periodic progress reports and fully evaluate these reintroduction efforts after 5 and 10 years to determine whether to continue or terminate the reintroduction efforts.

Dated: March 20, 2001.

Joseph E. Doddridge,

Acting Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 01–14454 Filed 6–7–01; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AH56

Endangered and Threatened Wildlife and Plants; Proposed Rule To Remove *Potentilla robbinsiana* (Robbins' cinquefoil) From the Endangered and Threatened Plant List

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to remove *Potentilla robbinsiana*, commonly called Robbins' cinquefoil, from the List of Endangered and Threatened Plants. We propose this action because the available data indicate that this species has met the goals for delisting. The main population of the species currently has more than 14,000 plants, and the 2 transplant

populations have reached or surpassed minimum viable population size. The proposed action, if finalized, would remove Potentilla robbinsiana as an endangered species from the List of Endangered and Threatened Plants and would remove the designation of critical habitat.

This proposed rule includes a proposed 5-year post-delisting monitoring plan as required for species that are delisted due to recovery. The plan will include monitoring of population trends of natural and transplant populations.

DATES: Comments from all interested parties on the Potentilla robbinsiana delisting proposal must be received by August 7, 2001. Public hearing requests must be received by July 23, 2001.

ADDRESSES: Comments and other information concerning this proposal to remove Robbins' cinquefoil from the list of endangered species should be sent to Diane Lynch, U.S. Fish and Wildlife Service, Northeast Regional Office, 300 Westgate Center Drive, Hadley, Massachusetts 01035 (facsimile: 413–253–8482). Comments and materials received will be available for public inspection by appointment during normal business hours at the above address.

Comments and suggestions on specific information collection requirements should be sent to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS 224 ARLSQ, 1849 C Street, NW., Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Diane Lynch at the above address, or at 413–253–8628. To request a copy of the information collection request, explanatory information, and related forms, contact 703–358–2287.

SUPPLEMENTARY INFORMATION:

Background

Although its discovery was not formalized until 1840 (Torrey and Gray, 1840), the first recorded collection of *Potentilla robbinsiana* (Robbins' or dwarf cinquefoil) by Thomas Nuttall in 1824 generated a strong interest among botanists and others in this diminutive member of the rose family (*Rosaceae*). Initially, there was confusion as to its taxonomic status, and it was designated as a variety of various European cinquefoils, but it was eventually recognized as a distinct species (Rydberg, 1896).

Potentilla robbinsiana is a long-lived perennial herb. Its hairy three-part compound leaves are deeply toothed, and mature plants form a dense 2–4 centimeter (1–1.5 inch) rosette. Individual plants develop a deep central taproot, which helps to anchor them and resists frost heaving. *Potentilla robbinsiana* is one of the first plants to bloom in the alpine zone where it is found, flowering soon after the snows recede, from late-May to mid-June. Adult plants produce from 1 to 30, 5-petalled yellow flowers on individual stems. The achenes mature by late July, and disperse on dry windy days. These seeds seldom disperse more than 20 cm from the parent plant, which limits natural reestablishment (Kimball and Paul, 1986). The seeds remain dormant for at least one winter, and germination begins the following year during June and July. Although seed viability is generally high, seedling survival is low (Iszard-Crowly and Kimball, 1998).

Various experiments have shown that *Potentilla robbinsiana* produces seed asexually so that seedlings are genetically identical (Lee and Greene, 1986). This species has the chromosome number 49 that allows it to maintain itself through asexual reproduction, which partially explains the low genetic variability found within the sampled population (David O'Malley, personal communication, 2000).

Potentilla robbinsiana is endemic to the White Mountains of New Hampshire and is restricted to two small, distinct areas on lands administered by the White Mountain National Forest. Herbaria collections suggest that historically there may have been a number of small populations in close proximity to these two areas. Currently there are only two natural populations. Reports of occurrences outside of New Hampshire have been discounted (Cogbill, 1993), and records indicate that *Potentilla robbinsiana* has always had a very narrow geographic distribution.

The largest natural population of *Potentilla robbinsiana* occurs on Monroe Flats located just above treeline on a col between Mt. Monroe and Mt. Washington on the Presidential Range. Within this small area (less than 1 hectares (ha) (2 acres)), the population is well established with more than 14,000 plants at present. Considering its local abundance and density at this one location, it is assumed that some of the unique features of Monroe Flats are important habitat requirements for *Potentilla robbinsiana*. Monroe Flats (elev. 1,550 meters (m) (5,115 feet (ft.)) consists of an exposed low dome that is covered with alternating bands of relatively barren small-stoned terraces and thickly vegetated mats. Blowing winds keep the Monroe Flats mostly free of snow and ice throughout the winter, leaving the vegetation exposed to the abrasive action of blowing snow and ice and desiccating winds. The moist barren soils are also susceptible to frost disturbance from freeze-thaw cycles for much of the year. In this extreme environment of moderate solifluction and exposed topography, *Potentilla robbinsiana* fills a narrow niche: it is likely a poor competitor with other species, but is able to thrive in a harsh environment where few other species can survive (Cogbill, 1987).

The second extant natural population occurs on Franconia Ridge, 30 kilometers (km) (8.6 miles (mi)) to the west of the Monroe Flats population. Although still within the alpine zone, the habitat here is markedly different. A handful of plants grow at a site on the south end of the Franconia Ridge in crevices along the side of a vertical cliff just below the ridgeline. Although records indicate that the Franconia population was never very large, it is likely that these few plants are the remnants of a larger population from more suitable habitat that previously existed along the top of the ridge. The habitat has long since eroded and the plants have disappeared due to hiking activity along a ridgeline trail.

Potentilla robbinsiana was listed as endangered on September 17, 1980, and critical habitat encompassing the Monroe Flats population was designated at that time. Overzealous specimen collecting and unregulated hiker disturbance were the reasons for listing. At the time, the extent of the Monroe Flats population was shrinking (Graber and Brewer, 1985) and the Franconia Ridge population was thought to be extirpated.

The first Robbins' Cinquefoil Recovery Plan, completed in 1983, featured two main objectives: to protect the existing Monroe Flats colony, encouraging its expansion to previously occupied habitat; and to establish self-maintaining populations in at least four additional potential habitats not occupied at the time.

To accomplish the first objective, a scree wall surrounding the Monroe Flats population was constructed and posted with ''closed to entry'' signs, and two hiking trails that had previously traveled through the Monroe Flats population were relocated away from the population. Plants have since been successfully transplanted back into the habitat where the trails had resulted in the localized demise of the plants, primarily at the highest locations of the Monroe Flats population. The ability of seed to move downhill from this recolonized site should benefit the Monroe Flats population. In addition, personnel from the White Mountain

National Forest and Appalachian Mountain Club continue to provide stewardship, enforcement, and educational resources on site.

Several tasks were necessary to meet the second objective of establishing four additional self-maintaining transplant populations: (1) Protocols were developed to monitor the Monroe Flats population to better understand its demographic trends and natural rates of recruitment and mortality, and to collect data to model minimum viable population size; (2) the Franconia Notch population (rediscovered in 1984) was annually monitored; (3) micro-habitat components were identified and used to locate unoccupied, potentially suitable habitat; and (4) effective propagation and transplant techniques were developed. Transplant techniques varied over the years. However, the most successful efforts used 2-year-old plants germinated from seed, and transplanted with the soil media intact in mid-June to early July. Each year a portion of the seed collected for use in transplants is placed in cold storage at the New England Wildflower Society to establish a seed bank for this species.

Prior to listing, there had been a number of attempts to establish transplant populations at approximately 20 locations throughout the White Mountains (Graber, 1980). Although some of these efforts showed signs of initial success, all but one eventually failed due to unsuitable habitat or because patches of suitable habitat were too small to support viable populations. The Appalachian Mountain Club Research Department reviewed these efforts, and, using the lessons learned, narrowed recovery efforts to four potential sites as outlined in the updated 1991 recovery plan: two used in the previous transplant efforts and two new ones.

The experience gained from previous transplant efforts and the additional life history and demographic information gathered from ongoing research were used to determine the four most appropriate transplant sites. Two of these chosen sites had previously established transplant populations (Camel Patch and the Viewing Garden), both located on or near Mt. Washington, and two of the sites were unoccupied sites, one on Boott's Spur and one on the Franconia Range near what was thought potentially to be a historic site.

Transplant efforts at these 4 locations began in 1986 with the introduction of 160 plants over 3 years at the Boott's Spur site. The site showed some initial promise, but by 1991 mortality was 100%. Although the Boott's Spur location was recognized as suboptimal habitat and had failed in a previous transplant effort, another 27 plants were transplanted in 1995, but survival was 0% after the first year. The new Franconia population was established in 1988 with 61 plants transplanted over 2 years and an additional 108 plants through 1996, the date of the last transplant efforts. Like the natural populations, this transplant population has fluctuated over the years, but now appears well established with over 331 plants counted in 1999 and good natural recruitment occurring. Of the transplant populations created prior to this species listing, one continues to persist (Camel Patch) and has been supplemented with additional transplants. The transplant records for the Camel Patch by Graber from the 1980s to 1991 were not available, but the Appalachian Mountain Club inventoried this site starting in 1984 when they located 84 plants. Only one of the transplant zones in this habitat showed viable natural reproduction occurring. An additional 6 transplants were done at this location in 1999, which boosted this population to 23 adults, 60 juveniles, and 6 new transplant adults. The Viewing Garden had received 19 known adult transplants from about 1980 through 1997. Though the adults survived for some time, viable natural reproduction was problematic and these individuals died out over time.

The Robbins' Cinquefoil Recovery Plan: First Update, published in 1991, retained recovery criteria for the protection of existing natural populations and establishing additional transplant populations, contained minor changes to incorporate the rediscovered natural Franconia population, and acknowledged that suitable additional unoccupied habitat may be a limiting factor. In addition to the protection of the natural populations, this plan determined that a historically occupied zone within the Monroe Flats should be recolonized. Transplant efforts began in 1996 to meet this objective, and successful juvenile recruitment has since been observed.

To delist *Potentilla robbinsiana*, long-term demographic evidence must show that the Monroe Flats population is stable or increasing in size. Although counts were undertaken in 1973, 1983, and 1992, the methodology used to count the plants differed. The most reliable comparison between the three prior censuses and the most recent census (1999) is the number of plants found that were greater than 14 millimeters (mm.) (0.5 in.) in stemdiameter. Comparing the number of plants greater than 14 mm. in diameter for censuses in 1983, 1992, and 1999 clearly demonstrates that the Monroe Flats population has dramatically increased (Table 1). Transplant efforts in three different zones historically occupied by *Potentilla robbinsiana* began in 1996, and juvenile recruitment has been established in two of the zones.

TABLE 1.—MONROE FLATS CENSUS COUNTS FOR POTENTILLA ROBBINSIANA

Year	Number of plants with stems greater than 14 mm. in diameter	Increase from previous count (Percent)
1999	4,575	36
1992	3,368	118
1983	1,547	−14
1973	1,801	.....

While the 1991 recovery plan still calls for the establishment of four transplant populations, it also recognizes that suitable habitat may be a limiting factor, and requires that only two of the four transplant populations need to be viable. Boott's Spur has subsequently been dropped as a result of the unsuccessful transplant efforts resulting in 100% mortality. The Viewing Garden also reached 100% mortality in 1998. There are no plans to reestablish a population at this location because the suitable habitat is very limited and cannot support more than a few individual plants that are unlikely to persist under natural population fluctuations. Biologists familiar with this species are confident that little if any suitable habitat in the White Mountains remains to be discovered (K. Kimball, Appalachian Mountain Club, pers. comm. 2000). Therefore, given that the discovery of additional suitable habitat for the establishment of new transplant attempts is unlikely, recent efforts have focused on ensuring viable populations at the two remaining transplant locations.

Both the Camel Patch and Franconia Ridge transplant populations have persisted for more than 10 years. Both have juvenile recruitment and successful second generation seedling establishment. Transplant and/or monitoring efforts for these populations continue on a near annual basis (Kimball, 1998). The high level of soil movement throughout Camel Patch makes much of the site unsuitable for transplant efforts, nevertheless a population located along the edge of the encircling vegetation is well established. The Franconia Ridge population has increased dramatically in recent years and is now well established. Although

precise historic records are lacking, even if the present Franconia transplant population happens to be located at a historical location, the amount of suitable habitat would eventually limit the population size.

An 11-year demographic study, funded by us, the U.S. Forest Service, and Appalachian Mountain Club, was conducted along four permanent transects within the Monroe Flats population, in part, to determine a minimum viable population for the transplant populations based on the stage-based survival of the Monroe Flats population. The study recommended a minimum viable population of 50 plants (Iszard-Crowley and Kimball, 1998). Both the Franconia transplant location with a current population of 331 plants and the Camel Patch location with a current population of 87 plants meet this criteria.

Previous Federal Action

Section 12 of the Endangered Species Act of 1973 directed the Secretary of the Smithsonian Institution to prepare a report on those plants considered to be endangered, threatened, or extinct. This report, designated as House Document No. 94–51, was presented to Congress on January 9, 1975. On July 1, 1975, the Director published a notice in the **Federal Register** (40 FR 27823) of his acceptance of the report of the Smithsonian Institution as a petition within the context of section 4(c)(2) of the Act, and of his intention thereby to review the status of the plant taxa named within. On June 16, 1976, the Service published a proposed rulemaking in the **Federal Register** (41 FR 24523) to determine approximately 1,700 vascular plant species to be endangered species pursuant to section 4 of the Act. Comments on this proposal were summarized in the April 26, 1978, **Federal Register** publication of a final rule, which also determined 13 plants to be either endangered or threatened species (43 FR 17909). *Potentilla robbinsiana* was included in the Smithsonian's report, the July 1, 1975, notice of review, and the June 16, 1976, proposal.

The amendment of the Act in 1978 required that all proposals over 2 years old be withdrawn. A 1-year grace period was give to proposals already over 2 years old. On December 10, 1979, we published a notice withdrawing the June 16, 1976, proposal to list *Potentilla robbinsiana*.

Based on sufficient new information, we again proposed *Potentilla robbinsiana* for listing on March 24, 1980, and proposed its critical habitat for the first time (45 FR 19004). A public meeting was held on this proposal on April 28, 1980, in Concord, New Hampshire. On September 17, 1980, we published a final rule in the **Federal Register** (45 FR 61944) listing *Potentilla robbinsiana* as endangered and designating critical habitat.

Summary of Factors Affecting the Species

Section 4 of the Act and regulations (50 CFR part 424) promulgated to implement the listing provision of the Act, set forth the procedures for listing, reclassifying, and delisting species on the Federal lists. A species may be listed if one or more of the five factors described in section 4(a)(1) of the Act threatens the continued existence of the species. A species may be delisted according to 50 CFR 424.11(d), if the best scientific and commercial data available substantiate that the species is neither endangered nor threatened (1) because of extinction, (2) because of recovery, or (3) because the original data for classification of the species were in error.

After a thorough review of all available information, we determined that substantial *Potentilla robbinsiana* recovery has taken place since listing in 1980. We have also determined that none of the five factors identified in section 4(a)(1) of the Act, and discussed below, are currently affecting the species in such a way that the species is endangered (in danger of extinction throughout all or a significant portion of its range) or threatened (likely to become endangered in the foreseeable future throughout all or a significant portion of its range). These factors and their application to Robbin's cinquefoil, *Potentilla robbinsiana* (Torrey and Grey, 1840), are as follows:

A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

Potentilla robbinsiana utilizes a substrate described as a shallow loamy sand topped with a stony, pavement-like surface. This stony surface layer protects the soil from being either blown or washed away. The 1980 final listing rule determined that the plant and its habitat were damaged by trampling from hikers. Hiking through the habitat is unimpeded due to the lack of most vegetation. Because the plants are small, it is easy for hiker boots to crush adult, juvenile, and seedling plants.

Since listing, the threat from trampling has been reduced by rerouting trails and protecting habitat. The section of the Appalachian Trail that bisected the Monroe Flats population is referred to locally as the Crawford Path, named after Abel Crawford who constructed the path in 1819. In 1915, the Appalachian Mountain Club constructed Lakes of the Clouds Hut, 270 m. (295 yards (yd.)) to the north of the trail. The Crawford Path was relocated at this time to bring the trail by the Hut, and although the trail was no longer directly bisecting *Potentilla robbinsiana* habitat, it still went through the northwest corner of the critical habitat. In 1983, the Crawford Path and Dry River Trails were rerouted a second time in response to the Federal listing, to move the trails outside of the plant's critical habitat. A low scree wall was constructed in conjunction with the trail relocation, around the critical habitat, and has been particularly effective in places where the trail abuts critical habitat. Signs posted around the Monroe Flats population notify hikers that there is a federally listed species present and no admittance is allowed without a permit. These signs are replaced as needed. Hiker traffic and trespassers into the critical habitat were recorded by pressure plates during 1985 to assess the effectiveness of hiker management. The plates were operated from June through October 1985 and checked several times weekly. Of 4,286 hikers counted over 115 days the counters were functional, the trespass rate was 2 percent (Kimball and Paul, 1986). The target compliance level established by the 1983 recovery plan was 95 percent of the hikers not trespassing into the critical habitat, an objective that has been maintained or exceeded since 1981. Outreach has also been a strong recovery component for ensuring hiker compliance of no trespassing into the *Potentilla robbinsiana* habitat. A naturalist is stationed at the Lakes of the Clouds Hut throughout the summer. The Hut naturalist is available during the day to answer questions and give interpretive talks regarding *Potentilla robbinsiana*. The naturalist and other Hut staff are also instrumental in monitoring the Monroe Flats population for human disturbance.

In 1973, prior to listing, the Monroe Flats population contained approximately 1,801 individual plants larger than 14 mm. As of 1999, this population included approximately 4,575 individuals of similar size. This represents a greater than 250% increase in this population. Counting plants of all sizes (seedlings to adults) in 1999, the established population size was 14,195 individuals.

The second natural population is near the Appalachian Trail on Franconia Ridge. The location of this population has been purposefully kept undisclosed

and is presently out of the way of the average hiking public.

Records indicated the extant Franconia Ridge population was never very large. Nevertheless, it is considered to be a reproducing population, with 18 individual plants consisting of 4 adults, 13 juveniles, and 1 seedling, as of 1999.

B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

The 1980 final listing identified that the collecting of specimens for herbaria probably contributed to the loss of *Potentilla robbinsiana* and possibly the cause for the extirpation of one of the Franconia sites (Steele, 1964). It was noted that over 40 herbarium sheets containing nearly 100 plants (6 percent of the known mature population at the time of listing) were counted in various New England herbaria (Graber, 1980). Cogbill's more recent paper (1993) documents the collection of over 850 plants in herbaria collections worldwide, which represents one of the most extensive collections known for a single species. However, collection of the species has, to date, not been a threat. Commercial trade in the species occurred in the early 1900s but has not occurred since and is not expected to occur in the future. Import or export of this species also is not anticipated. Therefore, taking of *Potentilla robbinsiana* for these purposes is not considered to be a threat.

C. Disease and Predation

This species is not known to be threatened by disease or predation.

D. The inadequacy of Existing Regulatory Mechanisms.

Potentilla robbinsiana is currently afforded limited protection by the Endangered Species Act. Section 9 of the Act prohibits the removal and possession of endangered plants from lands under Federal jurisdiction and the malicious damage and destruction of endangered plants in such areas, and the damage or destruction of endangered plants from any other area in knowing violation of any State law or regulation, or in the course of a violation of State criminal trespass law. Section 7 of the Act requires Federal agencies to ensure that their actions do not jeopardize the continued existence of listed species or destroy or adversely modify designated critical habitat.

Section 7(a)(1) requires Federal agencies to carry out programs for the conservation of threatened and endangered species. The entire range of *Potentilla robbinsiana* occurs on Forest Service lands. Forest Service regulations prohibit removing, destroying, or damaging any plant that is classified as a threatened, endangered, rare or unique species (36 CFR 261.9). On December 2, 1994, we, the Forest Service, and the White Mountain National Forest, signed a Memorandum of Understanding for the conservation of *Potentilla robbinsiana*. The MOU states that the Forest Service agrees to carry out specific management measures, with our assistance, both through the recovery period, and if and when *Potentilla robbinsiana* is removed from the list of endangered and threatened plants. The MOU further states that the change in the species' legal status will not affect the Forest Service's commitment to implement management programs to promote long-term conservation of this sensitive species regardless of its standing under the Federal Act.

Potentilla robbinsiana does appear on the Forest Service Region 9 list of ''species of concern'' and on the New Hampshire State list, although State legislation currently offers it no protection. However, the State of New Hampshire has a cooperative plant agreement with us as specified under section 6(c)(2) of the Act that allows the State to apply for funds from the Service to aid in the conservation of threatened, endangered, or rare plants.

E. Other Natural or Manmade Factors Affecting its Continued Existence

Recovery efforts have been directed toward protection and environmental education. A number of approaches have been used to educate the hiking public and the scientific community about *Potentilla robbinsiana*. Providing information to the public regarding the species' biology and management satisfies their curiosity and increases their willingness to participate in protection of this species. These efforts include a permanent display and presentations about *Potentilla robbinsiana* by the seasonal Appalachian Mountain Club naturalist at Lakes of the Clouds Hut.

The 1980 final listing rule mentioned that *Potentilla robbinsiana* is vulnerable to the harsh climate in which it lives. The weather regime experienced by the species is highly variable from year to year. During demographic studies over the past 16 years it has been observed that late frosts in June have the potential to damage flowers and greatly reduce the seed crop for that year. By virtue of a deep taproot, the species appears to be adapted to a moderate level of frost-heaving, a stress that may limit competing species. At the same time, it cannot tolerate frost induced movement of more that 18 mm/yr, or frost action sufficient to produce stone stripes or other patterned ground (Cogbill, 1987). Overall, however, this species is now thriving in a very localized part of the alpine zone of the White Mountains, and adapts to the harsh climate conditions, where few other species survive.

Summary of Status

Delisting *Potentilla robbinsiana*, as described in the 1991 updated recovery plan, requires that (1) four transplant colonies are viable, with self-reproducing capability; (2) the Monroe Flats population demonstrates population stability for a full generation; and (3) the two natural existing populations are protected from human disturbance. This delisting objective was based on the best information available at that time. The habitat of the two existing natural populations is protected from human disturbance, and the Monroe Flats population is considered viable and increasing. Though the recovery plan calls for the establishment of four transplant populations, it also recognizes that suitable habitat may be a limiting factor. We have determined that at the two sites where transplanting has proven to be unsuccessful, Boott's Spur and the Viewing Garden, no further attempts to reestablish populations will be considered. Discovery of additional suitable habitat for the establishment of new transplant populations is unlikely, so recent efforts are focusing on maintaining viable populations at the two remaining transplant locations. Two of the three delisting components have been met. It is unlikely additional habitat for future transplants will be found, and achieving the third component is improbable. We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats faced by this species in determining to propose this rule: The threats to the species have been reduced or removed, the number of plants is increasing, the species is not in imminent danger of extinction, and the species appears unlikely to become endangered within the foreseeable future.

Effects of This Rule

If finalized, the proposed action would remove *Potentilla robbinsiana* from the List of Endangered and Threatened Plants. Furthermore, the critical habitat for this plant, one location in the White Mountain National Forest, New Hampshire (50 CFR 17.96(a)), would be removed. The

prohibitions and conservation measures provided by the Act would no longer apply to this species. Therefore, taking, interstate commerce, import, and export of *Potentilla robbinsiana* would no longer be prohibited under the Act. In addition, Federal agencies would no longer be required to consult with us under section 7 of the Act to insure that any action they authorize, fund, or carry out, is not likely to jeopardize the continued existence of *Potentilla robbinsiana* or destroy or adversely modify designated critical habitat.

The take and use of *Potentilla robbinsiana* must comply with appropriate Forest Service regulations, since the entire population lies within the White Mountain National Forest in New Hampshire.

Future Conservation Measures

Section 4(g)(1) of the Act requires that the Secretary of the Interior, through the Service, implement a monitoring program for not less than 5 years for all species that have been recovered and delisted. The purpose of this requirement is to develop a program that detects the failure of any delisted species to sustain itself without the protective measures provided by the Act. If at any time during the 5-year monitoring program, data indicate that protective status under the Act should be reinstated, we can initiate listing procedures, including, if appropriate, emergency listing.

Monitoring

Our Northeast Region will coordinate with the Forest Service, the Appalachian Mountain Club, and State resource agencies to develop and implement an effective 5-year monitoring program to track the population status of *Potentilla robbinsiana*. To detect any changes in the status of *Potentilla robbinsiana*, we will use, to the fullest extent possible, information routinely collected by the Appalachian Mountain Club Research Department and the Forest Service. During the fifth year of the 5-year monitoring period, a quantitative population assessment of the Monroe Flats population will be conducted using transects to further evaluate the stability and health of this population.

It is believed that the two transplanted sites have reached viable population status. However, during the required 5-year monitoring period, transplants at the Camel Patch site will continue annually to supplement the current population or until the habitat is thought to be saturated with plants.

If we determine at the end of the mandatory 5-year monitoring period, and the fifth year population assessment of Monroe Flats, that recovery is complete, and factors that led to the listing of *Potentilla robbinsiana*, or any new factors, remain sufficiently reduced or eliminated, monitoring may be reduced or terminated. If data show that the species is declining or if one or more factors that have the potential to cause a decline are identified, we will continue monitoring beyond the 5-year period and may modify the monitoring program based on an evaluation of the results of the initial 5-year monitoring program, or reinitiate listing if necessary.

Public Comments Solicited

We intend that any final action resulting from this proposal will be as accurate and as effective as possible. Therefore, we solicit comments or suggestions from the public, other concerned governmental agencies, the scientific community, industry, or any other interested party concerning this proposed rule. Comments should be sent to our Northeast Regional Office (see **ADDRESSES** section). We particularly seek comments concerning; biological, commercial trade, or other relevant data concerning any threat, or lack thereof, to this species; and information and comments pertaining to the proposed monitoring program contained in this proposal.

Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the rulemaking record, which we will honor to the extent allowable by law. There may also be circumstances in which we would withhold from the rulemaking 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. Comments and materials received, as well as supporting information used to write this rule, will be available for public inspection, by appointment, during normal business hours at the above address.

The final decision on this proposal for *Potentilla robbinsiana* will take into consideration the comments received by us during the comment period. Such communications may lead to a final regulation that differs from this proposal.

The Act provides for one or more public hearings on this proposal, if requested. Requests must be received within 45 days of the date of publication of this proposal. Such requests must be made in writing and sent to our Northeast Regional Office identified in the **ADDRESSES** section at the beginning of this proposed rule.

Executive Order 12866

This proposed rule is not subject to review by the Office of Management and Budget under Executive Order 12866.

Paperwork Reduction Act

The OMB regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act, require that Federal agencies obtain approval from OMB before collecting information from the public. The OMB regulations at 5 CFR 1320.3(c) define a collection of information as the obtaining of information by or for an agency by means of identical questions proposed to, or identical reporting, record keeping, or disclosure requirements imposed on, 10 or more persons. Furthermore, 5 CFR 1320.3(c)(4) specifies that ''ten or more persons'' refers to the persons to whom a collection of information is addressed by the agency within any 12-month period. For purposes of this definition, employees of the Federal Government are not included.

This rule does not include any collections of information that require approval by OMB under the Paperwork Reduction Act. *Potentilla robbinsiana* occurs entirely on lands administered by the Forest Service and only in one State, New Hampshire. The information needed to monitor the status of *Potentilla robbinsiana* following delisting will be collected primarily by a limited number of personnel from the Forest Service and the Appalachian Mountain Club. We do not anticipate a need to request data or other information from 10 or more persons during any 12-month period to satisfy monitoring information needs. If it becomes necessary to collect information from 10 or more non-Federal individuals, groups, or organizations per year, we will first obtain information collection approval from OMB.

National Environmental Policy Act

We have determined that we do not need to prepare an Environmental Assessment, as defined under the authority of the National Environmental

Policy Act of 1969, in connection with regulations adopted pursuant to section 4(a) of the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

References Cited

A complete list of all references cited herein is available upon request from our Northeast Regional Office (see **ADDRESSES** section).

Author

The primary author of this notice is Diane Lynch, Endangered Species Biologist (See **ADDRESSES** section), and Doug Weihrauch, staff scientist for the Appalachian Mountain Club Research Department, provided assistance with the summary of the biological record for this species.

Lists of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

For the reasons set out in the preamble, we propose to amend part 17, subpart B of chapter I, title 50 Code of Federal Regulations, as set forth below:

PART 17—[AMENDED]

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

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500; unless otherwise noted.

§ 17.12 [Amended]

2. Section 17.12(h) is amended by removing the entry for ''*Potentilla robbinsiana,* Robbins' cinquefoil' under ''FLOWERING PLANTS,'' from the List of Endangered and Threatened Plants.

§ 17.96 [Amended]

Section 17.96(a) is amended by removing the critical habitat entry for ''*Potentilla robbinsiana,* (Robbin's cinquefoil)'' which is under Family Rosaceae.

Dated: May 12, 2001.

Marshall Jones, Jr.,

Director, Fish and Wildlife Service.

[FR Doc. 01–14453 Filed 6–7–01; 8:45 am]

BILLING CODE 4310–55–U

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[I.D. 052201E]

Gulf of Mexico Fishery Management Council; Public Meetings

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

ACTION: Notice of scoping meetings; request for comments.

SUMMARY: The Gulf of Mexico Fishery Management Council (Council) will convene scoping meetings to obtain public comments on essential fish habitat (EFH) issues to be discussed in and potentially added to a Supplemental Environmental Impact Statement (SEIS) for the Council's Generic Essential Fish Habitat Amendment to the Fishery Management Plans of the Gulf of Mexico (EFH Generic Amendment).

DATES: The scoping meetings will be held in June. See **SUPPLEMENTARY INFORMATION** for specific dates and times of the scoping meetings.

ADDRESSES: Written comments on the scope of issues that should be addressed in and potentially added to the SEIS should be sent to and copies of the EFH Generic Amendment are available from the Council. The Council's address is: Gulf of Mexico Fishery Management Council, The Commons at Rivergate, 3018 U.S. Highway 301, North, Suite 1000, Tampa, FL 33619–7015; telephone (813) 228–2815; fax (813) 225–7015. See **SUPPLEMENTARY INFORMATION** for specific dates, locations, and times of the scoping meetings.

FOR FURTHER INFORMATION CONTACT: Dr. Richard Leard, Senior Fishery Biologist, Gulf of Mexico Fishery Management Council; telephone (813) 228–2815.

SUPPLEMENTARY INFORMATION: The scoping meetings will be convened to obtain public comments on the range of issues to be discussed in the SEIS for the EFH Generic Amendment. The Council is especially interested in public views on what alternatives should be considered for the designation of EFH, the identification of Habitat Areas of Particular Concern (HAPC), and the recommendation of management measures to minimize the adverse impacts of fishing activities and gear on identified EFH and HAPC areas.

The Council prepared the EFH Generic Amendment in response to provisions of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). The EFH Generic Amendment identifies and describes EFH for the species managed under the Council's fishery management plans; it also discusses threats to EFH from both fishing and non-fishing activities, discusses EFH conservation and enhancement opportunities, and identifies HAPCs. NMFS partially approved the EFH Generic Amendment in 1999 after conducting Secretarial review under Magnuson-Steven Act procedures. NMFS and the Council previously published a notice in the **Federal Register** (66 FR 15405; March 19, 2001) announcing their intent to prepare a SEIS for the EFH Generic Amendment that will supersede the environmental assessment originally prepared in support of this amendment.

Meeting Dates, Locations, and Times

The scoping meetings will be held at the following dates, locations, and times:

1. Thursday, June 14, 2001, 3 p.m.–5 p.m., Omni Bayfront Hotel, 900 North Shoreline Boulevard, Corpus Christi, TX 78401; telephone (361) 887–1600

2. Friday, June 15, 2001, 1 p.m.–3 p.m., Courtyard by Marriott, 9190 Gulf Freeway, Houston, TX 77017; telephone (713) 910–1700

3. Monday, June 18, 2001, 2 p.m.– 4 p.m., New Orleans Airport Hilton, 901 Airline Drive, Kenner, LA 70062; telephone (504) 469–5000

4. Tuesday, June 19, 2001, 3 p.m.–5 p.m., Imperial Palace Hotel, 850 Bayview, Biloxi, MS 39530; telephone (228) 436–3000

5. Thursday, June 21, 2001, 3 p.m.–5 p.m., National Marine Fisheries Service, 3500 Delwood Beach Road, Panama City, FL 32408; telephone (850) 234–6541

6. Monday, June 25, 2001, 3 p.m.–5 p.m., Holiday Inn Beachside, 3841 North Roosevelt Boulevard, Key West, FL 33040; telephone (305) 294–2571

7. Thursday, June 28, 2001, 3 p.m.–5 p.m., Tampa Airport Hilton, 2225 Lois Avenue, Tampa, FL 33607; telephone (813) 877–6688

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Anne Alford at the Council (see **ADDRESSES**) by June 8, 2001.

Dated: June 4, 2001.

Bruce C. Morehead,

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

[FR Doc. 01–14521 Filed 6–7–01; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[I.D. 052201D]

Western Pacific Fishery Management Council; Public Meetings

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

ACTION: Notice of public meetings/public hearings.

SUMMARY: The Western Pacific Fishery Management Council (Council) Advisory Panels will meet on June 15 and 16, 2001; the Standing Committees will meet on June 18, 2001; and the Council will hold its 110th meeting June 18 through June 21, 2001, in Honolulu, HI.

At the full Council meeting, a public hearing will be held prior to the Council taking final action on its Coral Reef Ecosystem Fishery Management Plan/Draft Environmental Impact Statement (CREFMP/DEIS).

The Council will also be holding a public hearing to accept comments on a proposed action that would implement the prohibitions specified in the Shark Finning Prohibition Act, that was signed by the President in December 2000.

DATES: The meetings and the hearings will be held during June 2001. See **SUPPLEMENTARY INFORMATION** for specific dates, and times for the meetings and the hearings.

ADDRESSES: The meetings and the hearings will be held at the Ala Moana Hotel, 410 Atkinson Drive, Honolulu, HI 96813; telephone: 808–955–4811.

FOR FURTHER INFORMATION CONTACT: Kitty M. Simonds, Executive Director; telephone: 808–522–8220.

SUPPLEMENTARY INFORMATION:

Dates and Locations

Advisory Panels

The Commercial, Recreational, Subsistence/Indigenous, and Ecosystem and Habitat sub-panels will meet jointly on Friday, June 15, 2001, from 8:30 a.m. to 5 p.m. Sub-panels will meet individually on Saturday, June 16, 2001, but will reconvene jointly before the end of the day to finalize recommendations. In addition, the Panels will hear reports from plan teams, the scientific and statistical committee, and other ad hoc groups. Public comment periods will be provided throughout the meetings. The order in which agenda items are addressed may change. The Advisory Panels will meet as late as necessary to complete scheduled business.

The agenda for the Advisory Panel meetings will include the items listed below:

1. Welcome and introductions
2. Overview of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), Council program, and decision-making process, and other applicable laws
3. Role of advisors
4. Report on island area Advisory Group meetings
5. Fisheries data collection and monitoring programs, including the Western Pacific Fisheries Information Network (WesPacFIN) and the Marine Recreational Fishery Survey
6. Research priorities and needs
7. Coral reef management
8. Protected species issues, including turtles, seabirds and marine mammals
9. Enforcement and safety issues
10. American Samoa longline fishery issues
11. Indigenous initiatives, including the Community Development Program, Community Demonstration Projects, cultural take of green sea turtles, and the native Observer program
12. Education and outreach efforts
13. Presentation on fish aggregation devices
14. Sub-panel break-out sessions to discuss issues and develop recommendations
15. Joint panel session to review and finalize recommendations to the Council

Public Hearings

A public hearing will be held at 6 p.m. on June 20, 2001, on upcoming actions with respect to shark finning.

A public hearing will be held at 9:30 a.m. on June 21, 2001, on the CREFMP/DEIS.

Committee Meetings

The following Standing Committees of the Council will meet on June 18, 2001. Enforcement/Vessel Monitoring System (VMS) from 8 a.m. to 10 a.m.; Fishery Rights of Indigenous People from 9 a.m. to 10 a.m.; International Fisheries/Pelagics from 10 a.m. to 12 noon; Precious Corals from 1:30 p.m. to 3 p.m.; Crustaceans from 1:30 p.m. to 3 p.m.; Bottomfish from 3 p.m. to 4:30 p.m; Ecosystem and Habitat from 3 p.m. to 4:30 p.m.; and Executive/Budget and Program from 4:30 p.m. to 6 p.m.

In addition, the Council will hear recommendations from its advisory panels, plan teams, scientific and statistical committee, and other ad hoc groups. Public comment periods will be provided throughout the agenda. The order in which agenda items are addressed may change. The Council will meet as late as necessary to complete scheduled business.

The agenda during the full Council meeting will include the items listed below:

1. Introductions
2. Approval of agenda
3. Approval of 108th and 109th Meeting Minutes
4. Island Reports
   A. American Samoa
   B. Guam
   C. Hawaii
   D. Commonwealth of the Northern Mariana Islands
5. Federal Fishery Agency and Organization Reports
   A. Department of Commerce
   (1) NMFS
   (a) Southwest Region, Pacific Islands Area Office
   (b) Southwest Fisheries Science Center, La Jolla and Honolulu Laboratories
   (2) NOAA General Counsel, Southwest Region
   B. Department of the Interior/U.S. Fish and Wildlife Service
   C. U.S. State Department
6. Enforcement
   A. U.S. Coast Guard activities
   B. NMFS activities
   C. Commonwealth, Territories, and State activities
   D. Archipelago Marine Research Ltd. - digital monitoring
   E. Digital Observer project
   F. Report on Enforcement meeting
   G. Status of Violations
7. VMS
   A. NMFS status of VMS report
   B. USCG request to use VMS for targeting boardings
   C. Report on VMS issues from the Enforcement meeting
8. Hawaiian Monk Seals
   A. Current population trends and factors affecting monk seal populations
   B. Recommendations of the Hawaiian Monk Seal Recovery Team
   C. Bottomfish/monk seal mitigation measures
9. Precious Corals
   A. Status of 1999 framework amendment regarding new harvesting requirements
   B. Status of 2000 framework adjustment regarding Hawaiian Islands exploratory area quota increase

C. Precious Coral DEIS
10. Bottomfish Fisheries
A. Summary of the draft 2000 Bottomfish Annual Report modules
B. Status of the fishery: litigation, biological opinion (BO), Observers
C. Status of DEIS
D. Permit transfer to replacement vessel in the Northwest Hawaiian Islands bottomfish fishery
11. Crustacean Fisheries
A. NMFS plans for proposed charter cruises and model workshop
12. Pelagic Fisheries
A. Fourth quarter 2000 Hawaii and American Samoa longline fishery report
B. American Samoa limited entry
C. Turtle conservation and management
(1) Emergency rule for Hawaii longline fishery, including discussion of the BO, the final environmental impact statement, and the March 30, 2001, Court order modifying the injunction issued pursuant to *Center for Marine Conservation* v. *NMFS.*
(2) Council Turtle Conservation Plan
(3) Turtle research, including NMFS fishing experiment, other research, and turtle dive patterns
(4) Endangered Species Act recommendations from the Chairmen's meeting
D. Seabird conservation and management
E. Preparatory Conference for the establishment of the Western and Central Pacific Fisheries Commission
13. Shark finning
A. Public hearing on shark finning action

In December 2000, Congress enacted and the President signed the ''Shark Finning Prohibition Act'' (Public Law 106-557). The Act amended the Magnuson-Stevens Act to prohibit any person subject to U.S. jurisdiction from (a) engaging in shark-finning (shark-finning means the taking of a shark, removing the fin or fins (whether or not including the tail) of a shark, and returning the remainder of the shark to the sea); (b) possessing shark fins aboard a fishing vessel without the corresponding carcass; and (c) landing shark fins without the corresponding carcass. The rule that is being proposed by NMFS to implement the prohibitions specified in the Act applies to U.S. and foreign fishing vessels and associated businesses that engage in finning or in the buying and selling of fins or providing goods and services to vessels engaged in finning.

14. Ecosystems and Habitat
A. Public and agency comments on CREFMP/DEIS including Rose Atoll, Palmyra, overfishing/maximum sustainable yield (MSY), permits, and other issues
B. Other issues, including status of Northwestern Hawaiian Island Coral Reef Reserve and Advisory Council, and status of request for fisheries disaster relief
C. Public hearing on CREFMP/DEIS

The DEIS was prepared to examine the impacts of implementing the proposed CREFMP. The DEIS also addresses potential problems due to human interactions with coral reefs in the Western Pacific exclusive economic zone (EEZ). Although local regulations control many of the impacts of harvesting nearshore coral reef resources in settled areas, exploitation of the coral reef ecosystem remains relatively uncontrolled in Federal waters of the EEZ. Although these areas have been minimally exploited to date, industry has expressed an interest in expanding fisheries in these areas. In addition, the DEIS was prepared to provide for better understanding of impacts due to natural environmental changes, other FMP-managed fisheries, and non-fishing related impacts such as dredging. To address these problems, four alternatives were examined: (1) No action or status quo; (2) minimal additional protection for coral reef resources; (3) substantial additional protection to coral reef resources (preferred alternative); and (4) maximum additional protection for coral reef resources. The environmental effects of each of the alternatives, management measures, components, and options have been analyzed in the DEIS. In June 2000, the Council adopted a preferred alternative and management options. Management measures proposed in the FMP represent a combination of choices made by the Council based on a comparison of alternatives.

Alternatives were a product of numerous public meetings and meetings of the Council's various advisory bodies. The proposed management measures include: (a) Ddesignating marine protected areas (MPAs), including no-take marine reserves and areas zoned for specific fishing activities allowed only with a special permit; (b) establishing fishing permit and reporting requirements for fishing for coral reef resources in the EEZ; (c) specifying the use of selective, non-destructive gears and methods for harvesting management-unit species; and (d) establishing a framework process to allow for future regulatory adjustments to the coral reef ecosystem management program. In addition, the Council recommends that a formal procedure be established for assessing and controlling ecosystem effects of reef-related fisheries managed under the Fishery Management Plan for the Bottomfish and Seamount Groundfish Fisheries of the Western Pacific Region, the Fishery Management Plan for the Crustacean Fisheries of the Western Pacific Region, and the Fishery Management Plan for the Precious Corals Fisheries of the Western Pacific Region.

15. Fishery Rights of Indigenous People
A. Status of Community Demonstration Projects and Community Development Program
B. Native observer program for Western Pacific fisheries
C. Western Pacific sea turtle conservation plan
D. Status of Marine Conservation Plans
16. Program Planning
A. Report on annual Regional Chairmen and Executive Directors meeting
B. Status of Congressional legislation (Magnuson-Stevens Act and ESA)
C. Report on program planning activities
D. NMFS overfishing/MSY workshop
E. Digital video monitoring policy
F. Education initiatives
G. WesPacFIN/Fisheries Data Coordinating Committee
17. Administrative Matters
A. Administrative reports
B. Upcoming meetings and workshops, including the 111th Council meeting
C. Advisory group member changes

Other Business

Although non-emergency issues not contained in this agenda may come before the Council for discussion, those issues may not be the subject of formal Council action during this meeting. Council action will be restricted to those issues specifically listed in this document and any issue arising after publication of this document that requires emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kitty M. Simonds, 808–522–8220 (voice) or 808–522–8226 (fax), at least 5 days prior to the meeting date.

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

Dated: June 6, 2001.

Richard W. Surdi,

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

[FR Doc. 01–14623 Filed 6–6–01; 3:14 pm]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 010108006–1136–02; I.D. 050101D]

RIN 0648–AO97

Fisheries off West Coast States and in the Western Pacific; Pacific Coast Groundfish Fishery; Amendment 14

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes a rule to implement portions of Amendment 14 to the Pacific Coast Groundfish Fishery Management Plan (FMP). Amendment 14 would create a permit stacking program for limited entry permits with sablefish endorsements. This permit stacking program would lengthen the duration of the limited entry, fixed gear primary sablefish fishery. It is intended to increase safety in that fishery and provide flexibility to participants. Amendment 14 would allow a single vessel to carry up to three permits and fish the sablefish cumulative limits with those permits during the primary sablefish fishery.

DATES: Comments must be submitted in writing by July 9, 2001.

ADDRESSES: Comments on Amendment 14 or supporting documents should be sent to Donna Darm, Acting Administrator, Northwest Region, NMFS, Sand Point Way NE., Seattle, WA 98115–0070; or to Rebecca Lent, Administrator, Southwest Region, NMFS, 501 West Ocean Boulevard, Suite 4200, Long Beach, CA 90802–4213. Copies of Amendment 14 and the environmental assessment/regulatory impact review (EA/RIR) are available from Donald McIsaac, Executive Director, Pacific Fishery Management Council (Council), 2130 SW Fifth Ave., Suite 224, Portland, OR 97201.

FOR FURTHER INFORMATION CONTACT: Yvonne deReynier or Becky Renko (Northwest Region, NMFS), phone: 206–526–6140; fax: 206–526–6736 and; e-mail: *yvonne.dereynier@noaa.gov, becky.renko@noaa.gov* or Svein Fougner (Southwest Region, NMFS) phone: 562–980–4000; fax: 562–980–4047 and; e-mail: svein.fougner@noaa.gov.

SUPPLEMENTARY INFORMATION:

Electronic Access

This **Federal Register** document is also accessible via the Internet at the website of the Office of the Federal Register: http://www.access.gpo.gov/su–docs/aces/aces140.html.

NMFS is proposing this rule to implement Amendment 14 to the FMP, a permit stacking program for limited entry permits with sablefish endorsements. These regulations would lengthen the duration of the major limited entry, fixed gear season for sablefish and provide participation requirements for that season. This proposed rule is based on recommendations of the Council, under the authority of the Pacific Coast Groundfish FMP and the Magnuson Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). Implementing Amendment 14 would significantly increase safety in the fishery, allow individual fishery participants to more fully use their existing vessel capacity, and reduce overall capacity in the primary fixed gear sablefish fishery. The background and rationale for the Council's recommendations are summarized here. Further detail appears in the EA/RIR prepared by the Council for Amendment 14.

Background

For many years, sablefish harvested by the limited entry, fixed gear fleet has been separated into a small, year-round daily trip limit fishery and a two-part ''primary'' fishery. Annually, about 85 percent of the limited entry fixed gear sablefish allocation is taken in the primary fishery. The two parts of the primary fishery have been the ''regular'' season, which was a derby fishery until 1997, and the ''mop-up'' season to take any primary season sablefish not taken in the regular season. Prior to 1997, the Council managed harvest in the regular season by setting the season length short enough to ensure that the fishery would not exceed its quota. During the regular season, there were no cumulative sablefish limits for participating vessels. The mop-up season was commonly 2 weeks in duration, with each participant allowed to fish against a small, vessel-specific cumulative limit. Over time, sablefish fleet capitalization increased and the Council needed to set ever shorter regular seasons to control catch levels. By 1996, the regular season was just 5 days long.

Concern for the safety of participants in the sablefish derby led the Council to develop Amendment 9 to the FMP, a sablefish endorsement program for limited entry permit holders. Amendment 9, implemented in 1997, limited the number of vessels allowed to participate in the primary (regular + mop-up) fixed gear sablefish fishery. Limited entry permit holders with at least 16,000 lb (7,257 kg) of sablefish landed in any one year from 1984 through 1994 received sablefish endorsements. This program was intended to restrict primary fishery participation to those permit holders with historical participation in and dependence upon the sablefish fishery. Today, 164 limited entry permit holders have sablefish endorsements.

The Council saw the sablefish endorsement as a first step in improving management of the limited entry, fixed gear primary sablefish fishery. In 1998, NMFS implemented the Council's next step, which was to manage the season with a three-tiered cumulative limit regime (63 FR 38101, July 15, 1998.) For the three-tier system, the Council divided sablefish endorsement holders into three tiers based on historical landings associated with their permits. During the limited entry fixed gear regular season, a participant has been allowed to land an amount of sablefish up to the cumulative limit associated with his/her permit's tier.

To qualify for the highest tier, Tier 1, a permit had to be associated with at least 898,000 lb (407.33 mt) of sablefish landings made from 1984 through 1994. To qualify for the middle tier, Tier 2, a permit had to be associated with between 380,000 lb (172.36 mt) and 897,999 lb (407.33 mt) of sablefish landings made from 1984 through 1994. Permits with sablefish endorsements that were associated with less than 380,000 lb (172.36 mt) of sablefish landings from 1984 through 1994 qualified for the lowest tier, Tier 3. The three-tier system also set a between-tier ratio to describe the relationship between the cumulative limits that would be available to each tier during the regular season. That ratio is 1 (Tier 3): 1.75 (Tier 2):3.85 (Tier 1). For example, if Tier 3 had a cumulative limit of 10,000 lb (4,536 kg), Tier 2 would have a corresponding cumulative limit of 17,500 lb (7,938 kg), and Tier 1 would have a corresponding cumulative limit of 38,500 lb (17,463 kg).

The three-tier system has been in place since the 1998 season and has somewhat slowed the pace of the fishery and the rate of capitalization in the fishery. Vessels owners no longer have an incentive to increase their fishing speed because they are limited in how much sablefish they can catch by the tiered cumulative limits. Even under the three-tier system, however, the Council continued to constrain regular season

harvest by setting a short duration season, followed by the longer mop-up season. Three-tier system regulations set the regular fishery at no more than 10 days in duration.

A fishery where all participants have the opportunity to catch a cumulative limit and are all able to catch that limit is an Individual Fishing Quota (IFQ) fishery as defined by the Magnuson-Stevens Act. The Magnuson-Stevens Act includes a moratorium on the implementation of new IFQ programs. To avoid having its three-tier management program classified as an IFQ program, the Council set short season lengths intended to prevent all participants from catching their cumulative limits. Cumulative limits were also set high, to ensure that some participants would not attain those limits during the short season. To provide a resource conservation buffer against the possibility that more vessels than expected would meet their cumulative limits in the regular season, the Council set season lengths and cumulative limits to take 80–87 percent of the primary season quota. Any quota not taken in the regular season as a result of this buffer was available during the mop-up season as an equal cumulative limit for all participating vessels. This conservative management provision successfully kept the primary season within its quota for the 1998–2000 three-tier seasons.

The moratorium on new IFQ programs has been extended to October 1, 2002 (Pub. L. 106-553.) However, Congress exempted from the moratorium a Pacific Council IFQ program for the fixed gear sablefish fishery that: (1) allows the use of more than one limited entry groundfish permit per vessel; and/or (2) sets cumulative trip limit periods, up to 12 months in any calendar year, that allow fishing vessels a reasonable opportunity to harvest the full amount of the associated trip limits. At its November 2000 meeting, the Council recommended a permit stacking program that met the moratorium exemption requirements.

Permit Stacking and Amendment 14

Amendment 14 to the FMP, which the Council adopted at its November 2000 meeting, would introduce a permit stacking program to the limited entry, fixed gear primary season. Under this permit stacking program, a vessel owner would be allowed to register more than one sablefish-endorsed permit for use with his/her vessel to harvest the cumulative limits associated with each of the stacked permits. This is referred to as stacking permits. Current groundfish regulations associate cumulative limits with vessels, so that no vessel may take more than one cumulative limit of a particular species during a single cumulative limit period. Amendment 14 would associate the sablefish cumulative limits of the three-tier system with permits. A vessel carrying more than one permit could harvest more than one sablefish cumulative limit per cumulative limit period.

By exempting the Pacific Coast fixed gear permit stacking program from the IFQ moratorium, Congress removed the need to set short seasons designed to prevent participants from catching their full cumulative limits. The initial season recommendation is for an April through October season, which would allow participants ample time to catch their full sablefish cumulative limits. In 2001, the season would run from August 15 through October 31, a significant improvement over the brief seasons of past years. Under Amendment 14, the primary season would no longer be separated into regular and mop-up sub-seasons because the Council would simply divide the overall quota available to the fishery among the participants with the expectation that each vessel would be able to take its cumulative limits. With this increased harvest control, the Council would not need to use the traditional buffer of a mop-up season to prevent over-harvest in a regular season. Amendment 14 would also eliminate the need for the pre- and post-season closure periods that the Council used to control regular season sablefish harvest rates. The 48-hour pre-season closure requires that all participating vessels keep their gear out of the water, to prevent vessels from fishing in advance of the start time. The 36-hour post-season closure allows vessels to fish up until the last minute of the season end time, and then unload their catch during the closure period without penalty.

Beyond the basic provisions of allowing vessels to harvest more than one sablefish cumulative limit during the season and lengthening the season, Amendment 14 includes numerous provisions for managing the permit stacking program. There is not enough time to implement all of these provisions for the 2001 season. The provisions not included in this proposed rule will be implemented for the 2002 season by another rule.

Gear Endorsements

Each limited entry permit has a gear endorsement for trawl, longline, or pot. Most permits have only one gear endorsement, although there are a few with more than one gear endorsement. A permit's gear endorsement indicates the gear that a vessel registered to the permit may use to participate in the limited entry fishery. Of the 164 permits with sablefish endorsements, 131 permits have longline endorsements, 1 has both a longline and trawl endorsement, 27 have pot endorsements, 1 has both a pot and trawl endorsement, and 4 have both longline and pot endorsements. The relatively small number of pot permits limits the permit market for vessels that fish with pot gear. In developing Amendment 14, the Council decided that it wanted to provide flexibility for vessel owners wishing to stack permits, regardless of whether they use longline or pot gear.

Amendment 14 would allow a vessel owner to stack permits with different gear endorsements together, allowing the vessel to fish for sablefish with any of the fixed gears endorsed on at least one of the stacked permit. For example, a pot vessel could own a pot permit with a sablefish endorsement and a longline permit with a sablefish endorsement, and then fish against the cumulative limits associated with each permit using pot gear. A vessel could not participate in the primary sablefish fishery using any gear other than the fixed gear indicated on at least one of the permits associated with that vessel. If one of the permits registered for use with a vessel includes a trawl endorsement in addition to the required fixed gear endorsement, and if that permit's length endorsement is equal to or greater than that of the base permit, the vessel may continue to use trawl gear, but not in the fixed gear fishery. In such a case, if the permit is registered for use with a vessel more than 5 ft (1.52 m) shorter than the length endorsement on the trawl endorsed permit, the trawl endorsed permit would not be subject to trawl permit size reduction requirements at § 660.333 (h)(2). These provisions would be implemented for the 2001 fishery via this action.

Separating and ''Unstacking'' Permits

Under Amendment 14, a permit owner who has stacked multiple permits on a single vessel may separate, or ''unstack,'' those permits from each other and transfer those permits individually to another vessel. That is, once two or more permits have been stacked together, they are not required to remain permanently stacked. The Council supported this provision because it will allow permit holders flexibility for moving permits within the fleet. If Amendment 14 had required stacked permits to remain permanently

stacked, it would have been more effective at permanently removing effort from the sablefish fishery. However, Council members felt that a requirement for permanent stacking would have been a disincentive to stack permits, particularly because there is uncertainty whether permits will include other species endorsements or IFQs in the future. Thus, this provision of Amendment 14 is intended to provide an incentive for vessels to stack permits to decrease the number of vessels in the fishery, while allowing permit holders flexibility for the future.

As discussed earlier, the permit stacking program would associate sablefish cumulative limits in the primary fishery with permits rather than with vessels. This means that if a vessel owner unstacks and transfers a permit associated with his/her vessel during the primary season, the next vessel using that permit would only have access to that portion of the sablefish cumulative limit not caught by the first vessel. Provisions to allow unstacking and to require association of cumulative limits with permits for purposes of transferring permits with sablefish endorsements would be implemented for the 2001 season via this action.

Ownership Controls

One of the Council's concerns in developing Amendment 14 was that, without controls, a permit stacking program could allow a few permit owners to control most of the sablefish catch and landings in the primary fishery. In IFQ programs where percentage of ownership has not been restricted, like the Atlantic surf clam fishery, a few large corporations own most of the access privileges for the fishery. The Council wanted to maintain the traditional character of the primary sablefish fishery, which has historically consisted of small business owners operating vessels throughout the length of the West Coast.

In 2000, approximately 139 vessels participated in the primary fishery. During the 2000 primary season, 136 people owned sablefish endorsed permits, which meant that some persons owned more than one of the 164 sablefish endorsed permits. As of November 1, 2000, 2 people owned 5 permits, 3 people owned 3 permits, and 14 people owned 2 permits. The Council included several provisions in Amendment 14 intended to prevent a small number of permit owners from controlling access to the primary sablefish fishery.

First, Amendment 14 would allow permit holders to stack no more than three permits on any one vessel. As there are 164 permits with sablefish endorsements, the restriction to no more than three permits per vessel would make the minimum fleet size 55 vessels. Permit transfers must be made through the NMFS Northwest Region Fisheries Permits Office, so the agency will be able to track the number of permits registered for use with each vessel participating in the fishery. This provision would be implemented for the 2001 season through this proposed action.

Second, no person would be allowed to have ownership interest in more than three permits with sablefish endorsements. Both persons owning a whole permit outright and persons owning a portion of a corporation or partnership where the corporation or partnership is the permit-owning entity would be subject to this provision. When the Council finalized Amendment 14, there were some permit owners who already owned more than three permits. People (including partnerships and corporations) who had an ownership interest in more than three permits with sablefish endorsements on November 1, 2000, would not be allowed to accumulate more permits, but neither would they be required to sell their excess permits. NMFS announced this restriction in an Advance Notice of Proposed Rulemaking on April 3, 2001 (66 FR 17681). This ''grandfathering'' of the privilege to own more than three permits would last only for as long as a permit holder owns the particular permits that he/she owned as of November 1, 2000. This provision would be implemented for the 2001 season in that the Fisheries Permits Office will monitor ownership levels with information that it can obtain from public records. NMFS will collect ownership information on permit-owning partnerships and corporations during the 2002 season.

Third, only individual (human) persons would be allowed to own limited entry permits with sablefish endorsements. Corporations and partnerships that owned permits with sablefish endorsements as of November 1, 2000, could continue to own the permits as corporations and partnerships. Exemptions for a particular corporation or partnership that owned permits on November 1, 2000, would cease with a change in the identity of that corporation or partnership. Amendment 14 requires that permits be owned by individuals to increase the probability that harvest privileges would remain under the ownership of fishers within local fishing communities. Requiring that permits be owned by an individual would not restrict other aspects of the business operation from being organized as a partnership, corporation or other type of legal entity. This provision would be implemented for the 2001 season in that the Fisheries Permits Office would not transfer a permit to a partnership or corporation that did not own a permit as of November 1, 2000. This provision will be fully implemented for the 2002 season by another rule.

Fourth, Amendment 14 would require that permit owners be on board the vessel when the vessel is participating in the primary sablefish fishery. Persons, partnerships or corporations who were owners of permits with sablefish endorsements as of November 1, 2000, would again have the grandfathered privilege to be exempt from this requirement. During the primary fishery, grandfathered permit owners would not have to be on board the vessel during the primary fishery. However, permit owners acquiring permits after November 1, 2000, would be required to be on board the vessel while participating in the primary fishery. This provision is intended to ensure that permits are owned by persons within the fishing community who will fish their permits, rather than leasing them out to others. Like the requirement that permit owners be individual human persons, the owner-on-board requirement is designed to retain the character of the fishery as one populated by small businessmen who work their own vessels, rather than allow absentee owners to control the fishery. Amendment 14 allows NMFS to grant exemptions from the owner-on-board requirement for medical and personal emergencies beyond the control of the permit owner. NMFS does not have time to implement the owner-on-board requirement for the 2001 season. This requirement will be implemented for the 2002 season by another rule.

Cumulative Limits for Groundfish Fisheries Outside of the Primary Sablefish Fishery

Under Amendment 14, only the tiered sablefish cumulative limits for the primary fishery would be associated with permits rather than with vessels. This means that a vessel with more than one permit will still be allowed only one cumulative limit per cumulative limit period of any species except sablefish taken in the primary fishery. Vessels participating in the daily trip limit fishery for sablefish will also be subject to a single daily trip limit and a single monthly or two-month cumulative limit per vessel. These provisions are intended to allow the

permit stacking program to consolidate some of the effort in the groundfish fishery. A vessel owner who wishes to carry more than one permit on his/her vessel will have to buy or lease a permit from another vessel owner. The vessel owner who sells or leases his permit would be removing his/her vessel from the entire groundfish fishery while the recipient vessel owner will only be able to harvest multiple cumulative limits in the primary sablefish fishery. Thus, permit stacking will result in fewer limited entry vessels participating in groundfish fisheries for species other than sablefish. This provision would be implemented for the 2001 season.

Daily Trip Limit Fishery for Sablefish

Under Amendment 9 to the FMP, the limited entry sablefish daily trip limit fishery may not occur during either the regular or mop-up seasons that make up the limited entry, fixed gear primary sablefish fishery. This provision was essentially an enforcement measure intended to prevent permit holders without sablefish endorsements from trying to access the larger sablefish cumulative limits associated with the regular and mop-up fisheries. However, the effect of that provision has mainly been to eliminate some of the confusion of having multiple unendorsed vessels on the water during the rapid pace derby. Most enforcement activities occur after the fact, when investigators check landings records and processor receipts to ensure that vessels are landing amounts appropriate to their permits. At-dock enforcement efforts would include checking permits for sablefish endorsements and any suspected forgery would be investigated after the landing.

Restricting unendorsed vessels to participating in the daily trip limit fishery only outside of the regular and mop-up seasons is not overly burdensome when those fisheries together take up 3–4 weeks per year. Under Amendment 14, however, the primary season would be 3 months duration in 2001 and 6 months duration in 2002 and beyond. To ensure that the limited entry daily trip limit fishery could continue throughout the longer primary season, Amendment 14 removed the Amendment 9 prohibition. This change is not expected to significantly affect enforcement practices and will relieve a burden for permit holders wishing to participate in the daily trip limit fishery. This provision would be implemented for the 2001 season.

Processing Sablefish At Sea

Amendment 14 would prohibit participants in the primary sablefish fishery from processing their sablefish at sea. A longer sablefish season would give vessels the opportunity to slow their fishing operations and have more time to dress their catch. Many sablefish fishers dress their catch at sea, removing the head and entrails from the sablefish before landing it at processing plants. Most West Coast sablefish is sold frozen in headed-and-gutted form to Japanese markets. Processing a sablefish involves either receiving a whole fish and heading and gutting it or receiving a headed-and-gutted fish, and then further cleaning and bleeding the headed-and-gutted fish. These headed-and-gutted, cleaned fish are glazed with an ice-water wash and then frozen for market. Although processing sablefish that is already headed-and-gutted is not as demanding as processing species that require filleting, processors ensure that West Coast marketed sablefish meets the high standards of Japanese fish buyers.

In prohibiting primary fishery participants from landing processed sablefish, the Council wished to ensure that allowing a longer sablefish primary season would not deprive processing plants of a traditional income opportunity. The Council also wanted to discourage the large longlining catcher-processors that operate off Alaska from entering into the West Coast sablefish fishery. In addition to changing the character of the fishery and eliminating an income opportunity for shore-based processors, allowing at-sea processing could complicate efforts to monitor sablefish landings. A vessel that processes its catch at sea could also sell that fish at sea, which could make enforcement of individual vessel quotas difficult. This prohibition would not preclude a primary fishery participant from processing his/her sablefish catch once that catch has been landed on shore, and then marketing that catch without the aid of a processing plant.

In past primary fisheries, very few vessels have landed fully processed sablefish. Because there are some permit owners that have done so, however, the Council wished to also provide grandfathering privileges to exempt those permit owners from the prohibition on at-sea sablefish processing. Amendment 14 would allow permit owners who can prove that they landed at least 2,000 lb (907 kg) of frozen sablefish in one year of 1998, 1999, or 2000 to continue to land processed or frozen sablefish in future primary fisheries. NMFS does not have enough time to determine a permit owner's qualification for the grandfathered privilege to land frozen sablefish for the 2001 season. Thus, for 2001, primary fishery vessels would not be prohibited from processing their sablefish catch at sea. This prohibition and the associated grandfathering allowance will be implemented for the 2002 season by another rule.

Fees

NMFS is required under Section 304(d)(2) of the Magnuson-Stevens Act to collect fees from participants in an IFQ program to recover the actual costs directly related to the management and enforcement of the program. These fees shall not exceed 3 percent of the ex-vessel value of sablefish harvested under this IFQ program, to be collected as landings fees. NMFS has not yet analyzed the cost of managing and enforcing this program and will be better able to predict this cost with data from the 2001 primary season. This required fee system will be implemented for the 2002 season by another rule.

Classification

At this time, NMFS has not determined whether Amendment 14, which this proposed rule would implement, is consistent with the national standards of the Magnuson-Stevens Act and other applicable laws. NMFS, in making that determination, will take into account the data, views, and comments received during the comment period.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

The Council prepared an initial regulatory flexibility analysis that describes the effect this proposed rule, if adopted, would have on small entities as follows:

This proposed rule would primarily affect the owners of the 164 limited entry permits with sablefish endorsements, with some minor positive effects on the 66 permit holders without sablefish endorsements. These permit holders use longline or pot gear to participate in the limited entry, primary sablefish fishery. Most sablefish endorsed longline vessels are under 50 ft(15.24 m) in length while most sablefish endorsed pot vessels are over 50 ft (15.24 m) in length. While there is a statistical relationship between size of vessel and amount of sablefish harvest, there are smaller sablefish vessels (under 40 ft) (12.192 m) that catch as much and more than larger vessels each year. All of the permit owners and vessels in the Pacific Coast, limited entry, fixed gear fleet are considered

small entities under Small Business Administration (SBA) standards.

Amendment 14 would significantly improve the safety of the primary fishery for participating vessels. Under the current management system, the primary fishery is less than 10 days long- a brief and intense fishery. This proposed rule would lengthen the fishery to 3 months duration in 2001 and a rule to be implemented in 2002 would extend the season to 6 months duration for the future. Participants would have the opportunity to fish against their tiered cumulative limits at a more safe and rational pace than in past years. Changes to expenses associated with participating in the fishery could be both positive and negative. Vessel owners would likely hire fewer crew members if they do not have to fish in the same rapid-pace manner. Similarly, participants would have fewer gear costs, because they would not be trying to maximize catch over a brief period. However, if these vessel owners catch their cumulative limits over a longer period of time, they may take more trips to do so and thereby use more fuel to catch the same amount of fish. The major financial benefit to fishery participants would be that they would have more flexibility in deciding where and how to distribute operating expenses.

Permit owners who decide to purchase additional permits to have access to more sablefish within the primary season will have to contend with the initial cost of those additional permits. Some of the permit owners who have not participated in the primary season in past years may decide to sell their permits and will receive compensation for leaving the fishery.

In the past, limited entry permit holders without sablefish endorsements have been prohibited from participating in the daily trip limit fishery during the primary (regular + mop-up) season. Amendment 14 would revise the FMP to allow the daily trip limit fishery to occur during the primary season. This change would relieve a burden for limited entry permit holders without sablefish endorsements and allow them to schedule their sablefish fishing at their convenience.

On the whole, Amendment 14 is expected to bring greater operational safety and more business planning flexibility to the participants in both the primary sablefish fishery and the daily trip limit fishery for sablefish. A copy of the RFA analysis for this action is available from the Council (see **ADDRESSES**).

List of Subjects in 50 CFR Part 660

Administrative practice and procedure, American Samoa, Fisheries, Fishing, Guam, Hawaiian Natives, Indians, Northern Mariana Islands, Reporting and recordkeeping requirements.

Dated: June 4, 2001.

William T. Hogarth,

Acting Assistant Administrator for Fisheries, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 660 is proposed to be amended as follows:

PART 660—FISHERIES OFF WEST COAST STATES AND IN THE WESTERN PACIFIC

l. The authority citation for part 660 continues to read as follows:

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

2. In § 660.302, a new definition for ''Ownership interest'' is added to read as follows:

§ 660.302 Definitions.

* * * * *

Ownership interest, with respect to a sablefish endorsed permit, means participation in ownership of a corporation, partnership or other entity that owns a sablefish endorsed permit. Participation in ownership does not mean owning stock in a publicly owned corporation.

* * * * *

3. In § 660.306, paragraphs (s) and (t) are revised to read as follows:

§ 660.306 Prohibitions.

* * * * *

(s) Take, retain, possess or land sablefish under the cumulative limits provided for the ''primary'' limited entry, fixed gear sablefish season, described in § 660.323(a)(2), from a vessel that is not registered to a limited entry permit with a sablefish endorsement.

(t) Take, retain, possess, or land more than a single cumulative limit of a particular species, per vessel, per applicable cumulative limit period, except for sablefish taken in the ''primary'' limited entry, fixed gear sablefish season from a vessel authorized under § 660.323 (a)(2)(i) to participate in that season, as described at § 660.323(a)(2)(ii)(C).

* * * * *

4. In § 660.323, paragraph (a)(2) is revised to read as follows:

§ 660.323 Catch restrictions.

(a) * * *

(2) *Fixed gear sablefish.* This paragraph (a)(2) applies to the primary season for the fixed gear limited entry sablefish fishery north of 36° N. lat., except for paragraph (a)(2)(iii) of this section, which also applies to the open access fishery north of 36° N. lat. Limited entry and open access fixed gear sablefish fishing south of 36° N. lat. is governed by routine management measures imposed under paragraph (b) of this section.

(i) *Sablefish endorsement.* A vessel may not participate in the primary season for the fixed gear limited entry fishery, unless the vessel's owner holds (by ownership or otherwise) at least one limited entry permit for that vessel, affixed with both a gear endorsement for longline or trap (or pot) gear, and a sablefish endorsement. Permits with sablefish endorsements are assigned to one of three tiers, as described at § 660.336.

(ii) *Primary season—limited entry, fixed gear sablefish fishery.* (A) *Season dates.* North of 36° N. lat., the primary sablefish season for limited entry, fixed gear vessels will begin on August 1 and end on October 31. Unless otherwise announced, the primary season will begin and end at 12 noon, l.t.

(B) *Gear type.* During the primary season and when fishing against primary season cumulative limits, each vessel authorized to participate in that season under paragraph (a)(2)(i) of this section may fish for sablefish with any of the gear types, except trawl gear, endorsed on at least one of the permits registered for use with that vessel.

(C) *Cumulative limits.* (*1*) A vessel participating in the primary season will be constrained by the sablefish cumulative limit associated with each of the permits registered for use with that vessel. The Regional Administrator will annually calculate the size of the cumulative trip limit for each of the three tiers associated with the sablefish endorsement such that the ratio of limits between the tiers is approximately 1:1.75:3.85 for Tier 3: Tier 2: and Tier 1, respectively. The size of the cumulative trip limits will vary depending on the amount of sablefish available for the primary fishery. The size of the cumulative trip limits for the three tiers in the primary fishery will be announced in the **Federal Register** each year before the fishery opens.

(2) During the primary season, each vessel authorized to participate in that season under paragraph (a)(2)(i) of this section may take, retain, possess, and land sablefish, up to the cumulative limits for each of the permits registered for use with that vessel. If multiple limited entry permits with sablefish endorsements are registered for use with a single vessel, that vessel may land up

to the total of all cumulative limits announced in the **Federal Register** for the tiers for those permits, except as limited by paragraph (a)(2)(ii)(c)(*3*) of this section. Up to 3 permits may be registered for use with a single vessel during the primary season; thus, a single vessel may not take and retain, possess or land more than 3 primary season sablefish cumulative limits in any one year. A vessel registered for use with multiple limited entry permits is subject to per vessel limits for species other than sablefish, and to per vessel limits when participating in the daily trip limit fishery for sablefish under paragraph (a)(2)(iii) of this section.

(3) If a permit is registered to more than one vessel during the primary season in a single year, the second vessel may only take the portion of the cumulative limit for that permit that has not been harvested by the first vessel to which the permit is registered. The combined primary season sablefish landings for all vessels registered to that permit may not exceed the cumulative limit for the tier associated with that permit.

(4) A cumulative trip limit is the maximum amount of sablefish that may be taken and retained, possessed, or landed per vessel in a specified period of time, with no limit on the number of landings or trips.

(iii) *Limited entry daily trip limit fishery.* (A) Before the start of the primary season, all sablefish landings made by a vessel authorized under paragraph (a)(2)(i) of this section to participate in the primary season will be subject to the restrictions and limits of the limited entry daily trip limit fishery for sablefish, which is governed by routine management measures imposed under paragraph (b) of this section.

(B) Following the start of the primary season, all landings made by a vessel authorized under paragraph (a)(2)(i) of this section to participate in the primary season will count against the primary season cumulative limit(s) associated with the permit(s) registered for use with that vessel. Once a vessel has reached its total cumulative allowable sablefish landings for the primary season under paragraph (a)(2)(ii)(C) of this section, any subsequent sablefish landings by that vessel will be subject to the restrictions and limits of the limited entry daily trip limit fishery for sablefish for the remainder of the calendar year.

(C) Vessels registered for use with a limited entry, fixed gear permit that does not have a sablefish endorsement may participate in the limited entry, daily trip limit fishery for as long as that fishery is open during the year, subject to routine management measures imposed under paragraph (b) of this section.

(D) Open access vessels may participate in the limited entry, daily trip limit fishery for as long as that fishery is open during the year, subject to the routine management measures imposed under paragraph (b) of this section.

(iv) *Trip limits.* Trip and/or frequency limits may be imposed in the limited entry fishery on vessels that are not participating in the primary season, under paragraph (b) of this section. Trip and/or size limits to protect juvenile sablefish in the limited entry or open-access fisheries also may be imposed at any time under paragraph (b) of this section. Trip limits may be imposed in the open-access fishery at any time under paragraph (b) of this section.

* * * * *

5. In § 660.333, paragraphs (a), (f)(1), and (h)(1)(i) are revised, and new paragraphs (h)(3) and (j) are added to read as follows:

§ 660.333 Limited entry fishery—general.

(a) *General.* Participation in the limited entry fishery requires that the owner of a vessel hold (by ownership or otherwise) a limited entry permit affixed with a gear endorsement registered for use with that vessel for the gear being fished. A sablefish endorsement is also required for a vessel to participate in the primary seasons for the nontrawl, limited entry sablefish fishery, north of 36° N. lat. There are three types of gear endorsements: trawl, longline, and pot (or trap.) More than one type of gear endorsement may be affixed to a limited entry permit. While participating in the limited entry fishery, the vessel registered to the limited entry permit is authorized to fish the gear(s) endorsed on the permit. While participating in the limited entry, primary fixed gear fishery for sablefish described at § 660.323(a)(2), a vessel registered to more than one limited entry permit is authorized to fish with any gear, except trawl gear, endorsed on at least one of the permits registered for use with that vessel. During the limited entry fishery, permit holders may also fish with open access gear; except that vessels fishing against primary sablefish season cumulative limits described at § 660.323(a)(2)(ii)(C) may not fish for sablefish with open access gear.

* * * * *

(f) *Transfers.* * * *

(1) The permit owner may convey (by sale, assignment, lease, bequest, intestate succession, barter, trade, gift, or other form of conveyance) the limited entry permit to a different person. The new permit owner will not be authorized to use the permit until the change in permit ownership has been registered with and approved by the SFD. The SFD will not approve a change in permit ownership for limited entry permits with sablefish endorsements that does not meet the ownership requirements for those permits described at § 660.336(e).

* * * * *

(h) *Vessel size endorsements*—(1) *General.* (i) If the permit is registered for use with a trawl vessel that is more than 5 ft (1.52 m) shorter than the size for which the permit is endorsed, it will be endorsed for the size of the smaller vessel. This requirement does not apply to a permit with a sablefish endorsement that is endorsed for both trawl and either longline or pot gear and which is registered for use with a longline or pot gear vessel for purposes of participating in the limited entry primary fixed gear sablefish fishery described at § 660.323(a)(2).

* * * * *

(3) *Size endorsement requirements for sablefish endorsed permits.* Notwithstanding paragraphs (h)(1) and (2) of this section, when multiple permits are ''stacked'' on a vessel as described in paragraph (j) of this section, only one of the permits must meet the size requirements of those sections. Any additional permits that are stacked for use with a vessel participating in the limited entry primary fixed gear sablefish fishery may be registered for use with a vessel more than 5 ft (1.52 m) longer or shorter than the size endorsed on the permit.

* * * * *

(j)*''Stacking'' Limited Entry Permits.* ''Stacking'' limited entry permits, refers to registering more than one permit for use with a single vessel. Only limited entry permits with sablefish endorsements may be ''stacked.'' Up to three limited entry permits with sablefish endorsements may be registered for use with a single vessel during the primary sablefish season described at § 660.323(a)(2)(ii). Privileges, responsibilities, and restrictions associated with stacking permits to participate in the primary sablefish fishery are described at § 660.323(a)(2) and at § 660.336(e).

6. In § 660.336, paragraphs (a) and (e) are revised to read as follows:

§ 660.336 Limited entry permits—sablefish endorsement and tier assignment.

(a) *General.* Participation in the limited entry fixed gear sablefish fishery during the primary season described in

§ 660.323 (a)(2) north of 36° N. lat., requires that an owner of a vessel hold (by ownership or lease) a limited entry permit, registered for use with that vessel, with a longline or trap (or pot) endorsement and a sablefish endorsement. Up to three permits with sablefish endorsements may be registered for use with a single vessel. Limited entry permits with sablefish endorsements are assigned to one of three different cumulative trip limit tiers, based on the qualifying catch history of the permit.

* * * * *

(e) *Ownership requirements and limitations.* (1) No partnership or corporation may own a limited entry permit with a sablefish endorsement unless that partnership or corporation owned a limited entry permit with a sablefish endorsement on November 1, 2000. Otherwise, only individual human persons may own limited entry permits with sablefish endorsements.

(2) No person, partnership, or corporation may have ownership interest in more than three permits with sablefish endorsements, except for persons, partnerships, or corporations that had ownership interest in more than 3 permits with sablefish endorsements as of November 1, 2000. The exemption from the maximum ownership level of 3 permits only applies to ownership of the same permits that were owned on November 1, 2000. Persons, partnerships or corporations that had ownership interest in more than 3 permits with sablefish endorsements as of November 1, 2000, may not acquire additional permits beyond those owned on November 1, 2000, until they own fewer than 3 permits; at that time they may not exceed the ownership cap of 3 permits.

(3) A partnership or corporation will lose the exemptions provided in paragraphs (e)(1) and (2) of this section on the effective date of any change in the corporation or partnership from that which existed on November 1, 2000. A ''change'' in the partnership or corporation means a change in the corporate or partnership membership, except a change caused by the death of a member providing the death did not result in any new members. A change in membership is not considered to have occurred if a member becomes legally incapacitated and a trustee is appointed to act on his behalf, nor if the ownership of shares among existing members changes, nor if a member leaves the corporation or partnership and is not replaced. Changes in the ownership of publicly held stock will not be deemed changes in ownership of the corporation.

[FR Doc. 01–14517 Filed 6–7–01; 8:45 am]

BILLING CODE 3510–22–S

Notices

Federal Register
Vol. 66, No. 111
Friday, June 8, 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

Commodity Credit Corporation

Request for Reinstatement and Revision of a Previously Approved Information Collection

AGENCY: Commodity Credit Corporation, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the Commodity Credit Corporation (CCC) to request a Reinstatement and Revision of a Previously Approved Information Collection. These collection reinstatements are necessary to support the procurement of agricultural commodities for CCC's domestic and export food donation programs. CCC issues invitations to purchase or process commodities for food donation programs on a monthly, multi-month, quarterly, and yearly basis. Special invitations, however, are issued throughout the month.

DATES: Comments on this notice must be received on or before August 7, 2001, to be assured consideration.

ADDITIONAL INFORMATION OR COMMENTS: Comments regarding this information collection requirement may be directed to Gregory Borchert, Chief, Planning and Analysis Division, Kansas City Commodity Office (KCCO), 6501 Beacon Drive, Kansas City, Missouri 64133–4676, telephone (816) 926–6509 or fax (816) 926–1648; e-mail gmborchert@kcc.fsa.usda.gov.

SUPPLEMENTARY INFORMATION:

Title: CCC Commodity Offer Forms.

OMB Control Number: 0560–0177.

Expiration Date: January 31, 2001.

Type of Request: Reinstatement and revision of a previously approved information collection.

Abstract: The United States donates agricultural commodities domestically and overseas to meet famine or other relief requirements, to combat malnutrition, and sells or donates commodities to promote economic development.

CCC issues invitations to purchase or sell agricultural commodities and services for use in domestic and export programs. Vendors respond by making offers using various CCC commodity offer forms. The Export Offer forms and the KC–333 are now prepared and received electronically through the Electronic Bid Entry System (EBES). Most of the Domestic Offer forms (KC–327) are now prepared and received electronically through the Domestic Bid Entry System (DEBES) via the Internet. Vendors can access EBES or DEBES on-line to see the date/time the system shows for receipt of bid, bid modification, or bid cancellation. At bid opening date/time, the bids are system evaluated. Acceptance wires are sent to the successful offerors. Awarded contracts are posted on our website. The prior bid system required hard-copy bids and manual entry into our computer system. We are seeking approval for the following forms: KC–156, Export Certification For Export Title II Commodities; KC–269/KC–269–A (Reverse), Notice to Deliver; KC–324, Steamship Line Service Offer Form; KC–327, Domestic Offer Form; KC–331, Bulk Grain Procurement Offer Form; KC–332, Bulk Grain Sales Offer Form; KC–333 and Export Offer forms; KC–334, Discharge/Delivery Survey Summary; KC–337, Rate Schedule; and KC–366, Shipment Information Log.

Regulations governing paperwork burdens on the public require that before an agency collects information from the public, the agency must receive approval from OMB. In accordance with those regulations, CCC is seeking approval for these forms to provide for the submission of offers.

Estimate of Burden: Public reporting burden for collection information under this notice is estimated to average 15–30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Respondents: Business and other for profit organizations.

Estimated Number of Respondents: 1,288.

Estimated Number of Responses per Respondent: 405.

Estimated Total Annual Burden on Respondents: 5,890.

Proposed topics for comment include: (a) Whether the continued collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of CCC's estimate of burden including the validity of the methodology and assumptions used; (c) enhancing the quality, utility, and clarity of the information collected; or (d) minimizing 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. Comments should be directed to the Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for USDA, Washington, DC 20503, and to Gregory Borchert, Chief, Planning and Analysis Division, Kansas City Commodity Office, 6501 Beacon Drive, Kansas City, Missouri 64133–4676. All comments will become a matter of public record.

A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication.

Signed at Washington, D.C., on June 1, 2001.

James R. Little,

Executive Vice President, Commodity Credit Corporation.

[FR Doc. 01–14494 Filed 6–7–01; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Proposed Collection: Comment Request: FNS–583, Employment and Training Program Report

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on proposed information collection for the

FNS–583, Employment and Training Program Report. The proposed collection is an extension of collection currently approved under OMB No. 0584–0339.

DATES: Written comments must be submitted on or before August 7, 2001.

ADDRESSES: Send comments and requests for copies of this information collection to John Knaus, Chief, Program Design Branch, Program Development Division, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Alexandria, VA 22302.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden of the proposed collection of information, including validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other form of information technology.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

FOR FURTHER INFORMATION CONTACT: John Knaus at (703) 305–2098, or send e-mail to john_knaus@fns.usda.gov via the Internet.

SUPPLEMENTARY INFORMATION:

Type of Information Collection Request: Extension of a currently approved collection.

Title of Information Collection: FNS–583, Employment and Training Program Report.

OMB Number: 0584–0339.

Expiration Date: September 30, 2001.

Abstract: Title 7 CFR 273.7(c)(6) requires State agencies to submit quarterly Employment and Training (E&T) Program reports containing monthly figures for participation in the program. The FNS–583 report includes the number of participants newly work registered; work registrants exempted from the E&T Program; participants who volunteered and began an approved E&T component; E&T mandatory participants who began an approved E&T component; number of able-bodied adults without dependents (ABAWDs) exempted from the 3-month food stamp participation limit under each State agency's 15 percent ABAWD exemption allowance; the number of filled and offered (unfilled) workfare slots in waived and unwaived geographic areas of the State; the number of filled and offered education and training slots in waived and unwaived geographic areas of the State; the amount of Federal 100 percent E&T funding spent on workfare slots that meet the requirements of section 6(o)(2)(C) of the Food Stamp Act of 1977, as amended (the Act); and the amount of Federal 100 percent E&T funding spent on education and training slots that meet the requirements of section 6(o)(2)(B) of the Act. The first quarter FNS–583 report includes the number of work registered persons in a State as of October of the new fiscal year. On the fourth quarter FNS–583 report State agencies list the components of their E&T programs and the number of participants in each.

Frequency: The FNS–583 report must be completed and submitted to FNS on a quarterly basis by the 45th day following the end of the quarter.

Affected Public: Individual households and State and local governments.

Estimated Number of Respondents: 4,870,542.

Estimated Number of Responses: 4,870,701.

Estimated Time per Response: .025 hours per individual; 347.17 hours per State agency.

Estimated Total Annual Burden: 195,363 hours.

Dated: May 31, 2001.

George A. Braley,

Acting Administrator, Food and Nutrition Service.

[FR Doc. 01–14452 Filed 6–7–01; 8:45 am]

BILLING CODE 3410–30–U

DEPARTMENT OF AGRICULTURE

Forest Service

Rocky Mountain Region: Colorado, Kansas, Nebraska, South Dakota, Eastern Wyoming; Legal Notice of the Opportunity To Comment on Certain Proposed Actions and of Decisions Subject to Notice and Comment

AGENCY: Forest Service, USDA.

ACTION: Notice; Newspapers for Legal Notices.

SUMMARY: This is a list of those newspapers that will be used to publish notice of all decisions which are subject to appeal under 36 CFR 217, notice of the opportunity to comment on certain proposed actions pursuant to 36 CFR 215.5, and notice of decisions subject to appeal under the general provisions of 36 CFR part 215. As required at 36 CFR 215.5 and 215.9, such notice shall constitute legal evidence that the agency has given timely and constructive notice of decisions that are subject to public notice and comment and administrative appeal. Newspaper publications 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 in or affected by a specific decision.

EFFECTIVE DATES: Use of these newspapers for purposes of publishing the notices required under the provisions of 36 CFR part 215 shall begin April 16, 2001.

FOR FURTHER INFORMATION CONTACT: Paul Momper, Regional Appeals and Litigation Coordinator, Rocky Mountain Region, Box 25127, Lakewood, Colorado 80225, Area Code 303–275–5161.

SUPPLEMENTARY INFORMATION: Responsible Officials in the Rocky Mountain Region shall give notice of the opportunity to comment on certain proposed actions and of decisions subject to appeal pursuant to 36 CFR part 215 in the following newspapers which are listed by Forest Service unit. Where more than one newspaper is listed for any unit, the first newspaper listed is the primary newspaper which shall be used to constitute legal evidence that the agency has given timely and constructive notice of decisions that are subject to administrative appeal. The day after the publication of the public notice in the primary newspaper shall be the first day of the appeal filing period.

Decisions by the Regional Forester: The Denver Post, published daily in Denver, Denver County, Colorado, for decisions affecting National Forest System lands in the States of Colorado, Nebraska, Kansas, South Dakota, and eastern Wyoming and for any decision of Region-wide impact. In addition, notice of decisions made by the Regional Forester will also be published the day after in the *Rocky Mountain News,* published daily in Denver, Denver County, Colorado. For those Regional Forester decisions affecting a particular unit, the day after notice will also be published in the newspaper specific to that unit.

Arapaho and Roosevelt National Forests, Colorado

Forest Service Decisions:

The Denver Post, published daily in Denver, Denver County, Colorado.

District Ranger Decisions:

Canyon Lakes District: Coloradoan, published daily in Fort Collins, Larimer County, Colorado.

Pawnee District: Greeley Tribune, published daily in Greeley, Weld County, Colorado.
Boulder District: Daily Camera, published daily in Boulder, Boulder County, Colorado.
Clear Creek District; Clear Creek Courant, published weekly in Idaho Springs, Clear Creek County, Colorado.
Sulphur District: Sky High News, published weekly in Granby, Grand County, Colorado.

Grand Mesa, Uncompahgre and Gunnison National Forests, Colorado

Forest Supervisor Decisions:
Grand Junction Daily Sentinel, published daily in Grand Junction, Mesa County, Colorado.
District Range Decisions:
Collbran and Grand Junction Districts: Grand Junction Daily Sentinel, published daily in Grand Junction, Mesa County, Colorado.
Paonia District: Delta County Independent, published weekly in Delta, Delta County, Colorado.
Cebolla and Taylor River Districts: Gunnison Country Times, published weekly in Gunnison, Gunnison County, Colorado.
Norwood District: Telluride Daily Planet, published daily in Telluride, San Miguel County, Colorado.
Ouray District: Montrose Daily Press, published daily in Montrose, Montrose County, Colorado.

Pike and San Isabel National Forests

Forest Supervisor Decisions:
Pueblo Chieftain, published daily in Pueblo, Pueblo County, Colorado.
District Ranger Decisions:
San Carlos District: Pueblo Chieftain, published daily in Pueblo, Pueblo County, Colorado.
Comanche District: Plainsman Herald, published weekly in Springfield, Baca County, Colorado. In addition, notice of decisions made by the District Ranger will also be published in the *La Junta Tribune Democrat,* published daily in La Junta, Otero County, Colorado, and in the *Ag Journal,* published weekly in La Junta, Otero County, Colorado.
Cimarron District: Tri-State News, published weekly in Elkhart, Morton County, Kansas.
South Platte District: News Press, published weekly in Castle Rock, Douglas County, Colorado.
Leadville District: Herald Democrat, published weekly in Leadville, Lake County, Colorado.
Salida District: The Mountain Mail, published daily in Salida, Chaffee County, Colorado.
South Park District: Fairplay Flume, published weekly in Fairplay, Park County, Colorado.
Pikes Peak District: Gazette, published daily in Colorado Springs, El Paso County, Colorado.

Rio Grande National Forest, Colorado

Forest Supervisor Decisions:
Valley Courier, published daily in Alamosa, Alamosa County, Colorado.
District Ranger Decisions:
Valley Courier, published daily in Alamosa, Alamosa County, Colorado.

Routt National Forest, Colorado

Forest Supervisor Decisions:
Laramie Daily Boomerang, published daily in Laramie, Albany County, Wyoming. In addition, for decisions affecting an individual district(s), the local district(s) newspaper will also be used.
District Ranger Decisions:
Hans Peak-Bears Ears District: Steamboat Pilot, published weekly in Steamboat Springs, Routt County, Colorado is the newspaper of record for decision made by the Hans Peak Bears Ears District Ranger. Additional notice to inform local communities about decisions made by the District Ranger will also be placed in the *Hayden Valey Press,* published weekly in Hayden, Routt County, Colorado and in the *Northwest Colorado Daily Press,* published daily in Craig, Moffat County, Colorado.
Yampa and District: Steamboat Pilot, published weekly in Steamboat Springs, Routt County, Colorado.
Middle Park District; North Park District: *Jackson County Star,* published weekly in Walden, Jackson County, Colorado.

San Juan National Forest, Colorado

Forest Supervisor Decisions:
Durango Herald, published daily in Durango, La Plata County, Colorado.
District Ranger Decisions:
Durango Herald, published daily in Durango, La Plata County, Colorado.

White River National Forest, Colorado

Forest Supervisor Decisions:
The Glenwood Post, published Monday through Sunday in Glenwood Springs, Garfield County, Colorado.
District Ranger Decisions:
Aspen District: Aspen Times, published weekly in Aspen, Pitkin County, Colorado.
Blanco District: Meeker Herald, published weekly in Meeker, Rio Blanco County, Colorado.
Dillion District: Summit Daily News, published daily in Frisco, Summit County, Colorado.
Eagle District: Eagle Valley Enterprise, published weekly in Eagle, Eagle County, Colorado.
Holy Cross District: Vail Trail, published weekly in Vail, Eagle County, Colorado.
Rifle District: Citizen Telegram, published weekly in Rifle, Garfield County, Colorado.
Sopris District: Valley Journal, published weekly in Carbondale, Garfield County, Colorado.

Nebraska National Forest, Nebraska

Forest Supervisor Decisions:
The Rapid City Journal, published daily in Rapid City, Pennington County, South Dakota for decisions affecting National Forest System lands in the State of South Dakota.
The Omaha World Herald, published daily in Omaha, Douglas County, Nebraska for decisions affecting National Forest System lands in the State of Nebraska.
District Ranger Decisions:
Bessey District/Charles E. Bessey Tree Nursery: The North Platte Telegraph, published daily in North Platte, Lincoln County, Nebraska.
Pine Ridge District: The Chadron Record, published weekly in Chadron, Dawes County, Nebraska.
Samuel R. McKelvie National Forest: The Valentine Midland News, published weekly in Valentine, Cherry County, Nebraska.
Fall River and Wall Districts, Buffalo Gap National Grassland: *The Rapid City Journal,* published daily in Rapid City, Pennington County, South Dakota.
Fort Pierre National Grassland: The Capital Journal, published Monday thru Friday in Pierre, Hughes County, South Dakota.

Black Hills National Forest, South Dakota and Eastern Wyoming

Forest Supervisor Decision:
The Rapid City Journal, published daily in Rapid City, Pennington County, South Dakota.
District Ranger Decisions:
The Rapid City Journal, published daily in Rapid City, Pennington County, South Dakota.

Bighorn National Forest, Wyoming

Forest Supervisor Decisions:
Sheridan Press, published daily in

Sheridan, Sheridan County, Wyoming. In addition, for decisions affecting an individual district(s), the local district(s) newspaper will be used (see listing below).

District Ranger Decisions:

Tongue District: Sheridan Press, published daily in Sheridan, Sheridan County, Wyoming.

Buffalo District: Buffalo Bulletin, published weekly in Buffalo, Johnson County, Wyoming.

Medicine Wheel District: Lovell Chronicle, published weekly in Lovell, Big Horn County, Wyoming.

Tensleep District: Northern Wyoming Daily News, published daily in Worland, Washakie County, Wyoming.

Paintrock District: Greybull Standard, published weekly in Greybull, Big Horn County, Wyoming.

Medicine Bow National Forest, Wyoming

Forest Supervisor Decisions:

Laramie Daily Boomerang, published daily in Laramie, Albany County, Wyoming.

District Ranger Decisions:

Laramie District: Laramie Daily Boomerang, published daily in Laramie, Albany County, Wyoming.

Douglas District: Casper Star-Tribune, published daily in Casper, Natrona County, Wyoming.

Brush Creek and Hayden Districts: Rawlins Daily Times, published daily in Rawlins, Carbon County, Wyoming.

Shoshone National Forest, Wyoming

Forest Supervisor Decision:

Cody Enterprise, published twice weekly in Cody, Park County, Wyoming.

District Ranger Decisions:

Clarks Fork District: Powell Tribune, published twice weekly in Powell, Park County, Wyoming.

Wapiti and Greybull Districts: Cody Enterprise, published twice weekly in Cody, Park County, Wyoming.

Wind River District: The Dubois Frontier, published weekly in Dubois, Teton County, Wyoming.

Lander District: Wyoming State Journal, published twice weekly in Lander, Fremont County, Wyoming.

Dated: May 11, 2001.

David A. Heerwagen,

Deputy Regional Forester, Operations.

[FR Doc. 01–14503 Filed 6–7–01; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

Giant Sequoia National Monument Management Plan EIS

AGENCY: USDA, Forest Service.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The Department of Agriculture, Forest Service is preparing an environmental impact statement (EIS) to establish management direction for the land and resources within the Giant Sequoia National Monument (GSNM) created by Presidential Proclamation on April 15, 2000. The agency is to develop a management plan within three years of the signing of the Proclamation. The Forest Service, as the responsible agency, proposes to amend the Sequoia National Forest Land and Resource Management Plan (FLMP) to provide for the protection of the objects of interest identified in the Proclamation.

DATES: The public is asked to submit any issues (points of concern, debate, dispute, or disagreement) regarding potential effects of the proposed action by July 24, 2001. The draft EIS is expected to be available for public comment in February 2002 and the final EIS is expected to be published in September 2002.

ADDRESSES: Send written comments to: Jim Whitfield, EIS Team Leader, USDA Forest Service, Sequoia National Forest, 900 W. Grand Avenue, Porterville, CA 93257.

FOR FURTHER INFORMATION CONTACT: Jim Whitfield, EIS Team Leader, Sequoia National Forest, at the address listed above. The phone number is (559) 784–1500. Information regarding the monument and the planning process can also be found on the Giant Sequoia National Monument website located at *www.r5.fs.fed.us/giant_sequoia.* Public meetings will be held during the scoping period to allow the public to gather information prior to submitting comments. Information on the times, dates, locations, and agendas for these meetings will be provided in local newspapers, on the website, and by direct mailings.

SUPPLEMENTARY INFORMATION:

Background

On April 15, 2000, a Presidential Proclamation creating the Giant Sequoia National Monument was signed. The Proclamation designated 327,769 acres within the boundary of the Sequoia National Forest as a National Monument to provide protection for a variety of objects of historic and scientific interest, including giant sequoia trees and their surrounding ecosystem. The President directed the Secretary of Agriculture to prepare a management plan within three years, and that the plan is to include a transportation plan. The plan will provide for and encourage continued public access and use consistent with the purposes of the Giant Sequoia National Monument. A range of alternatives will be analyzed, including the no-action alternative, which is the management direction provided by the current Forest Land and Resource Management Plan, as amended.

Purpose and Need for Action

The Presidential Proclamation identifies the need to take action regarding two critical problems facing giant sequoias and their ecosystems: (1) The heavy buildup of surface fuels and woody debris, leading to an increased hazard form wildfires, and (2) a lack of regeneration of young giant sequoias to ensure long-term sustainability of the species. The proclamation also clearly identifies opportunities for scientific research, interpretation, recreation, and the need for a transportation plan. We are committed to preparing a management plan that is responsive to these needs and opportunities and that provides proper care for the objects of interest as identified in the proclamation. These objects include:

1. The naturally occurring groves of giant sequoia,

2. The ecosystems within the GSNM that surround the groves and provide enriching recreational and social experiences, outstanding landscapes, and an array of rare and endemic species, such as the fisher, the great gray owl, the American marten, the northern goshawk, the peregrine falcon, the spotted owl, and the California condor,

3. The historical landscape in and around the Hume Lake Basin associated with the Euro-American use of the giant sequoia since the late 1800's, and

4. The limestone caverns and prehistoric archaeological sites that provide a paleontological record of the ecological changes that giant sequoias have undergone, as well as a prehistoric record of the relationship of the area to the native tribes.

Management Direction

Current management direction for the Sequoia National Forest and the GSNM includes the Presidential Proclamation and the Forest Land and Resource Management Plan as amended by the Sierra Nevada Forest Plan Amendment. The Sierra Nevada Forest Plan

Amendment provides management direction for many important concerns such as aquatic, riparian, and meadow management; fire and fuel management; and old forest ecosystem management. It provides strategies, as well as standards and guidelines, to address the risk of catastrophic fire, although it is not focused on the objects of interest within the monument. The Sierra Nevada Forest Plan Amendment also provides some management direction to begin to address the restoration of giant sequoia ecosystems. More information on the Sierra Nevada Forest Plan Amendment is available at *www.r5.fs.fed.us sncf* or by calling (916) 492–7554.

Current management direction does address some key concerns raised by the public during and immediately after the establishment of the monument. New direction is not proposed for activities such as: Accessing private lands and special use facilities, issuing special use permits (permits for three organizational camps have recently been renewed), hunting and fishing, and limiting off-highway vehicle use.

Proposed Action

This plan amendment will provide new management direction for the proper care, management and enjoyment of the objects of interest in the monument, as well as highlight and emphasize the application of current direction specific to the objects of interest. The Proposed Action establishes or modifies desired conditions and management goals for key resources (giant sequoias, recreation, historic and prehistoric resources, transportation, caves, and scientific study).

To realize the desired conditions and meet management goals, new management areas and their associated management emphases are being proposed. Examples are given of potential projects to maintain or achieve the desired condition in a manner consistent with the management emphases for a given management area. An initial set of standards and guidelines applying to all management areas is also included. These are in addition to current direction and do not replace existing direction.

Management areas consist of areas within the monument with similar management emphases. Management emphasis is specific direction applicable to each management area. Standards and guidelines are the primary instructions for land managers, including required (standards) and recommended (guidelines) actions necessary for resource management activities.

Desired Condition for Giant Sequoias and the Surrounding Mixed-Conifer Ecosystems

The ecosystems that support giant sequoias will function much as they did prior to recent, but enduring human-induced environmental influences, such as fire suppression and timber harvesting. Indicators of key ecological elements will be within their historic ranges of variability when compared against an appropriate time frame. The genetic integrity of the giant sequoia population will be maintained.

The giant sequoia groves and mixed-conifer forest will be returned to an historic fire regime and fuel loading. Fire will be reintroduced to the ecosystem and fuel loads that contribute to stand-replacing fires will be reduced.

The overall stand conditions of the giant sequoia groves and their surrounding ecosystems will exhibit characteristics that are within natural ranges of variability, including, but not limited to, species composition, forest structure, and age class distribution.

Management Goals for Giant Sequoias and the Surrounding Mixed-Conifer Ecosystems

Protect giant sequoia groves and the surrounding ecosystems by ensuring that they are resilient to natural events (*e.g.* wildfire, epidemic outbreaks of insects and diseases) and other events that are contrary to, or disruptive of, ecological processes necessary to sustain a healthy and sustainable ecosystem. Preserve the genetic integrity of each separate giant sequoia grove. Protect the hydrologic functions and soil resources upon which the groves and surrounding ecosystems depend.

Restore groves and their surrounding ecosystems to reflect historic conditions, which includes a fire regime of frequent and generally low-intensity fires; a mosaic of different vegetative age and size classes; and a large amount of shade-intolerant species such as pines, giant sequoias, and hardwoods.

Coordinate planning and implementation of protection and restoration projects with adjoining agencies and private landowners, which include the Sequoia and Kings Canyon National Parks, Mountain Home State Forest, the Universities of California (Whitaker's Forest), and the Tule River Indian Tribe.

Desired Condition for Dispersed and Developed Recreation

Visitors to the GSNM will find a rich and varied range of recreational and social opportunities enhanced by giant sequoias and their ecosystems, historic and prehistoric artifacts, and unique geological features. The GSNM will offer a range of experiences, from primitive settings to developed settings.

To facilitate observation and interpretation of the objects of interest, landscapes will provide a high level of scenic integrity, helping visitors appreciate how healthy ecosystems function and how humans fit into them. Scenic opportunities will range from pristine landscapes to locations where management activities are apparent.

Any new recreational or administrative facilities to be constructed will emulate the character of the surroundings, remaining in context with scientific, historical, ecological, cultural, and economic values. High quality interpretive and educational facilities and services will be available to promote visitor understanding and enjoyment of the giant sequoia ecosystem and the values within the monument.

Management Goals for Developed and Dispersed Recreation

Provide visitors with a wide range of opportunities for recreation, interpretation, and education related to the objects of interest and the values of the monument.

Improve visitor facilities, information, and services to meet projected demand for recreation and visitation in cooperation with permittees; cooperators; county, state, and federal agencies; tribal governments; recreational user groups; and the business community.

Desired Condition for Historic and Prehistoric Resources

The historic and prehistoric resources of the GSNM will be protected, studied, interpreted, and managed to maintain their cultural and scientific integrity and to provide educational, cultural, and recreational opportunities to visitors.

A wide range of opportunities will allow visitors to make a personal connection with the land and to reflect on the past and its relevance to their daily lives.

The cultural and spiritual values of the monument will be protected, managed, and utilized for the benefit of local tribes, communities and visitors.

Management Goals for Historic and Prehistoric Resources

Protect historic and prehistoric values from impacts that could destroy them or accelerate their natural rate of deterioration.

Ensure that sites are interpreted for the education and enjoyment of visitors.

Local tribes will be consulted in the planning of projects in the monument. Ensure access to culturally important sites and resources for use by Native Americans.

Desired Condition for the Transportation System

The transportation system (roads and trails) within the monument will provide public access to recreation opportunities, private property, lands under special use permit, and other activities compatible with enjoying, managing and protecting the objects of interest.

Access will be adequate for management activities such as fire suppression, ecological restoration, research, fuels management, and maintenance of recreation facilities.

The transportation system will include a wide range of experiences, from primitive trails to highly developed roads. It will consist of ecologically stable roads and trails and will contribute to the proper care and management of the objects of interest.

Development, operation, maintenance, or decommissioning of roads and trails will be based on the need to provide proper care for the objects of interest, public access, or management access.

Management Goals for the Transportation System

Provide well-maintained roads and trails for public access to all national forest system lands within the monument. Coordinate transportation planning with Sequoia and Kings Canyon National Parks, and state and county agencies, to reduce traffic congestion and safety hazards, especially along major travel ways such as the General's Highway, Highway 180, and Highway 190.

Allow adequate access to private lands and facilities within the monument.

Provide a wide range of trail opportunities, including accessible trails for persons with disabilities, for hiking, horseback riding, bicycling, and cross-country skiing.

Provide a system of well-maintained roads to allow efficient and effective fire suppression, fuels treatment, restoration work, and other management use.

Repair or decommission roads that are unstable or are causing unacceptable impacts to the objects of interest.

Provide enjoyable and safe opportunities for riding off-highway vehicles, including snowmobiles, on designated roads within the monument.

Desired Condition for Caves

The natural condition of caves within the monument will be preserved, to the extent possible, to maintain natural functions and protect the unique resources that depend on cave environments for existence.

The caves will provide scientific knowledge, especially regarding the paleontological and archaeological artifacts that may shed light on thousands of years of change within the giant sequoia groves, their ecosystem, and the prehistoric people who helped shape the ecosystem.

Some caves will provide educational and recreational opportunities for visitors.

Management Goals for Caves

Protect caves and their associated resources from additional impacts that could damage or destroy them, including surface activities, activities within caves, and activities altering their sustaining groundwater conditions.

Inventory and classify caves according to their most notable values.

Provide for public use where appropriate including interpretation, education, and recreation.

Work with scientific groups, volunteer organizations, and recreational clubs to help protect, preserve, and stud caves and their associated resources.

Desired Condition for Scientific Study

Encourage scientific research in the monument that will explore a wide range of hypotheses designed to improve the care and management of the objects of interest. Cooperating partners may include Forest Service research stations, universities, and other interested scientific organizations or agencies, as well as tribes and interested members of the public.

Management Goals for Scientific Study

Guide opportunities for scientific research and study of the giant sequoia groves, the mixed conifer ecosystems that surround them, the historical landscape of the Hume Lake Basin, the limestone caverns, and prehistoric archaeological sites.

Management Areas, Emphases, Potential Projects, Standards and Guidelines

Designated Management Areas, the associated emphases for each management areas and examples of potential projects within the management areas are described below.

Management Area #1, Zones of Ecological Influence, consists the giant sequoia groves and their mixed-conifer ecosystem. These boundaries are described in the Forest Service draft report entitled ''Defining Ecological Zones of Influence for Giant Sequoia Groves of the Sequoia National Forest.'' The zones of influence are the areas within which management activities could both directly and indirectly affect grove ecology. Management Emphases: protect and restore the structure and functions of the giant sequoias and their associated ecosystems (both terrestrial and hydrologic); reduce fuel loads within the groves and their zones of influence and restore a more natural fire interval in the groves and surrounding areas; emphasize the recruitment, retention and long-term protection of young giant sequoia and pines; move the natural hydrologic and terrestrial functions and structure toward the desired conditions; encourage scientific research; encourage interpretation of and education about the objects of interest and provide access to and opportunities for dispersed and developed recreation. Examples of potential projects include:

1. The Converse Grove is a largely second-growth stand of mixed-conifer and giant sequoias that resulted from intensive logging prior to 1900. It is unique in its size and age classes of giant sequoias and associated mixed-conifer species. It offers a unique opportunity to study a range of protection and restoration measures, as well as interpret its logging history.

2. The Redwood Mountain Grove is a very large grove that is unique in that portions of it are management by three separate entities—the Forest Service, the National Park Service, and the University of California at Berkeley. The ecological characteristics of the grove and its multiple ownerships offer a unique opportunity for collaborative research efforts.

3. The Belknap Complex Grove provides a unique blend of known sightings of fisher, several giant sequoia groves, old forest characteristics, and urban intermix zones. This offers an outstanding opportunity to compare different management technique, such as prescribed fire and thinning, to meet the goals for the monument.

4. The Freeman Grove, the Indian Basin Grove, the Converse grove, the Bearskin Grove, and the Belknap Complex Grove, offer opportunities to develop new and existing interpretive trails.

5. The Packsaddle Grove offers the opportunity to develop an access trail signed with interpretive markers.

6. The Freeman Grove approaches the desired conditions for composition and

structure. This grove presents the opportunity to use prescribed fire and/or mechanical treatments to maintain this condition and improve the grove's resiliency to disturbance.

7. The Belknap Complex Grove is within the Urban Wildland Intermix Defense or Threat Zones and is highly susceptible to fire. There are communities situated within or adjacent to this grove. Using prescribed fire and/or mechanical treatments to remove surface and ladder fuels would help prevent the loss of life and property from wildland fire, as well as maintain the grove's resiliency to disturbance.

8. Young seral stages were created in the giant sequoia groves by harvesting, fuel treatments, and planting in the 1970s and 1980s. The harvesting removed stands of white fire, incense cedar, and pines that were growing below the mature giant sequoias. Approximately 775 acres of openings were created. Conifer seedlings were planted and young sequoias reseeded naturally. These areas will be managed to meet the goals of providing young sequoia trees for long-term sustainability.

Management Area #2, the Hume Lake Historic Area, is an area of extraordinary historical and cultural value and is the general site of the old logging operations of the late 1800s. Private logging companies harvested the sequoias from the surrounding areas and established a mill site, a dam, and a small town now known as Hume Lake. This management area will also include the Millwood, Abbott Mill, and Lower Abbott Mill sites.

Management Emphases: preserve and interpret this historical landscape and its associated ecosystems; provide interpretive and educational materials emphasizing the relevance, fragility, and values of the area's heritage resources and ecology; and provide a wide range of recreational and interpretive opportunities. Examples of potential projects include:

1. Through Indian Basin, develop interpretive trails that connect to Converse Basin Grove.

2. Where the historic logging operations took place, conduct a coordinated study to complete the survey of those operations so appropriate protection measures can be applied.

Management Area #3, General Monument Lands consists of the part of the monument not included in Management Area #1, Zones of Ecological Influence, or Management Area #2, the Hume Lake Basin. It includes a wide variety of vegetative types and ecological zones. Much of it is covered with mixed conifer stands but this management area also includes low elevation chaparral and lower Westside hardwood ecosystems. Management Emphases: maintain or restore the health of the varied ecological types; move the terrestrial and hydrologic functions toward the desired condition; reduce fuel loads, especially down slope of the groves, and return to a more natural fire interval; protect the objects of interests from unacceptable resource impacts such as catastrophic fire; provide access and opportunities for recreation, interpretation, and education focused on the objects of interest, especially the mixed conifer ecosystem, limestone caverns, and prehistoric and historic sites; and encourage scientific research and management to provide proper care for the objects of interest. Examples include:

1. Along the Kings Canyon Scenic Byway Corridor into Kings Canyon National Park, continue to coordinate Forest Service and National Park Service management.

2. Along the Big Meadows Road (14S11), enhance developed and dispersed recreation facilities to provide access to interpretive and educational opportunities focused on the objects of interest.

3. Within the Kings Wild and Scenic River Corridor, encourage and enhance day use opportunities, including interpretation, education, and scenic viewing.

4. Around Speas Ridge, develop an interpretive trail that discusses the prehistoric and historic uses of the area.

5. Along the Summit National Recreation Trail, add a loop accessing additional areas.

6. The Windy Gap, Needles, and Dome Rock areas, provide additional trailhead opportunities, picnic areas, and improvements to existing recreational facilities. Within the caves and limestone caverns, encourage scientific study and protection.

Monument-Wide (All Management Areas)

Management Emphasis in this management area (see above statements for individual management areas) include:

1. Along such highways as Highway 190 and the Western Divide Highway, expand the scenic byway program to provide a range of scenic and recreational opportunities, including viewing areas for giant sequoia groves, extraordinary landscapes, wildlife, historical and heritage sites, and scientific research sites.

2. Conduct historical and archeological research that contributes to a comprehensive knowledge of historical events and sites and how best to protect them.

3. Develop interpretive opportunities at well protected historic and heritage sites.

Standards and Guidelines proposed for implementation include:

1. Evaluate land-disturbing activities in the vicinity of caves that may impact caves or their associated resources.

2. Use fuel treatments to reduce the risk of catastrophic fire to giant sequoia trees and their surrounding ecosystems.

Decisions To Be Made and Responsible Official

The decision to be made is whether to implement the proposed action, as described above or to meet the Purpose and Need for action through some other combination of management actions or to defer any action at this time.

The Responsible Official if Forest Supervisor Arthur L. Gaffrey, Sequoia National Forest, 900 West Grand Ave., Porterville, California 93257.

Coordination With Other Agencies

In preparation of the EIS, the Forest Service will consult with the Bureau of Land Management, the National Park Service, the Fish and Wildlife Service, the State Historic Preservation Office, and other federal and state agencies as appropriate, as well as Native American Tribes. Scientific guidance will also be sought from the Giant Sequoia National Monument Scientific Advisory Board, established as directed in the President's Proclamation.

Commenting

Comments received in response to this invitation to participate in public scoping or any future solicitation for public comments on a draft EIS, including names and addresses of those who comment, will be considered part of the public record and will be available for public inspection. Comments submitted anonymously will be accepted and considered. Additionally, pursuant to 7 CFR 1.27(d), any person may request the agency to withhold a submission from the public record by showing how the Freedom of Information Act (FOIA) permits such confidentiality. Persons requesting such confidentiality should be aware that under the FOIA confidentiality may be granted in only very limited circumstances, such as to protect trade secrets. The Forest Service will inform the requester of the agency's decision regarding the request for confidentiality, and where the request is denied, the

agency will return the submission and notify the requester that the comments may be resubmitted with or without name and address.

The comment period on the draft EIS will be 90 days from the date of Environmental Protection Agency publishes the notice of availability in the **Federal Register**.

The Forest Service believes that, at this early stage, it is very important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of a draft EIS must structure their participation in the environmental review of the proposal so that it is meaningful and alerts the agency to the reviewer's position and contentions. *Vermont Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519,553 (1978). Also, environmental objections that could be raised at the draft EIS stage, but that are not raised until after completion of the final EIS, may be waived or dismissed by the courts. *City of Angoon* v. *Hodel*, 803 F.2d 1016, 1022 (9th Cir. 1986) and *Wisconsin Heritages, Inc.* v. *Harris*, 490 F. Supp. 1334 (E.D. Wis. 1980). Because of these court rulings, it is very important that persons interested in this proposed action participate by the close of the 45 day comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the final EIS.

To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the draft environmental impact statement should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft statement. Comments may also address the adequacy or the merits of the alternatives formulated and discussed in the statement. Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.

Dated: May 31, 2001.

Arthur L. Gaffrey,

Forest Supervisor, Sequoia National Forest, USDA Forest Service.

[FR Doc. 01–14182 Filed 6–7–01; 8:45 am]

BILLING CODE 3410–11–M

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Addition and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Addition to and Deletions from the Procurement List.

SUMMARY: This action adds to the Procurement List a commodity to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes from the Procurement List commodities previously furnished by such agencies.

EFFECTIVE DATE: July 9, 2001.

ADDRESS: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION CONTACT: Patrick T. Mooney (703) 603–7740.

SUPPLEMENTARY INFORMATION: On September 22, 2000 and April 13 and 20 2001, the Committee for Purchase From People Who Are Blind or Severely Disabled published notices (65 FR 57313 and 66 FR 19137 and 20234) of proposed addition to and deletions from the Procurement List:

Addition

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the commodity and impact of the addition on the current or most recent contractors, the Committee has determined that the commodity listed below is suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4. I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodity to the Government.

2. The action will not have a severe economic impact on current contractors for the commodity.

3. The action will result in authorizing small entities to furnish the commodity to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodity proposed for addition to the Procurement List.

Accordingly, the following commodity is hereby added to the Procurement List:

Commodity

Tire Inflator Gage
4910–00–441–8685

This action does not affect current contracts awarded prior to the effective date of this addition or options that may be exercised under those contracts.

Deletions

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action will not have a severe economic impact on future contractors for the commodity.

3. The action will result in authorizing small entities to furnish the commodity to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodity deleted from the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the commodities listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4. Accordingly, the following commodities are hereby deleted from the Procurement List:

Commodities

Bracket, Eye, Nonrotary
3040–01–240–4456
Aerosol Paint, Lacquer
8010–00–721–9487
8010–00–290–6984
8010–00–965–2389
8010–00–721–9479
8010–00–582–5382
8010–00–584–3150
8010–00–721–9747
8010–00–721–9744
8010–00–721–9752
8010–00–721–9751
8010–00–290–6983
8010–00–584–3149
8010–00–584–3154
8010–00–721–9742

8010–00–141–2952

Patrick T. Mooney,

Director, Pricing and Program Operations.

[FR Doc. 01–14506 Filed 6–7–01; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to and deletions from Procurement List.

SUMMARY: The Committee is proposing to add to the Procurement List services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and to delete commodities previously furnished by such agencies.

Comments Must be Received on or Before: July 9, 2001.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION CONTACT: Patrick T. Mooney (703) 603–7740.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a) (2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the possible impact of the proposed actions.

Additions

If the Committee approves the proposed addition, the entities of the Federal Government identified in this notice for each service will be required to procure the services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the services to the Government.

2. The action will result in authorizing small entities to furnish the services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the services proposed for addition to the Procurement List. Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information. The following services have been proposed for addition to Procurement List for production by the nonprofit agencies listed:

Services

Food Service Attendant
Alabama Air National Guard
HQ 117th Air Refueling Wing
Birmingham, Alabama
NPA: Alabama Goodwill Industries, Inc. Birmingham, Alabama

Food Service Attendant
Indiana Air National Guard
Hulman International Airport
Terre Haute, Indiana
NPA: Child-Adult Resource Services, Inc. Rockville, Indiana

Solid Waste Management Service
Basewide
Fort Hood, Texas
NPA: Disability Employment Opportunity, Inc. San Antonio, Texas

Deletions

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action will result in authorizing small entities to furnish the services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the services proposed for deletion from the Procurement List.

The following commodities have been proposed for deletion from the Procurement List:

Commodities

Bag, Cargo
1670–01–065–3748

Winterization Kit
4240–00–065–0319

Cap—Operating, Surgical
6532–00–083–6545

Original and Duplicate Microfiche, Program 1566–S
7690–00–NSH–0018

Lacquer
8010–00–085–0559

Box, Wood, Fiberboard
8115–00–L01–0679
8115–00–L01–0680
8115–00–L01–0681

Bag, Garment
8460–00–883–8673

Mask, Extreme Cold Weather
8415–01–006–3468
8415–01–181–1398

Patrick T. Mooney,

Director, Pricing and Program Operations.

[FR Doc. 01–14507 Filed 6–7–01; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

[Docket No.: 010323078–1141–02]

RIN 0693–ZA44

Critical Infrastructure Protection Grants Program

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice.

SUMMARY: On Friday, April 13, 2001, the National institute of Standards and Technology (NIST) announced in the **Federal Register** the availability of fiscal year 2001 funds for the Critical Infrastructure Protection Grants Program (CIPGP). The purpose of this notice is to inform the public that if additional funding is received by NIST for this program in fiscal year 2002, NIST may make additional awards to proposals evaluated under the fiscal year 2001 competition.

FOR FURTHER INFORMATION CONTACT: Donald G. Marks; National Institute of Standards and Technology; 100 Bureau Drive, Stop 8901; NIST North, Room 622; Gaithersburg, MD 20899–8901; Tel: (301) 975–3660; E-Mail: *CIP@nist.gov.*

Additional information will be available on the website, *http://csrc.nist.gov/grants.* Questions regarding administrative matters such as payments or required forms should be directed to the NIST Grants Office at (301) 975–5718.

SUPPLEMENTARY INFORMATION: On April 13, 2001, NIST published a document in the **Federal Register** announcing the availability of fiscal year 2001 funds for the Critical Infrastructure Protection Grants Program (CIPGP) (66 FR 19139). Should NIST receive additional funding for the CIPGP in fiscal year 2002, NIST may use that funding for making additional awards to proposals evaluated under the fiscal year 2001 competition. All information and requirements as published in the April 13, 2001 Notice will remain in effect.

Dated: June 1, 2001.

Karen H. Brown,

Deputy Director.

[FR Doc. 01–14444 Filed 6–7–01; 8:45 am]

BILLING CODE 3510–13–M

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Announcement of Telecommunication Certification Body Training Workshop

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice of workshop.

SUMMARY: The National Institute of Standards and Technology (NIST) invites interested parties to attend a three-day Telecommunication Certification Body (TCB) training workshop on Federal Communications Commission (FCC) Rules, the FCC's TCB Program and related issues. The FCC has asked NIST to help assure the technical competence of TCBS. FCC, NIST, and industry personnel will conduct this workshop. The workshop, co-sponsored by NIST, will help NIST fulfill its responsibilities and will aid TCBs by providing information and training to current and potential TCBs, assessors, interested testing laboratories, and equipment manufacturers on compliance with FCC requirements. There is a fee to attend the Workshop. All attendees must register no later than June 29, 2001. Attendance will be limited to the first 75 registered participants.

DATES: The TCB Training Workshop will be held July 10–12, 2001. All sessions will be held from 9 am to 5 pm.

ADDRESSES: TCB Training Workshop sessions will be held at the Gaithersburg Holiday Inn, 2 Montgomery Village Avenue, Gaithersburg, Maryland 20878 (Montgomery Village Avenue Exit, Route 124 East off Interstate I–270).

For Registration Information Contact:

Teresa Vicente at (301) 975–3883, teresa.vicente@nist.gov. You may register for the workshop electronically at *http://www.nist.gov/conferences.* If you do not wish to register electronically, you can print out the electronic form and fax it to (301) 948–2067. Please pre-register by no later than June 29, 2001. You may also mail a copy of the electronic form, by June 29, 2001, to: NIST Office of the Comptroller, 100 Bureau Drive, Stop 3732, Gaithersburg, MD 20899–3732.

For Technical Information Contact:

Jogindar Dhillon at 301–975–5521, dhillon@nist.gov.

SUPPLEMENTARY INFORMATION: The FCC, in its Report & Order 98–338 (Gen Docket No. 98–68) asked NIST to help assure the technical competence of TCBs. The workshop, co-sponsored by NIST, is aimed at providing information and training to current and potential TCBs, assessors, interested testing laboratories, and equipment manufacturers on compliance with FCC requirements. The first two days will be devoted to a TCB Tutorial for FCC requirements, which will include an overview of FCC Equipment Authorization Program, the TCB Program, electronic filing, unlicensed and licensed transmitters, telephone terminal equipment and Mutual Recognition Agreements/Arrangements. The tutorial will be followed by one-day session focusing on issues relating to market surveillance and RF exposure, TCB audits, common problems encountered by TCBs, and experiences in implementing the TCB program. There is a $390 fee to attend the Workshop. For those who are only interested in attending the session on the third day, July 12, the fee will be $250. All attendees must register no later than June 29, 2001. Attendance will be limited to the first 75 registered participants.

Workshop attendees are assumed to have basic familiarity with the FCC Rules, Parts 2, 15, 18, and 68. The text of the FCC Rules can be accessed at *http://www.fcc.gov/oet/info/rules/.* Information about the TCB program is posted on NIST web site at *http://ts.nist.gov/ts/htdocs/210/216/tcb-program.htm.*

Dated: June 1, 2001.

Karen H. Brown,

Acting Director.

[FR Doc. 01–14443 Filed 6–7–01; 8:45 am]

BILLING CODE 3510–13–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 060101A]

Marine Mammals; Permits

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

ACTION: Receipt of application No. 751–1614–00; and receipt of applications to amend permits (782–1532–00, 981–1578–00).

SUMMARY: Notice is hereby given of the following actions regarding permits for takes of marine mammal species for the purposes of scientific research:

NMFS has received a permit application from: Ocean Alliance/Whale Conservation Institute, 191 Weston Road, Lincoln, Massachusetts 01773 (Dr. Roger S. Payne, Principal Investigator) (Application No. 751–1614–00); NMFS has received applications for permit amendments from:; NMFS, National Marine Mammal Laboratory, 7600 Sand Point Way, N.E., BIN C15700, Seattle, WA 98115–0070 (Permit No. 782–532–00)); and Dr. Peter L. Tyack, Biology Department, Woods Hole Oceanographic Institution, Woods Hole, MA 02543 (Permit No. 981–1578).

DATES: Written or telefaxed comments on the new application or amendment requests must be received on or before July 9, 2001.

ADDRESSES: The application and related documents are available for review upon written request or by appointment. See **SUPPLEMENTARY INFORMATION.**

Written comments or requests for a public hearing on the application or amendment requests should be mailed to the Chief, Permits and Documentation Division, F/PR1, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910. Those individuals requesting a hearing should set forth the specific reasons why a hearing on this particular request would be appropriate.

FOR FURTHER INFORMATION CONTACT: Ruth Johnson or Tammy Adams, (301)713–2289.

SUPPLEMENTARY INFORMATION: The subject application and permit amendments are requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR 222–226), and the Fur Seal Act of 1966, as amended (16 U.S.C. 1151 *et seq.*)

New Application Received

For Application No. 715–1614–00, the applicant requests permission to conduct vessel and aerial surveys, collect tissue samples (sloughed skin and skin and blubber biopsies) from living, free-ranging animals and collect skin, blubber, blood, bone, baleen and other organ tissue samples from dead stranded animals from all age and sex

classes of 21 cetacean species in U.S., foreign, and international waters. Tissue samples would be used to quantify toxicant loads and immunochemical responses to these loads to test the hypothesis that there are demonstrable differences between different populations ans species with regard to the levels of toxic compounds present. Genetic analyses would also be performed on samples to investigate the genetic diversity and variability of the population groups sampled. This information would be used to establish a baseline for comparisons with future samples and to assist in making future management and conservation policies.

Permit Amendment Requests Received

For Permit No. 782–1532–00, the Permit authorizes the Holder to take Steller sea lions (*Eumetopias jubatus*) for research that involves takes by aerial and ship based surveys biennally, capture and take morphological measurements, collect specimens (blood and biopsy), brand, tag, and disturb during scat collection. The Holder now requests to amend the take authority to conduct aerial surveys each year, include Southeast Alaska in monthly surveys, increase the number of animals to be incidentally harassed during scat collection, allow additional procedures for animal handling such as: using gas anesthesia, branding pups ≥4 mos and juveniles to 3 yrs, injecting Evan's blue dye and deuterated water, collecting muscle biopsy, using noninvasive bioelectric impedance analysis, increasing blood sample volume, extracting a tooth, and pulling vibrissae. This Permit amendment will improve field techniques and incorporate collaborative efforts of scientists funded under the Steller Sea Lion Research Initiative.

For Permit No. 981–1578–00, the Permit authorizes the Holder to tag cetaceans with an advanced digital sound recording tag (DTAG) that can record the acoustic stimuli an animal hears, along with measuring vocal, behavioral, and physiological responses to sound played back at received levels of 120–160 dB re 1 micron Pa. The research was authorized in the Mediterranean and Ligurian Seas and off the coast of the Azores in the North Atlantic. The Holder requests an amendment to increase the source level but not the received level for a whale-finding sonar to 200 dB re 1 micron Pa at 1 m, add playbacks involving exposure to impulse signals from airguns as used in seismic surveys, include one additional baleen whale species and 12 species of Odontocete whale, and extend the study area to include North Atlantic and Gulf of Mexico.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activities proposed are categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Written comments or requests for a public hearing on the application or amendment requests should be mailed to the Chief, Permits and Documentation Division, F/PR1, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910. Those individuals requesting a hearing should set forth the specific reasons why a hearing on these particular requests would be appropriate.

Comments may also be submitted by facsimile at (301) 713–0376, provided the facsimile is confirmed by hard copy submitted by mail and postmarked no later than the closing date of the comment period. Please note that comments will not be accepted by e-mail or by other electronic media.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of thee application and amendment requests to the Marine Mammal Commission and its Committee of Scientific Advisors.

Documents may be reviewed in the following locations:

For all permits and permit amendments: Permits and Documentation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 713–2289; fax (301) 713–0376;

For permit 751–1614–00: Northwest Region, NMFS, 7600 Sand Point Way NE, BIN C15700, Bldg. 1, Seattle, WA 98115–0700; phone (206) 526–6150; fax (206) 526–6426;

For permits 751–1614–00 and 782–1532–00: Alaska Region, NMFS, P.O. Box 21668, Juneau, AK 99802–1668; phone (907) 586-7221; fax (907) 586–7249;

For permit 751–1614–00: Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802–4213; phone (562) 980–4001; fax (562) 980–4018;

For permits 751–1614–00 and 981–1578-00: Northeast Region, NMFS, One Blackburn Drive, Gloucester, MA 01930–2298; phone (978) 281–9200; fax (978) 281–9371; and

For permits 751–1614–00 and 981–1578–00: Southeast Region, NMFS, 9721 Executive Center Drive North, St. Petersburg, FL 33702–2432; phone (727) 570–5301; fax (727) 570–5320.

Dated: June 4, 2001.

Ann D. Terbush,

Chief, Permits and Documentation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 01–14522 Filed 6–7–01; 8:45 am]

BILLING CODE 3510–22–S

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Adjustment of Import Limits for Certain Cotton, Man-Made Fiber, Wool, Silk Blend and Other Vegetable Fiber Textiles and Textile Products Produced or Manufactured in Sri Lanka

June 4, 2001.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs adjusting limits.

EFFECTIVE DATE: June 11. 2001.

FOR FURTHER INFORMATION CONTACT: Roy Unger, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port, call (202) 927–5850, or refer to the U.S. Customs website at http://www.customs.gov. For information on embargoes and quota re-openings, refer to the Office of Textiles and Apparel website at http://otexa.ita.doc.gov.

SUPPLEMENTARY INFORMATION:

Authority: Section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); Executive Order 11651 of March 3, 1972, as amended.

The current limits for certain categories are being adjusted for recrediting of unused carryforward, carryover, swing, and special shift.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 65 FR 82328, published on December 28, 2000). Also

see 65 FR 69503, published on November 17, 2000.

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

June 4, 2001.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on November 13, 2000, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, wool, man-made fiber, silk blend and other vegetable fiber textiles and textile products, produced or manufactured in Sri Lanka and exported during the twelve-month period which began on January 1, 2001 and extends through December 31, 2001.

Effective on June 11, 2001, you are directed to adjust the limits for the following categories, as provided for under the Uruguay Round Agreement on Textiles and Clothing:

Category	Adjusted twelve-month limit [1]
237	447,322 dozen.
314	5,648,085 square meters.
331/631	4,659,365 dozen pairs.
333/633	25,375 dozen.
334/634	1,254,088 dozen.
335/835	251,160 dozen.
336/636/836	722,450 dozen.
338/339	2,135,227 dozen.
340/640	1,936,316 dozen.
341/641	2,973,258 dozen of which not more than 1,978,448 dozen shall be in Category 341 and not more than 2,038,483 dozen shall be in Category 641.
342/642/842	1,031,030 dozen.
345/845	288,820
350/650	191,686 dozen.
351/651	550,678 dozen.
352/652	1,958,180 dozen.
359–C/659–C [2]	1,488,053 kilograms
360	2,419,054 numbers.
363	19,853,359 numbers.
369–D [3]	481,668 kilograms.
369–S [4]	1,220,128 kilograms.
434	8,904 dozen.
435	17,270 dozen.
440	9,465 dozen.
611	4,707,753 square meters.
635	655,434 dozen.
638/639/838	1,379,608 dozen.
644	821,517 numbers.
645/646	166,922 dozen.
647/648	1,411,959 dozen.
840	270,887 dozen.

[1] The limits have not been adjusted to account for any imports exported after December 31, 2000.

[2] Category 359–C: only HTS numbers 6103.42.2025, 6103.49.8034, 6104.62.1020, 6104.69.8010, 6114.20.0048, 6114.20.0052, 6203.42.2010, 6203.42.2090, 6204.62.2010, 6211.32.0010, 6211.32.0025 and 6211.42.0010; Category 659–C: only HTS numbers 6103.23.0055, 6103.43.2020, 6103.43.2025, 6103.49.2000, 6103.49.8038, 6104.63.1020, 6104.63.1030, 6104.69.1000, 6104.69.8014, 6114.30.3044, 6114.30.3054, 6203.43.2010, 6203.43.2090, 6203.49.1010, 6203.49.1090, 6204.63.1510, 6204.69.1010, 6210.10.9010, 6211.33.0010, 6211.33.0017 and 6211.43.0010.

[3] Category 369–D: only HTS numbers 6302.60.0010, 6302.91.0005 and 6302.91.0045.

[4] Category 369–S: only HTS number 6307.10.2005.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception of the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 01–14451 Filed 6–7–01; 8:45 am]

BILLING CODE 3510–DR–F

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Availability of Funds for National Provider of Information and Training and Technical Assistance to Faith-Based and Small Community Organizations Using Service and Volunteerism as a Strategy To Meet Community Needs

AGENCY: Corporation for National and Community Service.

ACTION: Notice of availability of funds.

SUMMARY: The Corporation for National and Community Service (Corporation) announces the availability of funds for an organization selected under this Notice to provide information concerning available resources and training and technical assistance, to assist faith-based and small community organizations using service and volunteers to meet the needs of individuals whom prosperity has left behind. The Corporation intends to enter into a cooperative agreement of up to three years, beginning on or about August 1, 2001. The funds available under this Notice will support the initial phase of the agreement (generally the first year's budget), with additional funding contingent upon need, quality of service, and availability of appropriations for this purpose.

The Corporation anticipates making up to $400,000 available for the first year of this award. This amount is approximate and for the first year only and may change depending upon the availability of appropriations and the nature and scope of activities to be supported.

Note: This is a notice for selection of organizations to provide information concerning available resources, and training and technical assistance, to faith-based and small community organizations. This is not a notice for program grant proposals.

DATES: The Corporation must receive Proposals by 3 pm Eastern time on July 9, 2001.

ADDRESSES: Submit proposals to the Corporation for National and Community Service, 1201 New York Avenue, NW., Washington, DC 20525, Attention: Jim Ekstrom.

FOR FURTHER INFORMATION CONTACT: Arthurine Walker, Jim Ekstrom, or Christine Benero at the Corporation for National and Community Service, (202) 606–5000, extensions 423, 139, or 193; TTY (202) 565–2799; email *awalker@cns.gov,* or *jekstrom@cns.gov,* or *cbenero@cns.gov.* This Notice is available on the Corporation's web site, http://www.nationalservice.org/whatshot/notices/. Upon request, this information will be made available in alternate formats.

SUPPLEMENTARY INFORMATION:

I. Background

Earlier this year the President signed two Executive Orders emphasizing the role of faith-based organizations and community groups in assisting those whom prosperity has left behind. The Administration's document, A Blueprint for New Beginnings, notes that: ''In every instance where this Administration sees a responsibility to help people, it will look first to faith-based organizations, charities, and community groups that have shown the ability to save and change lives.''

The Corporation supports this agenda through all of its programs, which are described below. Since 1993, we have had extensive experience working with faith-based organizations such as Habitat for Humanity, Lutheran Services in America, the Catholic Network for Volunteer Services, and the National Jewish Coalition for Literacy.

The Corporation for National and Community Service was established in 1993 to engage Americans of all ages and backgrounds in service to their communities. The Corporation's national and community service programs provide opportunities for participants to serve full-time and part-time, with or without stipend, as individuals or as part of a team. AmeriCorps*State, National, VISTA, and National Civilian Community Corps

programs engage thousands of Americans on a full, or part-time basis, at over 1,000 locations to help communities meet their toughest challenges. Learn and Serve America integrates service into the academic life or experiences of nearly one million youth from kindergarten through higher education in all 50 states. The National Senior Service Corps uses the skills, talents and experience of over 500,000 older Americans to help make communities stronger, safer, healthier and smarter.

AmeriCorps*State and AmeriCorps*National programs, which involve over 40,000 Americans each year in results-driven community service, are grant programs managed by: (1) Governor-appointed state commissions (see ''Glossary of Terms'') that select and oversee programs operated by local organizations; (2) national non-profit organizations that act as parent organizations (see ''Glossary of Terms'') for operating sites across the country; (3) Indian tribes; or (4) U.S. Territories.

Learn and Serve America provides service-learning opportunities for approximately 1.2 million youth and students in 2,500 projects annually through grants to state education agencies (see ''Glossary of Terms''), Indian Tribes and U.S.Territories, nonprofit agencies, community-based organizations, and higher education institutions and organizations. The National Senior Service Corps awards grants to nearly 1,300 local organizations to operate the Retired and Senior Volunteer (RSVP), Foster Grandparent (FGP) and Senior Companion (SCP) programs in their communities.

In addition, the Corporation supports the AmeriCorps*VISTA (Volunteers in Service to America) and AmeriCorps*NCCC (National Civilian Community Corps) programs. Annually more than 6,000 AmeriCorps*VISTA members develop grassroots programs, mobilize resources and build capacity for service across the nation. AmeriCorps*NCCC provides the opportunity for approximately 1,000 individuals between the ages of 18 and 24 to participate each year in ten-month residential programs located mainly on inactive military bases. For additional information on the national service programs supported by the Corporation, go to http://www.nationalservice.org.

Training and technical assistance for Corporation programs takes place at local, state, regional and national levels, with most occurring at the local and state levels.

To ensure equity and to promote quality, the Corporation funds a series of national training and technical assistance agreements.

II. Eligibility

State and local government entities, non-profit organizations, institutions of higher education, Indian tribes, and commercial entities are eligible to apply. Pursuant to the Lobbying Disclosure Act of 1995, an organization described in section 501(c)(4) of the Internal Revenue Code of 1986, 26 U.S C. 501(c)(4), which engages in lobbying, is not eligible to apply. Organizations that operate or intend to operate Corporation-supported programs are eligible.

We will consider proposals from single applicants and applicants in partnership. We will also consider proposals from applicants proposing other approaches to meeting the requirement that we consider to be responsive to this Notice.

Organizations may apply to provide information, and training and technical assistance, in partnership with organizations seeking other Corporation funds. Based on previous training and technical assistance competitions and our estimate of potential applicants, we expect fewer than ten applications to be submitted in response to this notice.

III. Conditions

A. Legal Authority

This notice is authorized under the National and Community Service Act of 1990, 42 U.S.C. 12501 *et seq.*, and the Domestic Volunteer Service Act of 1973, 42 U.S.C. 4950 *et seq.*

B. Cooperative Agreements

The award made under this Notice will be in the form of a cooperative agreement. Administration of cooperative agreements is controlled by Corporation regulations, 45 CFR part 2541 (for agreements with state and local government agencies) and 45 CFR part 2543 (for agreements with institutions of higher education, non-profit organizations and commercial entities). The provider must comply with reporting requirements, including submitting semi-annual financial reports and progress reports linking progress on deliverables to expenditures.

Cooperative agreements require substantial involvement on the part of the government. Substantial involvement includes frequent and regular communication with, and monitoring by, the Corporation's cognizant officer.

C. Time Frame

The Corporation expects that activities assisted under the agreement awarded through this Notice will commence on or about August 1, 2001, following the conclusion of the selection and award process. The Corporation will make an award covering a period not to exceed three years. Applications must include a detailed work plan of proposed activities and a line-item budget for year one of the agreement and should note projected changes to proposed activities for years two and three of the award period. If the Corporation approves an application and enters into a multi-year award agreement, at the outset it will provide funding only for the first year of the award period. The Corporation has no obligation to provide additional funding in subsequent years. Funding for the second and third years of an award period is contingent upon satisfactory performance, the availability of funds, and any other criteria established in the award agreement.

D. Use of Materials

To ensure that materials generated with Corporation funding for training and technical assistance purposes are available to the public and readily accessible, the Corporation reserves a royalty-free, non-exclusive, and irrevocable right to obtain, use, reproduce, publish, or disseminate publications and materials produced under the agreement, including data, and to authorize others to do so. The provider must agree to make such publications and materials available to the national service field, as identified by the Corporation, at no cost or at the cost of reproduction. All materials developed with Corporation funding must be consistent with Corporation editorial and publication guidelines and must be accessible to individuals with disabilities to the extent required by law.

IV. Scope of Activities To Be Supported

The provider selected under this Notice will:

(a) Provide information concerning national service resources and other volunteer service resources;

(b) Make referrals to other federal government and state agencies;

(c) Assist state service commissions and others, where appropriate, with the development of statewide coalitions to coordinate local outreach and serve as intermediaries; and

(d) Provide or broker technical assistance and/or training services.

The majority of activities over the life of the agreement will likely fall into the first three categories. However, the provider should be prepared to provide, coordinate or broker training services, materials development, and ongoing technical assistance possibly in conjunction with other Corporation T/TA providers (for a current list go to www.etr/nsrc/org). The provider will tailor such training services to the specific needs of faith-based and small community organizations using service and volunteers to meet community needs. Training services may particularly come into play as the provider carries out the requirements of the third category; supporting state service commissions and others in the development of statewide coalitions. Under item (b), the provider is expected to handle general inquiries concerning programming and funding opportunities available throughout the federal government from small community and faith-based organizations. The services provided under item (d) will be available to faith-based and small community organizations without regard to whether such organizations become Corporation grantees or sub-grantees.

The Corporation recently conducted a meeting of faith-based and small community organizations to help us identify steps that we could take to make our resources more accessible to such organizations. We learned that such organizations need information about resources and support available at the Corporation and from other federal, state, and local agencies, as well as training and technical assistance in the use of volunteers and service in meeting community needs.

Based upon this meeting and input from other interested parties, the Corporation is seeking a provider who will meet these needs. The provider must integrate the deliverables and principles listed below into its service delivery. The provider is further expected to conduct activities that will reflect and support the diversity of faith-based and small community organizations.

A. Tasks Related to IV(a) and (b) Providing Information to Faith-Based and Community Organizations

1. Systems

a. Electronically track information requests, referrals and services provided based on guidance from the Corporation.

b. Provide follow-up to assure that the needs of the faith-based and small community organization are addressed.

2. Audience and Outreach

a. Respond to ongoing requests for information from faith-based and small community organizations concerning national and community service resources.

b. Advertise services to assure awareness.

c. Work with the faith-based and small community organizations that request assistance to identify and clarify their needs and determine an appropriate service response.

3. Delivery

a. Set up and staff a toll-free 800 number to provide support for faith-based and small community organizations.

b. Develop and set up an appropriate technological capacity to handle incoming requests for information.

c. Provide follow-up, ongoing support for organizations to assure connections with national and community service resources. Report on the results of this follow-up.

d. Refer small community and faith-based organizations to other federal government agencies, and states and local organizations, as appropriate, in those situations where requests cannot be met by national and community service resources.

4. Evaluation

a. Develop and submit a plan for evaluating the impact of information services, particularly the impact on the organization's needs and the principles and deliverables of this Notice.

b. Conduct an assessment after each training and technical assistance event.

B. Tasks Related to IV(c) and (d) Supporting State Service Commissions in the Development of State-Wide Coalitions and Brokering of Training and Technical Assistance

1. Systems

a. Electronically track requests, referrals and services provided based on guidance from the Corporation.

b. Develop a system for referring state service commissions and other organizations to local content area experts or Corporation T/TA providers who can provide staff, member and volunteer training to faith-based and small community groups.

2. Audience and Outreach

a. In collaboration with training and technical assistance staff, develop and implement an outreach plan to state service commissions, Corporation State Offices, State Education Agencies, and other key state-wide organizations regarding the usefulness of intermediaries in assisting faith-based and small community organizations and to promote the provider's services in helping to start and develop state-wide coalitions or intermediaries to support local faith-based and small community organizations.

b. Work with state service commissions and other statewide organizations that request assistance to identify and clarify their needs and determine an appropriate service response.

c. Develop and maintain a web site of research, effective practices, and training and technical assistance resources in the provider's area with links to national service sites, as directed by the Corporation.

d. Respond to any individual requests for guidance and support from faith-based and small community organizations and determine appropriate referral for technical assistance.

3. Capacity-Building Services

a. Provide information, materials, and consulting support to state service commissions and other statewide organizations interested in starting coalitions or intermediaries to support local faith-based and small community organizations in gaining greater access to federal resources.

b. If training services are determined to be needed in order to help state commissions or other statewide organizations develop capacity to support coalitions and intermediaries, schedule and coordinate logistics of training services with the state commission, state education agency, and Corporation state office or with state office cluster-wide training activities.

c. Where appropriate, directly provide or coordinate training and technical assistance for faith-based or small community organizations.

d. Develop course and publication outlines and descriptions in collaboration with Corporation staff.

e. Ensure that all training and technical assistance and resources including web sites are accessible to persons with disabilities as required by law to include the following:

i. Notifying potential participants that reasonable accommodations will be provided upon request;

ii. Providing reasonable accommodations when requested to do so, including provision of sign language interpreters, special assistance, and documents in alternate formats;

iii. Using accessible locations for training events;

iv. Providing training and technical assistance materials that are accessible to persons with disabilities, by using accessible technology, providing materials in alternate formats upon request, captioning videos and not using solely a non-voice-over format, and when indicating a telephone number, including a non-voice telephone alternative such as TDD or e-mail;

v. Deliver training that enhances the capacity of participants to function independently and effectively, which includes, but is not limited to, the following:

—Using transfer-of-skills methods and train-the-trainer models in delivering services following guidelines provided by the Corporation;

—Providing structured opportunities for peer-to-peer assistance during and after all on-request and scheduled training events;

—Developing and disseminating training event packets that include the training agenda, handouts and list of training event participants.

4. Effective Practices

a. Research, identify, document and transmit effective tools and practices through all the provider's training and technical assistance services.

b. Submit effective tools and practices in stipulated format to the Effective Practices Information Center database (EpiCenter—see ''Glossary of Terms''), and, if appropriate, to the National Service-Learning Clearinghouse; encourage grantee use of same.

c. Develop and implement a dissemination plan for all materials (e.g., publications, videotapes, etc.) produced under the agreement.

5. Evaluation

a. Develop and submit a plan for evaluating the impact of training and technical assistance services, particularly the impact of training events relative to each training event's objectives and the principles and deliverables of this Notice.

b. Conduct an assessment after each training and technical assistance event.

c. Maintain records of these evaluations and provide them to the Corporation, or an authorized representative, upon request.

d. Submit aggregate evaluation summaries of training and technical assistance events' evaluations as part of progress reports to the Corporation.

e. The Corporation may conduct an independent assessment of each provider's performance.

7. Reporting Requirements

The provider is responsible for submitting timely progress and financial reports during and at the conclusion of the award period to the Corporation as follows:

a. Semi-annual Progress Reports. Progress reports must be submitted semi-annually and are due January 31, 2002, for the period ending December 30, 2001, and July 31, 2002, for the period ending June 30, 2002. The provider must develop the capacity to submit this information electronically. At a minimum, progress reports must provide the information below:

i. A comparison of accomplishments with the goals and objectives for the reporting period;

ii. An annotated version of the approved budget that compares actual costs with budgeted costs by line item, and explains differences. The explanation should include, as appropriate, an analysis of cost overruns and high-cost units and a description of service requests not anticipated in the provider's original budget;

iii. A description of the services provided to include:

(a) Number of requests received;

(b) Activity conducted to address each request;

(c) Number of participants to whom information was provided and/or affected by each training and technical assistance event;

(d) Client feedback on the services; and

(e) Problems encountered in delivering services with recommendations for correcting them.

iv. List of upcoming activities and events with dates and locations;

v. Recommended training and technical assistance focus areas as suggested by analyses of service activities and trends;

vi. Discussion of developments that hindered, or may hinder, compliance with the cooperative agreement;

vii. List of materials submitted to the National Service Resource Center and National Service-learning Clearinghouse;

viii. List of practices and supporting documentation or materials submitted to the Effective Practices Information Center database (EpiCenter).

b. Financial reports must be submitted semi-annually to include a summary of expenditures during the period. A cumulative report must be submitted on the Financial Status Report (FSR) form SF 269A.

c. Final Reports. i. Upon completing the final year of the agreement, the provider must submit, in lieu of the last semiannual progress report, a final progress report that is cumulative over the entire award period. This final progress report is due within 90 days after the close of the agreement.

ii. Upon completing the final year of the award, the provider must submit, in lieu of the last semi-annual FSR, a final FSR that is cumulative over the entire award period. This FSR is due within 90 days after the end of the agreement.

d. Financial reports must be submitted in three (3) copies to the Office of Grants Management. Progress reports shall be submitted in three (3) copies to the Corporation's cognizant training officer of the award.

e. The provider must meet as necessary with the cognizant training officer or with other staff or consultants designated by the Corporation training official to exchange views, ideas, and information concerning T/TA. The provider must submit such special reports as may be reasonably requested by the Corporation.

7. Other Requirements

a. Assure that provider staff and consultants are fully versed in the background, approach, vocabulary, assets, needs and objectives of the Corporation and each of its program streams.

b. Participate in the planning and implementation of conferences and training events as requested by the Corporation.

c. Collaborate in materials' development and training events organized by other providers or the Corporation, as requested.

d. Share effective practices with other providers through the training and technical assistance listserv, the Effective Practices Information Center database (EpiCenter) and other mechanisms such as the National Service-Learning Clearinghouse and the National Service Resource Center (see ''Glossary of Terms'').

e. Creatively and effectively use technology as a cost-effective strategy for reaching large numbers of organizations.

V. Application Guidelines

A. Proposal Content and Submission

Applicants must submit one unbound, original proposal and two bound copies. Applicants may voluntarily submit two additional bound copies for a total of four copies. Proposals may not be submitted by facsimile. Page limits are provided as a guide. Proposals must include the following:

1. Cover Page

The cover page must include the name, address, phone number, fax number, e-mail address of the contact person and World Wide Web site URL (if available) of the applicant organization; the category for which the application is being submitted; a 25–50 word summary of proposed information and training and technical assistance activities; and, the total funding amount requested for the first year.

2. List of Activities and Materials

A one-two page list of all proposed information and training and technical assistance activities and materials.

3. Information and Capacity-Building Delivery Plan

A bulleted narrative of approximately 20 double-spaced, single-sided, typed pages in no smaller than 12-point font that includes:

a. The applicant's proposed strategy and rationale for providing information and capacity-building support to state service commissions, other statewide organizations, and a diverse audience of faith-based and small community organizations for year one with proposed changes (if any) for years two and three. The applicant should use the specific deliverables and requirements outlined in Section IV of this Notice as a starting point for a plan and should present these deliverables in a way that creatively reflects the applicant's areas of expertise and knowledge of faith-based and small community organization audiences. It is not sufficient to simply re-list the tasks stated in this Notice. As appropriate, the applicant should also include the following information for each proposed information and capacity-building support activity, product, or event: type of activity, number, frequency, audience, information, knowledge and skills individuals will gain, estimated audience size, content, skill level, proposed needs assessment and continuous improvement strategies.

b. A detailed one-year work plan and timeline for completing all information and training and technical assistance activities. The work plan should include all deliverables and the tasks leading to them.

c. A plan for regularly evaluating performance and using findings for continuous improvement.

4. Technology Strategy

A one-page description of how applicant proposes to use technology, particularly e-learning, to effectively broaden the reach of information and training delivery. Description should include target audience; proposed use of technology; rationale for approach; types of information being shared; concepts and skills to be delivered under training, including desired learner outcomes; and how outcomes will be achieved.

5. Description of Organizational Capacity

An organizational chart that clearly shows the place of the provider in the parent organization's structure and resumes and a narrative of approximately three double-spaced, single-sided, typed pages in no smaller than 12-point font which describes:

a. The organization's capacity to provide information and capacity-building support services nationwide, including descriptions of recent work similar to that being proposed.

b. The organization's knowledge of and experience with faith-based and community organizations and national and community service.

c. The organization's ability to leverage the expertise and resources of a broad base of organizations to achieve the objectives under this Notice.

d. References that can be contacted related to the organization's capacity.

e. List of proposed staff that includes each one's areas of expertise. (*Note:* Final list will be subject to Corporation approval.)

6. Budget

A detailed, line-item budget with costs organized by personnel, task and sub-task and related to the activities and deliverables outlined in the introductory narrative and work plan. Costs in proposed budgets must consist solely of costs allowable under applicable cost principles found in OMB Circulars.

Applicants should be mindful that a demonstrated commitment to providing services in the most cost-effective manner possible will be a major consideration in the evaluation of proposals. Provider match is not required. The budget should include:

a. Proposed staff and expert-consultant hours and pay rates by task and sub-task;

b. Types and quantities of other direct costs being proposed by task and subtask (for example, amounts of travel and volume of other task-related resources, such as communications, postage, etc.).

7. Budget Narrative

Provide a budget narrative that corresponds with all items in the line-item budget and that includes an explanation and cost basis for all cost estimates that appear in the line-item budget. The narrative should clearly show the following:

a. How each cost was derived, using equations to reflect all factors considered.

b. The anticipated unit cost (with derivation) of the various deliverables (such as training events, publications and technical assistance interventions).

B. Selection Criteria

The Corporation will assess applications based on the criteria listed below.

1. Quality (25%)

The Corporation will consider the quality of the proposed activities based on:

a. Evidence of the applicant's knowledge of faith-based and small community organizations, the goals of the Corporation and its various programs (see Section VI. ''Glossary''), and the Corporation's information sharing and training and technical assistance requirements and principles as outlined in this Notice and demonstrated by applicant's past experience and proposed approach.

b. Evidence of the applicant's knowledge of adult learning and experience in training adults; the audience appropriateness, strategic nature (i e., broad reaching and capacity-building), effectiveness and creativity of the applicant's approach.

2. Organizational and Personnel Capacity (35%)

The Corporation will consider the organizational capacity of the applicant to deliver the proposed services based on:

a. Evidence of the organization's experience in delivering high-quality information and capacity-building support to faith-based and small community organizations in a flexible, responsive, collaborative and creative manner; experience with or knowledge of national or community service as described by applicant; experience using technology as an outreach tool.

b. Evidence of experience providing information to, and training and technical assistance to, adults who work in or with faith-based or small community organizations on the part of the proposed staff and consultants as demonstrated by annotated staff lists or resumes.

c. Demonstrated ability to manage a federal grant or apply sound fiscal management principles to grants and cost accounting as evidenced by an annotated list of applicant's previous grants experience.

d. Demonstrated ability to provide information and capacity-building support services nationwide as evidenced by proposed technology plan, proposed staffing and previous levels of activity and experience.

e. Demonstrated ability to leverage the expertise and resources of a broad base of organizations.

3. Evaluation (15%)

The Corporation will consider how the applicant:

a. Proposes to assess the effectiveness and need for its services and products delivered under the award.

b. Plans to use assessments of its services and products to modify and improve subsequent services and products.

4. Budget (25%)

The Corporation will consider the budget based on:

a. Cost of each proposed activity in relation to the scope and depth of the services proposed (i.e., the number of states, programs and individuals the proposed activities are intended to reach);

b. The clarity and thoroughness of the budget and budget narrative (see specifications under ''Budget Narrative'').

VI. Glossary of Terms

Clusters

The Corporation's field offices are organized into five regions (''clusters'') as follows:

Atlantic:
Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Puerto Rico, Rhode Island, Vermont, Virgin Islands

North Central:
Illinois, Indiana, Iowa, Michigan, Minnesota, Nebraska, North Dakota, Ohio, South Dakota, Wisconsin

Pacific:
Alaska, American Samoa, California, Guam, Hawaii, Idaho, Mariannas, Montana, Nevada, Oregon, Utah, Washington, Wyoming

South:
Alabama, District of Columbia, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee, Virginia, West Virginia

Southwest:
Arizona, Arkansas, Colorado, Kansas, Louisiana, Missouri, New Mexico, Oklahoma, Texas

Cluster-Based Training

Training events planned in conjunction with the Corporation's training and technical assistance officer and the commissions, state offices, state education agencies or Tribal, national direct and higher education grantees in a particular region.

Corporation State Office

The Corporation-staffed office that, within a state, manages VISTA activities, oversees Senior Corps activities, and otherwise supports programs funded under the national service laws. Corporation state offices are organized by cluster.

Effective Practice(s)

The following definition is used to guide submissions of effective practice(s) to the Effective Practices Information Center (EpiCenter): An effective practices is an action or series of actions by a grantee, program staff, national service participant, or technical assistance provider that helps to solve an essential problem facing a national service program and the community it serves, leading to a successful outcome. Effective practices address issues shared by program staff or national service participants across local program or operating sites and can be replicated in or adapted to serve in more than one locale. Effective practices can be described and documented in terms of (1) the problem it solves; (2) the context in which it has been successful; (3) the level of outcome or impact it helped to achieve; and (4) evidence of success of the practice.

Effective Practices Information Center (EpiCenter)

EpiCenter is the Corporation's online database of effective program practices in national service. Its mission is to support practitioners in developing sustainable programs that lead to positive outcomes for beneficiaries, participants, institutions, and communities and to make this information widely accessible across the national service network. Providers are required to submit effective training and program practices to EpiCenter. The database can be visited at www.nationalservice.org/resources/epicenter.

Grantees

Entities funded directly by the Corporation. These include and are not limited to: state commissions; state education agencies; Tribes and U.S.Territories; national direct parent organizations; institutions, consortia and organizations of higher education; local governments; and non-profit organizations. Many grantees also subgrant a significant portion of their funds to others (e.g., a state commission conducts a competition and review process and funds AmeriCorps programs throughout a state; a state education agency (SEA) conducts a competition and review process and funds school systems throughout a state). Regulations do not allow the 1,300 Senior Corps grantees to subgrant.

Learn and Serve America National Service-Learning Clearinghouse

The Learn and Serve America National Service-Learning Clearinghouse is a collaborative effort among twelve national partner organizations to collect and disseminate information on service-learning for national service awardees and the general public engaged in service-learning. The Clearinghouse maintains and operates a web site and service-learning listservs, a library of print and media materials related to service-learning, and a toll-free information and referral service. Providers are required to submit copies of service-learning related training materials and training scripts to the Learn and Serve America National Service-Learning Clearinghouse.

National Service Resource Center (NSRC)

The National Service Resource Center (NSRC) serves as a repository of information on all aspects of national service. The NSRC manages most of the Corporation's listservs. Training and technical assistance publications are posted or distributed by the NSRC and its web site includes a calendar of training events and links to all current providers.

Parent Organization

The legal applicant for Corporation for National Service national direct funds; the organization responsible for the management and oversight of the national direct grant.

State Education Agency

Refers to the officer or agency primarily responsible for that state's supervision of public elementary and secondary schools.

State Service Commission

Refers to the State agency with responsibility for, among other things, selecting and overseeing national service programs, developing a unified state plan incorporating all streams of service, providing training and technical assistance to national service programs, and supporting recruitment and other public awareness activities.

Stream of Service

Refers to the Corporation's three programs: AmeriCorps, Learn and Serve America and National Senior Service Corps. Cross-stream activities, therefore, refer to activities conducted or attended by representatives from more than one program stream.

Subgrantees

Many Corporation awardees competitively award a significant portion of their funds to other entities known as subgrantees State commissions, for example, subgrant to local non-profit organizations. Senior Corps programs do not subgrant (see ''Grantees'').

Substream of Service

Refers to the categories within each of the above streams and includes the following:

AmeriCorps

AmeriCorps*State

AmeriCorps*National

AmeriCorps*Promise Fellows

AmeriCorps*VISTA

AmeriCorps*National Civilian Community Corps

Learn and Serve America

Learn and Serve America K–12 School-Based and Community-Based Programs

Learn and Serve America Higher Education Programs

National Senior Service Corps

Foster Grandparent Program

Retired and Senior Volunteer Program (RSVP)

Senior Companion Program

Training and Technical Assistance Listserv

Currently managed by the National Service Resource Center, the training and technical assistance listserv is one way providers share best practices with one another. Providers also share effective practices through the Effective Practices Information Center (EpiCenter) and the National Service-Learning Clearinghouse.

Dated: June 1, 2001.

George Gary Kowalczyk,

Coordinator, National Service Programs, Corporation for National and Community Service.

[FR Doc. 01–14402 Filed 6–7–01; 8:45 am]

BILLING CODE 6050–$$–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0078]

Federal Acquisition Regulation; Proposed Collection; Make-or-Buy Program

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for comments regarding an extension to an existing OMB clearance (9000–0078).

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Federal Acquisition Regulation (FAR) Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection requirement concerning Make-or-Buy Program. The clearance currently expires on September 30, 2001.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

DATES: Submit comments on or before August 7, 2001.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: FAR Desk Officer, OMB, Room 10102, NEOB, Washington, DC 20503, and a copy to the General Services Administration, FAR Secretariat (MVP), 1800 F Street, NW, Room 4035, Washington, DC 20405.

FOR FURTHER INFORMATION CONTACT: Jerry Olson, Acquisition Policy Division, GSA (202) 501–3221.

SUPPLEMENTARY INFORMATION:

A. Purpose

Price, performance, and/or implementation of socio-economic policies may be affected by make-or-buy decisions under certain Government prime contracts. Accordingly, Section 15.407–2, Make-or-Buy Programs, of the FAR—

(i) Sets forth circumstances under which a Government contractor must submit for approval by the contracting officer a make-or-buy program, i.e., a written plan identifying major items to be produced or work efforts to be performed in the prime contractor's facilities and those to be subcontracted;

(ii) Provides guidance to contracting officers concerning the review and approval of the make-or-buy programs; and

(iii) Prescribes the contract clause at FAR 52.215–9, Changes or Additions to Make-or-Buy Programs, which specifies the circumstances under which the contractor is required to submit for the contracting officer's advance approval a notification and justification of any proposed change in the approved make-or-buy program.

The information is used to assure the lowest overall cost to the Government for required supplies and services.

B. Annual Reporting Burden

The annual reporting burden is estimated as follows:

Respondents: 150.
Responses Per Respondent: 3.
Total Responses: 450.
Hours Per Response: 8.
Total Burden Hours: 3,600.

Obtaining Copies of Proposals

Requester may obtain a copy of the proposal from the General Services Administration, FAR Secretariat (MVP), Room 4035, Washington, DC 20405, telephone (202) 501–4755. Please cite OMB Control No. 9000–0078, Make-or-Buy Program, in all correspondence.

Dated: May 31, 2001.

Al Matera,

Director, Acquisition Policy Division.

[FR Doc. 01–14326 Filed 6–7–01; 8:45 am]

BILLING CODE 6820–34–P

DEPARTMENT OF DEFENSE

Department of the Army

Notice of availability of Optical Switching Technologies for Exclusive, Partially Exclusive or Non-exclusive Licenses

AGENCY: U.S. Army Research Laboratory, DoD.

ACTION: Notice of Availability.

SUMMARY: The Department of the Army announces the general availability of exclusive, partially exclusive or non-exclusive licenses relative to a novel optical switching technologies as described in U.S. Patent# 6,075,254, Shen, et al., June 13, 2000, ''Polarization Insensitive/Independent Semiconductor Waveguide Modulator Using Tensile Stressors''; U.S. Patent# 5,770,472, Zhou, et al., June 23, 1998, ''Method for Making Monolithically Integrated Signal Processing Circuit Having Active and Passive Components''; U.S. patent# 5,930,031, Zhou, et al., July 27, 1999, ''Monolithically Integrated Signal Processing Circuit Having Active and Passive Components''. Licenses shall comply with 35 U.S.C. 209 and 37 CFR part 404.

FOR FURTHER INFORMATION CONTACT: Michael D. Rausa, U.S. Army Research Laboratory, Office of Research and Technology Applications, ATTN: AMSRL–CS–TT/Bldg. 459, Aberdeen Proving Ground, Maryland 21005–5425, Telephone: (410) 278–5028.

SUPPLEMENTARY INFORMATION: None.

Luz D. Ortiz,

Army Federal Register Liaison Officer.

[FR Doc. 01–14516 Filed 6–7–01; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Intent To Prepare a Combined Environmental Impact Statement/ Environmental Impact Report (EIS/EIR) for Flood Damage Reduction Activities Along the Pajaro River in Santa Cruz and Monterey Counties, CA

AGENCY: U.S. Army Corps of Engineers, DOD.

ACTION: Notice of intent.

SUMMARY: The San Francisco District and the Counties of Santa Cruz and Monterey, California intend to prepare a combined EIS/EIR to support a cost shared study for flood damage reduction of lands surrounding the Pajaro River in the Lower Pajaro River Watershed. The project boundaries include the lower Pajaro River and its tributaries. The Pajaro River (or Main Stem) is the county border. The Pajaro River section begins at Murphy's Crossing and extends to the mouth of the Pajaro River, which empties into Monterey Bay. The tributary section located in Santa Cruz County is comprised of the lower Corralitos Creek running from Green Valley Road to Lake Avenue. Corralitos Creek empties into Salsipuedes Creek near College Lake. The project footprint continues from the confluence of Corralitos and Salsipuedes Creeks, down Salsipuedes Creek until it empties into the Pajaro River. The project area is mainly agricultural, but includes the incorporated City of Watsonville on the Santa Cruz County, California side of the river and the unincorporated Town of Pajaro on the Monterey County, California side. Proposed plans will include: No-action, non-structural, and structural alternatives to be determined during the planning process. The EIS/EIR will analyze potential impacts on the environment on these alternatives, including the recommended plan.

FOR FURTHER INFORMATION CONTACT: For further information contact Ms. Linda Ngim either by telephone at (415) 977–8538, by fax at (415) 977–8695, or by mail at the address below.

SUPPLEMENTARY INFORMATION: The Army Corps of Engineer and Santa Cruz and Monterey Counties intends to prepare a combined EIS/EIR to assess the environmental effects associated with the proposed project. The public will have the opportunity to comment on this environmental impact analysis before any action is taken to implement the proposed action.

1. Scoping

The Army Corps of Engineers will hold a scoping meeting on Thursday, June 21, 2001 at the Watsonville Senior Center, 114 East Fifth Street in Watsonville, California, 95076 from 5 p.m. to 7 p.m. Federal, State and Local agencies are invited to participate at the public meeting or by submitting data, information, and comments identifying relevant environmental and socioeconomic issues to be addressed in the environmental analysis. Useful information includes other environmental studies, published and unpublished data, alternatives that should be addressed in the analysis, and potential measures associated with the proposed action. Comments, suggestions, and requests to be placed on the mailing list for announcements and for the Draft EIS/EIR, should be sent to Ms. Linda Ngim, U.S. Army Corps of Engineers, San Francisco District, 333 Market Street, 7th floor (CESPN–ET–PP), San Francisco, California, 94105–2197. Deadline for comments to be included into the EIS/EIR is the Close of Business July 31, 2001.

2. Availability of the Draft EIS/EIR

The Draft EIS/EIR is expected to be published in early January 2002, and a public hearing to receive comments on the Draft EIS/EIR will be held after it is published.

Luz D. Ortiz,

Army Federal Register Liaison Officer.

[FR Doc. 01–14515 Filed 6–7–01; 8:45 am]

BILLING CODE 3710–19–M

DEPARTMENT OF DEFENSE

Department of the Army Corps of Engineers

Inland Waterways Users Board; Meeting

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Notice of open meeting.

SUMMARY: In Accordance with 10(a)(2) of the Federal Advisory Committee Act, Public Law (92–463), announcement is made of the next meeting of the Inland Waterways Users Board. The meeting will be held on July 18, 2001, in Davenport, Iowa, River Center, Iowa and Missouri Rooms, 136 East 3rd Street, (Tel. (563) 326–8500). Registration will begin at 7:30 am and the meeting is scheduled to adjourn at 1 pm. The meeting is open to the public. Any interested person may attend, appear before, or file statements with the committee at the time and in the manner permitted by the committee.

FOR FURTHER INFORMATION CONTACT: Mr. Norman T. Edwards, Headquarters, U.S. Army Corps of Engineers, CECW–PD, 441 G Street, NW., Washington, DC 20314–1000.

SUPPLEMENTARY INFORMATION: None.

Luz D. Ortiz,

Army Federal Register Liaison Officer.

[FR Doc. 01–14514 Filed 6–7–01; 8:45 am]

BILLING CODE 3710–92–M

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

SUMMARY: The Leader, Regulatory Information Management Group, Office of the Chief Information Officer, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before August 7, 2001.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and

Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Leader, Regulatory Information Management Group, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: June 4, 2001.

John Tressler,

Leader, Regulatory Information Management, Office of the Chief Information Officer.

Office of Elementary and Secondary Education

Type of Review: Reinstatement.
Title: Applications for Grants under the Smaller Learning Communities Program.
Frequency: Annually.
Affected Public: State, Local, or Tribal Gov't, SEAs or LEAs.
Reporting and Recordkeeping Hour Burden:
Responses: 700
Burden Hours: 45,500
Abstract: This application will be used to award grants to local educational agenices for the purpose of creating and implementing smaller learning environments in large high schools.

Requests for copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov,* or should be addressed to Vivian Reese, Department of Education, 400 Maryland Avenue, SW, Room 4050, Regional Office Building 3, Washington, DC 20202–4651. Requests may also be electronically mailed to the internet address *OCIO_IMG_Issues@ed.gov* or faxed to 202–708–9346.

Please specify the complete title of the information collection when making your request. Comments regarding burden and/or the collection activity requirements should be directed to Joseph Schubart at (202) 708–9266 or via his internet address *Joe.Schubart@ed.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 01–14433 Filed 6–7–01; 8:45 am]
BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

SUMMARY: The Leader, Regulatory Information Management Group, Office of the Chief Information Officer, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before August 7, 2001.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Leader, Regulatory Information Management Group, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: June 4, 2001.

John Tressler,

Leader, Regulatory Information Management, Office of the Chief Information Officer.

Office of Educational Research and Improvement

Type of Review: Revision.
Title: National Assessment of Educational Progress, 2002 Field Test for the 2003 Full Scale Assessment.
Frequency: Pilot and field test.
Affected Public: Individuals or households; Not-for-profit institutions; State, Local, or Tribal Gov't, SEAs or LEAs.
Reporting and Recordkeeping Hour Burden:
Responses: 9,750
Burden Hours: 2,500
Abstract: The NAEP Technology Based Assessment Project (TBA) is meant to explore the feasibility and best methods for assessing mathematics and writing on line. It is also intended to explore students' abilities to solve problems in technology-rich environments. It is anticipated that in the future such technology-based assessments will reduce assessment burden by allowing, among other things, for online administration and scoring of assessment instruments. The pilot study uses background questions and items from suitable subject questionnaires, including questions about computer use that are currently cleared for other NAEP studies.

Requests for copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov,* or should be addressed to Vivian Reese, Department of Education, 400 Maryland Avenue, SW, Room 4050, Regional Office Building 3, Washington, DC 20202–4651. Requests may also be electronically mailed to the internet address OCIO_IMG_Issues@ed.gov or faxed to 202–708–9346.

Please specify the complete title of the information collection when making your request. Comments regarding burden and/or the collection activity requirements should be directed to Kathy Axt at her internet address *Kathy.Axt@ed.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 01–14434 Filed 6–7–01; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC01–542–001, FERC–542]

Information Collection Submitted for Review and Request for Comments

June 4, 2001.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of submission for review of the Office of Management and Budget (OMB) and request for comments.

SUMMARY: The Federal Energy Regulatory Commission (Commission) has submitted the energy information collection listed in this notice to the Office of Management and Budget (OMB) for review under the provisions of section 3507 of the Paperwork Reduction Act of 1995 (Pub. L. 104–13). Any interested person may file comments on the collection of information directly with OMB and should address a copy of those comments to the Commission as explained below. The Commission did not receive comments in response to an earlier **Federal Register** notice of January 24, 2001 (66 FR 7634) and has made a notation in this submission.

DATES: Comments regarding this collection are best assured of having their full effect if received on or before July 9, 2001.

ADDRESSES: Address comments to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Federal Energy Regulatory Commission Desk Officer, 725 17th Street, NW., Washington DC 20503. A copy of the comments should also be sent to Federal Energy Regulatory Commission, Office of the Chief Information Officer, Attention: Mr. Michael Miller, CI–1, 888 First Street NE., Washington, DC 20426. Mr. Miller may be reached by telephone at (202) 208–1415, by fax at (202) 208–2425, and by e-mail at *mike.miller@ferc.fed.us.*

SUPPLEMENTARY INFORMATION:

Description

The energy information submitted to OMB for review contains:

1. *Collection of Information:* FERC–542 ''Gas Pipeline Rates: Rate Tracking''

2. *Sponsor:* Federal Energy Regulatory Commission.

3. *Control No:* 1902–0070. The Commission is requesting reinstatement, without change, of the previously approved data collection for which approval expired December 31, 2000, and a three-year approval of the collection of data. This is a mandatory information collection requirement.

4. *Necessity of Collection of Information:* Submission of the information is necessary to enable the Commission to carry out its responsibilities in implementing provisions of Sections 4, 5, and 16 of the Natural Gas Act (NGA) and Title IV of the Natural Gas Policy Act (NGPA), 15 U.S.C. 3301–3432. These statutes empower the Commission to collect natural gas transmission cost information from interstate natural gas transporters for the purposes of verifying that these costs, which are passed on to pipeline companies, are just and reasonable. The Commission implements these requirements in 18 CFR 154.4; 154.7; 154.101; 154.107; 154.201; 154.207–.209 and 154.401–.403. Interstate natural gas pipelines are required by the Commission to track their transportation associated costs to allow for the Commission's review and where appropriate, approval of the through of these costs to pipeline customers. Most of the FERC–542 tracking filings are scheduled accountings of the cost of fuel or electric power necessary to operate compressor stations. Other track the costs of Gas Research Institute fees, the Commission's annul charge adjustment assessments, and various cost reimbursements.

Tracking filings may be submitted to any time or on a regularly scheduled basis in accordance with the pipeline company's tariff. Filings may be either: (1) Accepted; (2) suspended and set for hearing; (3) suspended, but not set for hearing; or (4) suspended for further review, such as technical conference or some other type of Commission action.

5. *Respondent Description:* The respondent universe currently comprises approximately 55 natural gas pipeline companies.

6. *Estimated Burden:* 23,100 total burden hours, 55 respondents, 165 responses annually, 140 hours per response.

Authority: Sections 4, 5 and 16 of the NGA (15 U.S.C. 717–717w) and Title IV of the Natural Gas Policy Act (NGPA), 15 U.S.C. 3301–3432.

David P. Boergers,

Secretary.

[FR Doc. 01–14435 Filed 6–7–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP01–376–000]

Intermountain Municipal Gas Agency and Questar Gas Company; Notice of Petition for Declaratory Order

June 4, 2001.

On May 25, 2001, the Intermountain Municipal Gas Agency (IMGA) [1] and Questar Gas Company (Questar Gas), formerly Mountain Fuel Supply Company, filed a joint petition for a declaratory order by the Commission addressing jurisdictional issues raised by an agreement under which Questar Gas is to undertake natural gas transportation services for municipalities in Utah and Arizona for operation of their retain natural gas utilities.[2]

Questar Gas has agreed to provide transportation service to municipalities in Utah pursuant to a settlement agreement approved by the Public Service Commission of Utah (Utah PSC). The petitioners' joint filing may be viewed on the web at *http://www.ferc.fed.us/online/rims.htm* (call 202–208–2222 for assistance).

Questar Gas' northern Utah distribution system, which is a designated service area pursuant to section 7(f) of the Natural Gas Act (NGA),[3] includes Questar Gas' southern Idaho and northern Utah distribution facilities. Questar Gas' southern distribution system operates as an exempt Hinshaw system pursuant to NGA section 1(c). Questar Gas' northern

[1] IMGA is a group of Utah municipalities organized pursuant to the Interlocal Cooperation Act, Title 11 Chapter 13 of the Utah Code, which allows Utah municipalities to organize a cooperative legal entity having the same powers as a municipality including those given by the statute.

[2] Although the municipalities presently have requested only transportation service, Questar Gas believes the same issues will arise if it is requested in the future to make sales of natural gas for resale by the municipalities.

[3] 82 FERC ¶16,057 (1998).

and southern distribution systems are not interconnected.

Acting at the direction of member municipalities, including Hildale, Utah, Colorado City, Arizona, Kanab, Utah, and Fredonia, Arizona, IMGA has requested that Questar Gas deliver interstate gas supplies from its interconnections with interstate pipelines to the interconnection between Questar Gas' southern system feeder line and Hildale's municipal pipeline at the City of Hurricane, Utah. From that point, the gas supplies would then be transported by IMGA through Hildale's 22-mile municipal pipeline to Hildale, Utah. Some of the gas would then be delivered to a planned municipal pipeline that would cross the Utah border into northern Arizona and then back into Utah, terminating at Kanab, Utah, to service only the residents of Kanab, Utah. In the alternative, a new municipal pipeline could be jointly built to serve not only Kanab, Utah, but also Colorado City, Arizona, and Fredonia, Arizona. The Kaibab Paiute Indian tribe in Arizona may also participate.[4] Each city would connect to the pipeline and distribute and sell the gas through a municipal utility to their respective residential, commercial and industrial end-users.

In a recent proceeding before the Utah PSC, Hildale and IMGA requested that the Utah PSC order Questar Gas to provide wholesale transportation service for Hildale and similarly situated Utah municipalities. Under the terms of a stipulation resulting in an approved settlement in that proceeding, Questar Gas has agreed to provide such wholesale transportation service, provided it does not jeopardize Questar Gas' NGA section 1(c) Hinshaw exemption.

Accordingly, the petition seeks a declaratory order addressing Questar Gas' concerns regarding the jurisdictional consequences of providing transportation service directly to Kanab, Utah, where the pipeline serving Kanab crosses into Arizona before reentering Utah, and to municipalities, like Colorado City and Fredonia, Arizona, located outside of Utah. Questar Gas requests that the Commission address the jurisdictional implications of such transportation services on Questar's existing NGA section 1(c) Hinshaw exemption for its southern distribution system and Questar Gas' ability to seek in the future a service area determination for this system under NGA section 7(f).

The petition seeks clarification regarding whether Questar Gas would need NGA certificate authority, such as a blanket transportation certificate issued pursuant to section 284.224 of the Commission's regulations (18 CFR 284.224), to render wholesale transportation service or to construct facilities for transportation of gas to municipal utilities located within Questar Gas' existing designated NGA section 7(f) service area or any such service area designated for Questar Gas in the future. In addition, the petition raises the issue of whether Questar Gas would lose its Hinshaw exemption by providing wholesale transportation service, constructing facilities for such service, or connecting its northern section 7(f) system to its southern Hinshaw system so that gas could flow from one to the other.

IMGA requests clarification of the rate implications for Utah municipalities presently receiving wholesale transportation from Questar Gas, as a Hinshaw pipeline, if Questar Gas accepts a section 284.224 blanket transportation certificate to authorize Questar Gas' transportation of gas that ultimately would be distributed by municipal utilities in non-Utah cities.

The petition also raises the issue of whether Questar Gas may elect, pursuant to the Commission's regulations governing service under a section 284.224 blanket certificate, to charge the Utah PSC's currently approved rate for Questar Gas' existing Hinshaw transportation services for municipal utilities in Utah as Questar Gas' rate for transportation service for Arizona municipalities.

There are two ways to become involved in the Commission's review of this petition. First, any person wishing to obtain legal status by becoming a party to the proceeding should, on or before June 25, 2001, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10).

A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made with the Commission and must mail a copy to the applicants and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of the comments in support of or in opposition to matters raised in the petition. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition provide copies of their protests only to the party or parties directly involved in the protest.

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 at *http://www/ferc/fed/us/efi/doorbell/htm.*

David P. Boergers,

Secretary.

[FR Doc. 01–14437 Filed 6–7–01; 8:45 am]

BILLING CODE 6717–01–M

[4] The petition notes that Indian tribes are identified as entities that can participate in intergovernmental agreements with municipalities under Arizona law A.R.S. 11–951 (1998).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL01–84–000]

Salt River Project Agricultural Improvement and Power District v. California Independent System Operator Corporation; Notice of Complaint

June 4, 2001.

Take notice that on June 1, 2001, Salt River Project Agricultural Improvement and Power District (SRP) submitted a Complaint against the California Independent System Operator Corporation (CAISO) pursuant to Section 206 of the Federal Power Act (FPA) 16 U.S.C. 824e. SRP alleges that the CAISO over collected neutrality adjustment charges from SRP, for the time period January 2000 through December 31, 2000, in violation of the FPA, the rate cap contained in CAISO's tariff and orders of the Commission. SRP also alleges that the CAISO off-set these erroneous charges against payments owed by the CAISO to SRP for power supplies and that the CAISO's tariff violations are discouraging suppliers from providing wholesale power to the CAISO, contrary to the Commission's policy goals. SRP seeks refunds of the alleged over charges, plus

interest calculated in accordance with the Commission's regulations.

Copies of the filing were served upon the California Independent System Operator Corporation, the California Public Utilities Commission and all parties to Cities of Anaheim, Azusa, Banning, Colton and Riverside, California v. California Independent System Operator Corporation, Docket No. EL00–111–000, where similar issues concerning the CAISO's neutrality adjustment charges were raised.

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 June 21, 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 in the Public Reference Room. This filing may also be viewed on the Internet at *http://www.ferc.fed.us/online/rims.htm* (call 202–208–2222) for assistance. Answers to the complaint shall also be due on or before June 21, 2001. 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 at *http://www.ferc.fed.us/efi/doorbell.htm.*

David P. Boergers,

Secretary.

[FR Doc. 01–14436 Filed 6–7–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2232–413 South Carolina]

Duke Energy Corporation; Notice of Availability of Environmental Assessment

June 4, 2001.

An environmental assessment (EA) is available for public review. The EA analyzes the environmental impacts of Duke Energy Corporation's (Duke) application to grant a non-project use of project land to City of York (York) to install a pipeline and intake, for raw water withdrawal, in Lake Wylie, a reservoir for the Catawba-Wateree Hydroelectric Project. Duke's proposed grant would also allow York to withdrawal up to 6 million gallons of water per day from Lake Wylie. The Catawba-Wateree Project is on the Catawba River in Lancaster, York, and Fairfield Counties, South Carolina, and Gaston, Lincoln, and Burke Counties, North Carolina.

The EA was written by staff in the Office of Energy Projects, Federal Energy Regulatory Commission. In the EA, Commission staff conclude that approving Duke's application to grant the use would not constitute a major federal action significantly affecting the quality of the human environment. Copies of the EA can be viewed on the web at *www.ferc.fed.us/online/rims.htm.* Call (202) 208–2222 for assistance. Copies are also available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington DC 20426, or by calling (202) 208–1371.

David P. Boergers,

Secretary.

[FR Doc. 01–14438 Filed 6–7–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2114–091 Washington]

Public Utility District No. 2 of Grant County Washington; Notice of Availability of Environmental Assessment

June 4, 2001.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR part 380 (Order No. 486, 52 FR 47910), the Office of Energy Projects has reviewed Public Utility District No. 2 of Grant County's application for an amendment to temporarily waive for the current year the spill flow requirements applicable to its Priest Rapids Project, located on the Columbia River in Grant, Yakima, Kittitas, Douglas, Benton and Chelan Counties, Washington and has prepared an Environmental Assessment (EA). The project occupies 3,051.92 acres of federal lands administered by the Bureau of Land Management Department of Energy, Department of Army, Bureau of Reclamation, and the U.S. Fish and Wildlife Service.

The EA contains the staff's analysis of the potential environmental impacts of the proposed amendment and alternatives developed by staff and concludes that approval of the staff recommended alternative would not constitute a major federal action that would significantly affect the quality of the human environment.

The EA is attached to a Commission order issued on June 1, 2001 for the above application. Copies of the EA are available for review at the Commission's Public Reference Room, located at 888 First Street, NE., Washington, DC 20426, or by calling (202) 208–1371. The EA may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call (202) 208–2222 for assistance).

For further information, contact Charles Hall at (202) 219–2853.

David P. Boergers,

Secretary.

[FR Doc. 01–14466 Filed 6–7–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Protests

May 31, 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*: 11986–000.

c. *Date Filed*: May 4, 2001.

d. *Applicant*: Symbiotics, LLC.

e. *Name of Project*: Seven Oaks Dam Hydroelectric Project.

f. *Location*: The proposed project would be located on an existing dam owned by the U.S. Army Corps of Engineers, on the Santa Ana River in San Bernadino County, California. Part of the project would be on lands administered by the U.S. Army Corps of Engineers.

g. *Filed Pursuant to*: Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact*: Mr. Brent L. Smith, President, Northwest Power Services, Inc., P.O. Box 535, Rigby, ID 83442, (208) 745–8630, (fax) (208) 745–7909, or e-mail address: *npsihydro@aol.com.*

i. *FERC Contact*: Any questions on this notice should be addressed to Mr. Lynn R. Miles, Sr. at (202) 219–2671, or e-mail address: *lynn.miles@ferc.fed.us.*

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 recommendation, interventions, and protests, may be electronically filed via the internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at *http://www.ferc.fed.us/efi/doorbell.htm*.

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) An existing 550-foot-high and 500-foot-long earthfill dam (2) an existing reservoir having a surface area of 780 acres with a storage capacity of 145,000 acre-feet at a normal water surface elevation of 2,610 feet msl; (3) an 18-foot-diameter 800-foot-long steel penstock; (4) a powerhouse containing two generating units, with a total installed capacity of 5.8 MW; (5) a 25 kv transmission line approximately 20 miles long; and (6) appurtenant facilities.

The project would have an annual generation of 29 GWh.

l. A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 208–1371. The application may be viewed on http://www.ferc.fed.us/online/rims.htm (call (202) 208–2222 for assistance). A copy is also available for inspection and reproduction at the address in item h above.

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 protests, 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, N.E., Washington, D.C. 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 serve 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.

David P. Boergers,

Secretary.

[FR Doc. 01–14439 Filed 6–7–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application for Amendment of License and Soliciting Comments, Motions to Intervene, and Protests

June 4, 2001.

Take notice that the following application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Amendment of License to Change Project Boundary.

b. *Project No:* 2579–040.

c. *Date Filed:* April 2, 2001.

d. *Applicant:* Indiana Michigan Power Company.

e. *Name of Project:* Twin Branch.

f. *Location:* St. Joseph River, Mishawaka, St. Joseph County, Indiana.

g. *Filed Pursuant to:* Federal Power Act, 16 USC 791(a) 825(r) and 799 and 801.

h. *Applicant Contact:* Mr. Frank M. Simms, Fossil and Hydro Operations, American Electric Power, 1 Riverside

Plaza, Columbus, OH 43215–2373, (614) 223–2918, fmsimms@aep.com.

i. *FERC Contact:* Any questions on this notice should be addressed to: Anumzziatta Purchiaroni at (202) 219–3297, or e-mail address: anumzziatta.purchiaroni@ferc.fed.us.

j. *Deadline for filing comments and or motions:* July 12, 2001.

All documents (original and eight copies) should be filed with: David P. Boergers, Secretary, Federal 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 at http://www.ferc.fed.us/efi/doorbell.htm.

Please include the project number (P–2579–040) on any comments or motions filed.

k. *Description of Request:* Indiana Michigan Power Company (I&M) is requesting the Commission's approval to fill an existing channel located within the project boundary. The channel forms an island, and provides access to the St. Joseph River to four property owners. Accumulation of sediments has allowed for wetland type vegetation to grow on the channel surface. Additionally, accumulation of debris and other materials in the channel area have caused some health concerns among the City officials. To permanently solve this problem, I&M is proposing to fill the channel area, so as to connect the island with properties across the channel. I&M is proposing to remove the filled channel and island from the project boundary, and to replace the wetland area, that would be lost by channel filling, to another location within the project boundary. The channel and the island are both owned by the licensee.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 208–1371. This filing may be viewed on http://www.ferc.fed.us/online/rims.htm (call (202) 208–2222 for assistance). A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 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.

o. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''PROTESTS'', or ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

p. 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 any agency's comments must also be sent to the Applicant's representatives.

David P. Boergers,

Secretary.

[FR Doc. 01–14464 Filed 6–7–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application Accepted for Filing and Soliciting Comments, Protests, and Motions To Intervene

June 4, 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.*: 11976–000.

c. *Date filed*: April 19, 2001.

d. *Applicant*: Symbiotics, LLC.

e. *Name and Location of Project*: The Starvation Dam Project would be located on the Strawberry River, approximately 3 miles northwest of the Town of Duchesne, in Duchesne County, Utah. The project would be located on a federally owned dam administered by the U.S. Bureau of Reclamation.

f. *Filed Pursuant to*: Federal Power Act, 16 U.S.C. 791(a)–825(r).

g. *Applicant contact*: Mr. Brent L. Smith, President, Northwest Power Services, Inc., P.O. Box 535, Rigby, ID 83442, (208) 745–8630, fax (208) 745–7909.

h. *FERC Contact*: Tom Papsidero, (202) 219–2715.

i. *Deadline for filing comments, protests, and motions to intervene*: 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. Motions to intervene, protests, and comments 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 at http://www.ferc.fed.us/efi/doorbell.htm.

Please include the project number (P–11976–000) 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.

j. *Description of Project*: The proposed project would use the existing Starvation Dam which has a reservoir surface area of 3,300 acres and a storage capacity of 167,000 acre-feet at a normal elevation of 5,712 feet and include: (1) A proposed powerhouse with a total installed capacity of 1.75 megawatts; (2) a proposed 800-foot-long, 6-foot-diameter penstock; (3) a proposed 1-mile-long, 15 kv transmission line; and (4) appurtenant facilities. The project would operate in a run-of-river mode and would have an average annual generation of 12.2 GWh.

k. A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 208–1371. The application may be viewed on http://www.ferc.fed.us/online/rims.htm (call (202) 208–222 for assistance). A copy is also available for inspection and reproduction at the address in item g above.

l. 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.

m. 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

n. 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.

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'' or ''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.

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.

David P. Boergers,

Secretary.

[FR Doc. 01–14465 Filed 6–7–01; 8:45 am]

BILLING CODE 6717–01–M

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6992–8]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; TSCA Section 8(a) Preliminary Assessment Information Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that the following Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval: TSCA Section 8(a) Preliminary Assessment Information Rule [EPA ICR No. 0586.09; OMB Control No. 2070–0054]. The ICR, which is abstracted below, describes the nature of the information collection and its estimated cost and burden. The **Federal Register** document required under 5 CFR 1320.8(d), soliciting comments on this collection of information, was published on December 8, 2000 (65 FR 77022). EPA received one comment, which has been addressed in this ICR.

DATES: Additional comments may be submitted on or before July 9, 2001.

FOR FURTHER INFORMATION CONTACT: Sandy Farmer by phone on (202) 260–2740 or by e-mail: ''*farmer.sandy@epa.gov.''* You may also access the ICR via Internet at *http://www.epa.gov/icr/icr.htm.* Refer to EPA ICR No. 0586.09 and/or OMB Control No. 2070–0054.

ADDRESSES: Send comments, referencing EPA ICR No. 0586.09 and OMB Control No. 2070–0054, to the following addresses: Sandy Farmer, U.S. Environmental Protection Agency, Collection Strategies Division (Mail Code: 2822), 1200 Pennsylvania Avenue, NW., Washington, DC 20460; and to: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

SUPPLEMENTARY INFORMATION:

Title: TSCA Section 8(a) Preliminary Assessment Information Rule (OMB Control No. 2070–0054; EPA ICR No. 0586.09). This is a request for extension of an existing approved collection that is currently scheduled to expire on May 31, 2001. Under 5 CFR 1320.10(e)(2), the Agency may continue to conduct or sponsor the collection of information while the submission is pending at OMB.

Abstract: Section 8(a) of the Toxic Substances Control Act (TSCA) authorizes EPA to promulgate rules under which manufacturers, importers and processors of chemical substances must maintain records and submit reports to EPA. Promulgated under TSCA section 8(a), EPA uses the Preliminary Assessment Information Rule (PAIR) (40 CFR part 712) to collect information to identify, assess and manage human health and environmental risks from chemicals. PAIR requires chemical manufacturers and importers to complete a

standardized reporting form to help evaluate the potential for adverse human health and environmental effects caused by the manufacture or importation of identified chemicals. Chemicals for which a justifiable information need for production, use or exposure-related data can be satisfied by the use of the PAIR, are identified individually for one-time reporting under PAIR. In addition to EPA, other federal agencies may demonstrate a justifiable information need, and EPA will identify the chemical for reporting under PAIR. In most instances the information that EPA receives from a PAIR report is sufficient to satisfy the information need in question.

Responses to the collection of information are mandatory. Respondents may claim all or part of a notice confidential. EPA will disclose information that is covered by a claim of confidentiality only to the extent permitted by, and in accordance with, the procedures in TSCA section 14 and 40 CFR part 2. 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.

Burden Statement: The annual public reporting burden for this collection of information is estimated to be 28.45 hours per report. The Agency assumes that respondents will submit an average of 2.44 reports annually, for a per respondent burden of 69.41 hours. 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. The following is a summary of the estimates taken from the ICR:

Respondents/Affected Entities: Manufacturers, importers and processors of chemical substances and mixtures.

Frequency of Collection: One-time, on occasion.

Estimated No. of Respondents: 48.

Estimated Total Annual Burden on Respondents: 3,355 hours.

Estimated Total Annual Costs: $609,116.

Changes in Burden Estimates: The total burden associated with this ICR has decreased from 3,489 hours in the previous ICR to 3,355 hours for this ICR. This adjustment in burden is attributable to carrying through in the burden hour totals the adjustment made to the unit burden of the CBI substantiation requirement, i.e., only 75 percent of sites or reports are expected to make CBI claims. This adjustment was made in the unit burden calculations in the previous ICR but was not carried through in the industry totals. In addition, a few minor mathematical corrections were made to the estimates presented in the previous ICR.

According to the procedures prescribed in 5 CFR 1320.12, EPA has submitted this ICR to OMB for review and approval. Any comments related to the renewal of this ICR should be submitted within 30 days of this notice, as described above.

List of Subjects

Environmental protection, Hazardous substances, Reporting and recordkeeping requirements.

Dated: May 20, 2001.

Oscar Morales,

Director, Collection Strategies Division.

[FR Doc. 01–14478 Filed 6–7–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6993–3]

Agency Announcement of Information Collection Activities: Submission for OMB Review; Comment Request; Collection of 2000 Aquatic Animal Production Industry Data (EPA ICR 1988.01)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that the following Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval: ''Collection of 2000 Aquatic Animal Production Industry Data'' (EPA ICR No. 1988.01). The ICR supporting statement describes the nature of the information collection and its expected burden and cost; where appropriate, it includes the actual data collection instruments.

DATES: Comments must be submitted on or before July 9, 2001.

ADDRESSES: Send comments, referencing EPA ICR No. 1988.01, to the following addresses: Sandy Farmer, US Environmental Protection Agency, Collection Strategies Division (Mail Code 2822), 1200 Pennsylvania Avenue, NW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th St., NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: For a copy of the ICR contact Sandy Farmer at EPA by phone at (202) 260–2740 or e-mail at *farmer.sandy@epa.gov,* or download a copy off the Internet at *http://www.epa.gov/icr* and refer to EPA ICR No. 1988.01. For technical questions about the ICR, contact Marta Jordan by phone at (202) 260–0817 or by e-mail at *jordan.marta@epa.gov.* For economic questions about the ICR, contact Kristen Strellec by phone at (202) 260–6036 or by e-mail at *strellec.kristen@epa.gov.*

SUPPLEMENTARY INFORMATION: *Title:* Collection of 2000 Aquatic Animal Production Industry Data (EPA ICR No.1988.01). This is a new collection.

Abstract: EPA is planning to survey aquatic animal production facilities to collect the technical and economic information EPA will need to develop effluent limitations guidelines and standards. Currently, no nationally applicable effluent limitations guidelines and standards exist to regulate discharges from facilities in this point source category. EPA is developing proposed effluent regulations for this category due, in part, to the concern that excess nutrients and other chemicals may be entering the Nation's waters from animal production and feeding operations (both aquatic and land based).

EPA is required by section 304(m) of the Clean Water Act, 33 U.S.C. 1314(m), to identify categories of sources that discharge pollutants and to establish a schedule for establishing effluent limitations guidelines for these categories. EPA is also required by the terms of a Consent Decree with the Natural Resources Defense Council, Inc. (NRDC) to propose effluent limitations guidelines and standards for the aquatic animal production point source category. *NRDC* v. *EPA,* (D.D.C. Civ. No. 89–2980, January 31, 1992, as modified).

EPA is conducting the surveys to collect the information EPA needs to respond to these legislative and judicial requirements.

The Collection of 2000 Aquatic Animal Production Industry Data is intended to collect, from industry, the type of technical and economic information required by EPA to develop effluent limitations guidelines and pretreatment standards. The surveys cover aquatic animal production activities for both the private and public sector. EPA will issue the survey instruments under authority of section 308 of the Clean Water Act, 33 U.S.C. 1318. Responses from survey recipients will be mandatory. EPA will mail the survey instruments to aquatic animal producers after OMB approves the ICR. Respondents will have the right to claim information as confidential business information. An Agency may not conduct or sponsor, and a person is not required to respond to, an information collection unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR Chapter 15. The **Federal Register** document required under 5 CFR 1320.8(d) soliciting comments on this collection of information was published on September 14, 2000 (65 FR 55522).

Burden Statement: The data collection consists of 4 elements: the screener survey, a detailed survey, a follow-up collection of existing wastewater sampling data from a sample of the detailed questionnaire respondents, and a follow-up collection of economic information on multi-facility companies as necessary. The screener survey will help to identify basic information on all of the facilities EPA has identified, and will help EPA develop a more accurate mailing list and representative sampling frame for the detailed survey. The detailed survey will help EPA obtain from a representative sample of facilities more detailed information about facilities within the various industry sectors. The follow-up activities will allow EPA to obtain the additional information discussed above. The total nationwide public reporting and record keeping burden for this information collection is estimated to be 24,840 hours (5,000 hours for the screener survey; 19,565 hours for the detailed survey; and 275 for the follow-up activities). 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; to 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; to adjust the existing ways to comply with any previously applicable instructions and requirements; to train personnel to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information.

TABLE 1.—RESPONDENT AVERAGE BURDEN PER SURVEY RESPONSE ACTIVITY

Respondent activity	Total burden per activity (hours)					
	Survey				Follow-up	
	Screener	Detailed [1]			Econ.	Samp.
Read Instructions	.25	5	4	4	0	0
Gather Information/Data	.25	11	8	7	2	2
Complete Survey Form	.25	8	7	7	0	0
Review Survey Responses	.25	7	7	5	0	1
All Activities	1	31	26	23	2	3

[1] EPA prepared three burden estimates depending upon the type of respondent and whether the respondent availed himself or herself of some options to lessen the burden.

TABLE 2.—COLLECTION OF AQUATIC ANIMAL PRODUCTION FACILITIES DATA

Total number of responses	Average burden per respondent (in hours)	Total burden (in hours)	Average labor costs per respondent (in dollars)	Total labor costs (in dollars)	Average O&M costs per respondent (in dollars)	Total O&M cost (in dollars)	Total costs (in dollars)
Screener Survey, Total Respondent Burden and Costs							
5,000	1	5,000	21	105,000	0.84	4,200	109,200
Detailed Survey, Total Respondent Burden and Costs							
315	31	9,765	762	240,030	15	4,725	244,755
315	26	8,190	579	182,385	15	4,725	187,110
70	23	1,610	517	36,190	15	1,050	37,240
Follow-up Activities, Total Respondent Burden Costs							
100	2	200	50	$5,000	$10.50	1,050	6,050
25	3	75	67	1,675	9.50	238	1,913

EPA has identified approximately 5,000 facilities as potential aquatic animal producers. EPA will distribute the screener survey to all of the facilities identified, the detailed survey to a stratified random sample of about 500 to 700 facilities, and the follow-up to 125 facilities (this includes 25 for sampling data and 100 for economic data). The estimated cost to complete the screener survey is approximately $21 per site. The estimated cost to complete the

detailed survey is approximately $517 to $762 per site (depending on the type of respondent). The estimated cost for the follow-up activities is approximately $50 to $67 per site. The estimated total industry cost for the information collection burden is $0.6 million.

Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden including through the use of automated collection techniques to the addresses listed above. Please refer to EPA ICR No. 1988.01 in any correspondence.

Dated: May 21, 2001.

Oscar Morales,

Director, Collection Strategies Division.

[FR Doc. 01–14480 Filed 6–7–01; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

[Docket A–2001–13; FRL 6992–9]

Clean Air Act Operating Permit Program; Petitions for Objection to State Operating Permit for Orange Recycling and Ethanol Production Facility Pencor-Masada Oxynol, LLC; Orange County; Middletown, NY

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final order on petitions to object to State operating permit.

SUMMARY: This document announces that the EPA Administrator has partially granted and partially denied petitions to object to a State operating permit issued by the New York State Department of Environmental Conservation (NYSDEC) to the Orange Recycling and Ethanol Production Facility (Facility), proposed by Pencor-Masada Oxynol, LLC (Masada) for construction and operation in Middletown, NY. Pursuant to section 505(b)(2) of the Clean Air Act (Act), petitioners may seek judicial review of those portions of the petitions which EPA denied in the United States Court of Appeals for the appropriate circuit within 60 days of this decision under section 307 of the Act.

ADDRESSES: You may review copies of the final order, the petitions, and other supporting information at the EPA, Region 2, 290 Broadway, New York, New York 10007–1866. If you wish to examine these documents, you should make an appointment at least 24 hours before visiting day.

The final order is also available electronically at the following address: http://www.epa.gov/region07/programs/artd/air/title5/petitiondb/petitions/masada_decision2000.pdf

FOR FURTHER INFORMATION CONTACT: Steven C. Riva, Chief, Permitting Section, Air Programs Branch, Division of Environmental Planning and Protection, EPA, Region 2, 290 Broadway, 25th Floor, New York, New York 10007–1866, telephone (212) 637–4074.

SUPPLEMENTARY INFORMATION: The Act affords EPA a 45-day period to review, and object to as appropriate, operating permits proposed by State permitting authorities. Section 505(b)(2) of the Act authorizes any person to petition the EPA Administrator within 60 days after the expiration of this review period to object to State operating permits if EPA has not done so. Petitions must be based only on objections to the permit that were raised with reasonable specificity during the public comment period provided by the State, unless the petitioner demonstrates that it was impracticable to raise these issues during the comment period or the grounds for the issues arose after this period.

Between June and September, 2000, the EPA received 35 petitions from 29 different petitioners, requesting that EPA object to the issuance of the title V operating permit to the Facility owned and operated by Masada and located in the city of Middletown, Orange County, New York. Robert C. LaFleur, president of Spectra Environmental Group, Inc. (Spectra), submitted the most detailed petition. Spectra's petition raised many of the same issues posed by other petitioners. Other petitions were submitted by Lois Broughton, Wanda Brown, Louisa and George Centeno with Leslie Mongilia, Maria Dellasandro, R. Dimieri, Lori Dimieri, Dawn Evesfield, Marvin Feman, Deborah Glover, Anne Jacobs, Barbara Javalli-Lesiuk, Marie Karr, June Lee, Ruth MacDonald, Bernice Mapes, Donald Maurizzio, Alice Meola, Daniel Nebus, Jeanette Nebus, Mr. and Mrs. Hillary Ragin, M. Schoonover, Mildred Sherlock, LaVinnie Sprague, Matthew Sprague, Hubert van Meurs, Alfred and Catherine Viggiani, Paul Weimer and Leonard Wodka.

The petitions with respect to this facility raised a number of distinct claims, characterized as either administrative/public participation issues or technical/regulatory issues. The petitioners alleged that the NYSDEC did not comply with the applicable public participation requirements in issuing the Masada permit because NYSDEC did not: (1) Notify the public of the extended opportunity for comment; (2) make available to the public requisite information necessary to review the permit; (3) offer the public an opportunity to comment on significant changes to the draft permit; (4) properly inform the public of its right to petition to the EPA Administrator; (5) substantively review public comments; (6) grant requests for a second public hearing, and (7) translate the public notices and key documents for the non-English speaking members of the community. The petitioners also assert that the Masada permit did not comply with the applicable technical/regulatory requirements in that the permit: (1) Fails to assure compliance with major source preconstruction permitting requirements under the Act; (2) does not assure compliance with several allegedly applicable federal emissions standards, (3) omits required provisions governing chemical accident prevention requirements, namely section 112(r) of the Act and EPA's implementing regulations at 40 CFR part 68, and (4) does not comply with the Executive Order 12898 on environmental justice.

On May 2, 2001, the Administrator issued an order partially granting and partially denying the petitions. The order explains the reasons behind EPA's conclusion that NYSDEC must provide an opportunity for public review of certain operational requirements in the final permit issued to Masada, namely the methodology which limits the potential annual emissions of NO_X and SO_2 from the facility. The order also requires the inclusion of certain provisions of the New Source Performance Standards (NSPS) for Industrial, Commercial and Institutional Steam Generating Units, specifically the applicable reporting and recordkeeping requirements of NSPS Subpart Db. The order provides an explanation on the reasons for denying the petitioners' remaining claims.

Date: May 24, 2001.

William J. Muszynski,

Acting Regional Administrator, Region 2.

[FR Doc. 01–14482 Filed 6–7–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6993–5]

Recent Posting to the Applicability Determination Index (ADI) Database System of Agency Applicability Determinations, Alternative Monitoring Decisions, and Regulatory Interpretations Pertaining to Standards of Performance for New Stationary Sources and National Emission Standards for Hazardous Air Pollutants

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: This notice announces applicability determinations, alternative monitoring decisions, and regulatory interpretations that EPA has made under the new source performance standards (NSPS)(40 CFR part 60), and the national emission standards for hazardous air pollutants (NESHAP)(40 CFR parts 61 and 63).

FOR FURTHER INFORMATION CONTACT: An electronic copy of each complete document posted on the Applicability Determination Index (ADI) database system is available on the Internet through the ADI at http://es.epa.gov/oeca/eptdd/adi.html. The document may be located by date, author, subpart, or subject search. For questions about the ADI or this notice, contact Valerie Bynum at EPA by phone at (202) 564–4189, or by email at *bynum.valerie@epamail.epa.gov.* For technical questions about the individual applicability determinations or monitoring decisions, refer to the contact person identified in the individual documents, or in absence of a contact person, refer to the author of the document.

SUPPLEMENTARY INFORMATION:

Background

The General Provisions to the NSPS in 40 CFR part 60 and the NESHAP in 40 CFR part 61 provide that a source owner or operator may request a determination of whether certain intended actions constitute the commencement of construction, reconstruction, or modification. EPA's written responses to these inquiries are broadly termed applicability determinations. See 40 CFR 60.5 and 61.06. The NSPS and NESHAP also allow sources to seek permission to use monitoring or recordkeeping which is different from the promulgated requirements. See 40 CFR 60.13(i), 61.14(g), 63.8(b)(1), 63.8(f), and 63.10(f). EPA's written responses to these inquiries are broadly termed alternative monitoring decisions. Further, EPA responds to written inquiries about the broad range of NSPS and NESHAP regulatory requirements as they pertain to a whole source category. These inquiries may pertain, for example, to the type of sources to which the regulation applies, or to the testing, monitoring, recordkeeping or reporting requirements contained in the regulation.

EPA currently compiles EPA-issued NSPS and NESHAP applicability determinations, alternative monitoring decisions, and regulatory interpretations, and posts them on the Applicability Determination Index (ADI) on a quarterly basis. The ADI is an electronic index on the Internet with over one thousand EPA letters and memoranda pertaining to the applicability, monitoring, recordkeeping, and reporting requirements of the NSPS and NESHAP. The letters and memoranda may be searched by date, office of issuance, subpart, citation, control number or by string word searches.

Today's notice comprises a summary of 63 of such documents added to the ADI on April 17, 2001. The subject, author, recipient, and date (header) of each letter and memorandum is listed in this notice, as well as a brief abstract of the letter or memorandum. Complete copies of these documents may be obtained from the ADI at *http://es.epa.gov/oeca/eptdd/adi.html.*

Summary of Headers and Abstracts

The following table identifies the database control number for each document posted on the ADI database system on April 17, 2001, the applicable category, the subpart(s) of 40 CFR part 60, 61, or 63 (as applicable) covered by the document, and the title of the document, which provides a brief description of the subject matter. We have also included an abstract of each document identified with its control number after the table. These abstracts are provided solely to alert the public to possible items of interest and are not intended as substitutes for the full text of the documents.

ADI Determinations Uploaded on April 17, 2001

Control No.	Category	Subpart	Title
M010002	MACT	KK	Coating Finishing Lines with Some Rotogravure Printing
M010003	MACT	T, GG	Degreaser Subject to Aerospace MACT
M010004	MACT	DD	Applicability of OSWRO MACT to a Chute
M010005	MACT	GG	Aerospace MACT Applicability & Transition Policy
M010006	MACT	JJJ	Alternative Monitoring
M010008	MACT	H	Applicability to In-line Check Valves
M010009	MACT	LLL	Performance Test Deadline Extension
M010010	MACT	A	Test Waiver Request
M010011	MACT	DDD, NNN	Mineral Wool & Wool Fiberglass Resin Curing
Z000006	NESHAP	FF	Treatment and Control Requirements for TSD Facilities
Z010002	NESHAP	F, V	Equivalent Equipment and Procedures
0000117	NSPS	Db	Coke Oven Gas Under NSPS Subpart Db
0000118	NSPS	Dc	Request for Waiver for Monitoring Under Subpart Dc
0000119	NSPS	VVV	Subpart VVV Applicability to a Battery Pack Line
0000120	NSPS	OOO	Portable Automatic Aggregate Sampling Devices Applicability
0000121	NSPS	J	Definition of ''all 12 hour periods'' Under Subpart J
0000122	NSPS	OOO	Test Waiver for Stone & Lime Company
0000123	NSPS	NNN	Alternative Monitoring Methodology
0000124	NSPS	Db	Boiler Modification
0000125	NSPS	DDD	Waiver of Source Test
0000126	NSPS	Dc	Alternative Fuel Usage Recordkeeping
0000127	NSPS	BB	Brown Stock Washer Exemption

ADI Determinations Uploaded on April 17, 2001

Control No.	Category	Subpart	Title
0000128	NSPS	GG, A	Subpart GG—Alternative Monitoring and Testing
0000129	NSPS	GG, A	Subpart GG—Waiver of Initial Performance Test
0000130	NSPS	Db	Subpart Db—Coke Oven Gas & Furnace Oven Gas
0100001	NSPS	AAa	Alternative Sampling Procedure
0100002	NSPS	OOO, A	Relocated Crusher
0100003	NSPS	GG	Monitor Certification Deadline Extension
0100004	NSPS	Db	Predictive Emission Monitoring
0100005	NSPS	J	Alternative Monitoring Procedure
0100006	NSPS	Db	NO_X Emission Standard Applicability
0100007	NSPS	GG, A	Test Waiver
0100008	NSPS	Dc	Recordkeeping Waiver
0100009	NSPS	Db, A	Predictive Emission Monitoring
0100010	NSPS	Db, A	Predictive Emission Monitoring
0100011	NSPS	HH	Alternative Opacity Monitoring Under NSPS Subpart HH
0100012	NSPS	PPP	Request to Monitor Third Field of a Three-Field Wet ESP
0100013	NSPS	Db	Alternative Opacity Monitoring Under Subpart Db
0100014	NSPS	GG	Custom Fuel Monitoring Schedule
0100015	NSPS	AA	Applicability of Subpart AA to EAF at a Foundry
0100016	NSPS	Dc	Approval of Derate Proposal
0100017	NSPS	GG	Alternative Monitoring Schedule Under Subpart GG
0100018	NSPS	NNN, RRR, Dc	Alternative Monitoring Proposals
0100019	NSPS	GG	Alternative Monitoring for Subpart GG
0100020	NSPS	GG	Alternative Monitoring for Subpart GG
0100021	NSPS	OOO, LLL	Performance Test Deadline Extension
0100022	NSPS	BB	Exemption from TRS Standards for Brown Stock Washers
0100023	NSPS	GG	Nitrogen Monitoring Waiver
0100024	NSPS	EE	HVLP Transfer Efficiency
0100025	NSPS	VV	Applicability to In-line Check Valves/Limited VOC Equipment
0100026	NSPS	Dc	Opacity Monitoring Alternative
0100027	NSPS	GG, A	Test Deadline Extension
0100028	NSPS	Db	Opacity Monitoring Alternative
0100029	NSPS	Dc, A	Test Deadline Extension
0100030	NSPS	GG, A	Test Deadline Extension
0100031	NSPS	UU, A	Visible Emission Test Reduction
0100032	NSPS	Db	Opacity Monitoring Alternative
0100033	NSPS	GG	Custom Fuel Monitoring Schedule
0100034	NSPS	J, A	CEM Requirement for Measuring H2S Vapors in Loading Racks
0100035	NSPS	J, A	Approval of H2S Alternative Monitoring for Loading Racks
0100036	NSPS	VVV	Alternative Compliance Method Under Subpart VVV
0100037	NSPS	A, J	Refinery Fuel Gas Alternative Monitoring Plan
0100038	NSPS	QQQ	QQQ Applicability to Oil Refinery

Abstracts:

ADI Control #M010002

Q. Is a facility with finishing lines that perform rotogravure printing and coating excluded from the Printing and Publishing MACT if it maintains records under Section 63.829(f) for each finishing line?

A. Yes. The facility is excluded from the MACT provided it maintains records under Section 63.829(f) to show that for each month the mass of inks, solvents etc. applied by the print station on each finishing line does not exceed five weight-percent of the total mass of inks, solvents, etc. applied by that finishing line in that month.

ADI Control #M010003

Q1: How should potential to emit be calculated for the halogenated solvent cleaning MACT?

A1: The equation for PTE in the Halogenated Solvent Cleaning MACT is the correct equation to use when determining PTE for the MACT.

Q2: Is Component Repair Technology (CRT) a major source as defined at 40 CFR Sec. 63.2, subject to the Aerospace MACT?

A2: Yes. CRT is considered a major source as defined at 40 CFR 63.2 and is subject to the Aerospace MACT based on the PTE.

Q3: Is CRT subject to Title V permitting?

A3: Yes. CRT is subject to Title V permitting.

ADI Control #M010004

Q1: Does the client's portable funnel type ''chute'' meet the definition of transfer system under 40 CFR 63.681?

A1: Yes. Based on the information submitted and a phone call on March 01, 2000, your client's chute does meet the definition of transfer system under 40 CFR 63.681.

Q2: What emission control equipment, if any, is required during the transfer of material from container to container for the purpose of repackaging the waste?

A2: Required control equipment which are not individual drain systems are given at 40 CFR 63.689(c)(1)—(3). The control equipment includes covers, hard piping or an enclosed transfer

system vented through a closed vent system to a control device.

ADI Control #M010005

Q: Does the Aerospace MACT apply to the United Airlines Indianapolis Maintenance Center (IMC)?

A: Yes. Based upon the information submitted, IMC's hangars would be considered new sources subject to the Aerospace MACT. As a new source, compliance with the Aerospace MACT is required at the time of startup.

ADI Control #M010006

Q1: Is water flow rate an acceptable alternative to water temperature and specific gravity for monitoring the performance of a scrubber on 3M's Poly (ethylene terephthalate) line?

A1: Yes. Since the company uses a once-through water system, the water flow rate be a better indicator of scrubber performance than the water temperature and specific gravity. Q2: Is monitoring the chilled water temperature an acceptable alternative to monitoring the product side temperature on a condenser at the plant?

A2: No. The request did not provide enough information explaining why the proposed alternative parameter will be as good an indicator of condenser performance as the product side temperature.

Q3: Will EPA accept the use of Method 25D to determine the group status for the plant?

A3: Yes. The proposed test method is consistent with the applicable standard.

Q4: Will EPA accept the use of EPA Method 21 to identify leaks?

A4: Conditional. The proposal is unacceptable if the company only intends to repair leaks confirmed through Method 21. The proposal is acceptable if the company intends to use Method 21 to find and repair additional leaks that would not have been detected through visual, audible, olfactory, or other detection methods.

ADI Control #M010008

Q1: Are small valves which are less than 0.5 inches in diameter and are associated with instrumentation systems considered valves under 40 CFR 60.482–7? Because valves which are less than 0.5 inches in diameter are not considered valves under 40 CFR Part 63 Subpart H, should they be included in component counts under NSPS Subpart VV?

A1: Valves which are less than 0.5 inches in diameter and are associated with instrumentation systems are considered valves under NSPS Subpart VV. Although valves of less than 0.5 inches in diameter associated with instrumentation systems are not regulated as valves under 40 CFR Part 63 Subpart H, they are considered to be components of instrumentation systems, which are regulated by Subpart H.

Because NSPS Subpart VV does not specify an instrumentation system as a separate piece of equipment regulated by the standard, valves of less than 0.5 inches in diameter associated with instrumentation systems are regulated by the Subpart VV standard as valves.

Q2: Is an in-line check valve subject to the requirements of Sec. 60.482–7(f) or is it considered a no detectable emissions valve?

A2: Since in-line check valves are enclosed within process piping for directional control and do not have the potential for fugitive emissions which are regulated by the standard, they may be considered exempt from the Subpart VV regulation as valves.

Q3: Subpart H of the MACT standards at 40 CFR 63.160(a) exempts equipment that is in organic hazardous air pollutant service for less than 300 hours per year. Is equipment in VOC service less than 300 hours per year required to be monitored under Subpart VV?

A3: Since NSPS Subpart VV does not include an exemption for equipment that is in organic hazardous air pollutant service for less than 300 hours per year, equipment in VOC service less than 300 hours per year is not exempt from monitoring requirements.

ADI Control #M010009

Q: Due to weather conditions, a facility subject to Subpart LLL will not be able to test some control devices and maintain production levels required for testing by the deadline required by 40 CFR 63.7(b). Will EPA approve a 60 day extension of the deadline?

A: Yes. The request for an extension was approved.

ADI Control #M010010

Q: Can the requirement to conduct a performance test on a flare at a plant in Pensacola be waived?

A: Yes. Because continuous flow monitors that are installed on natural gas and process gas streams ducted to the flare provide information that can be use to verify compliance with the flare performance requirements in 40 CFR 63.11, it will not be necessary to conduct a test on the flare. As a condition for approval of this testing waiver, the company must recalibrate its flow monitors annually and report exceedances on a semiannual basis.

ADI Control #M010011

Q: Is a facility that cuts e-glass fiber from textile mills, mixes the fiber with thermoset plastic resin, and cures the mixture in an oven, subject to the mineral wool or wool fiberglass MACT?

A: No. The facility does not produce the fiber that it uses, does not use any of the sources or manufacturing lines named in the MACTs, except curing ovens, uses the ovens to cure the resin but not the fibers, and is not part of a manufacturing line stretching across separate facilities.

ADI Control #Z000006

Q: Although the annual quantity of benzene managed at a treatment, storage, and disposal (TSD) facility does not exceed 10 Mg, the TSD facility receives waste from facilities described in Sec. 61.340 which do generate an annual quantity of benzene greater than 10 Mg and are subject to Subpart FF. Will the treatment requirements in Sec. 61.342(c)(1)(i) and the control requirements in Sec. 61.342(c)(1)(ii) apply to the TSD facility?

A: Yes. A TSD facility is subject to the treatment and control requirements in Sec. 61.342(c)(1)(i) and (ii) if the total annual benzene (TAB) quantity received on-site is greater than or equal to 10 Mg per year, or if the TSD facility receives waste from any facility listed in Sec. 61.340(a) whose TAB exceeds 10 Mg.

ADI Control #Z010002

Q: A company plans to install a liquid ring vacuum compressor and has proposed that the compressor would meet the requirements of Subpart F as an equivalent piece of equipment. Does the company's proposal qualify as equivalent equipment and procedures as allowed by Sec. 61.66 of the Subpart F regulation?

A: Yes. The Subpart F regulation at Sec. 61.65(b)(3)(iii) indicates that compliance with the provisions of 40 CFR Part 61 Subpart V will also demonstrate compliance with the provisions of Sec. 61.65(b)(3)(iii). The company has proposed to demonstrate compliance by meeting the requirements of Subpart V at Sec. 61.242–3(i). The company has indicated that it will designate the compressor as having no detectable emissions as described in Sec. 61.242–3(i) and Sec. 61.246(e)(2).

ADI Control #0000117

Q: Is coke oven gas the same as coal for purposes of the Subpart Db requirements?

A: Yes, coke oven gas is the same as coal by definition under Subpart Db.

ADI Control #0000118

Q: May a residual oil fired boiler which has a heat input capacity greater than 30 million BTUs/hr and is subject to Subpart Dc use fuel supplier certifications for monitoring compliance with the SO_2 limit?

A: No. Under Subpart Dc, only distillate oil fired boilers of that size may use fuel supplier certifications for showing continued compliance with the SO_2 emission limit. With regard to the facility in question here, boilers greater than 30 million BTUs/hr in heat input capacity that burn residual oil are not allowed to show compliance via fuel supplier certifications.

ADI Control #0000119

Q: Is a new fiber coating pilot plant for battery manufacture subject to NSPS Subpart VVV?

A: Some lines are subject and others are not based on the definition of an affected facility. In this case, the plastic film coating line is not subject as there is a specific exemption for plastic film coating under Subpart VVV.

ADI Control #0000120

Q: Is a portable automatic aggregate sampling device subject to NSPS Subpart OOO?

A: No. Portable automatic aggregate sampling devices are not covered by the definition of an affected facility under Subpart OOO.

ADI Control #0000121

Q: What is the definition of ''periods of excess emissions'' under Subpart J Section 60.105(e)(4)?

A: Under Section 60.105, the language ''all 12-hour periods'' appears for SO_2 emissions. EPA interprets this to mean all periods during which the ''rolling 12 hour average Claus Sulfur Recovery Plant SO_2 emissions'' exceed 250 ppm for plants which are controlled by an oxidation or reduction system followed by incineration.

ADI Control #0000122

Q: Will EPA waive the Method 5 testing requirement for the new feed bin baghouse installation at a stone and lime company?

A: Due to the efficiency of the new baghouse and difficulty in doing the Method 5 testing, EPA will waive the particulate mass rate testing as allowed under Section 60.8 if it is satisfied that the source is in compliance with the regulations by other means. The Method 9 visible emission readings must still be taken.

ADI Control #0000123

Q: A company has a production unit which uses a vacuum seal pot for both product recovery and the control of total organic compound emissions, and has proposed to monitor the temperature of the seal pot as an alternate monitoring methodology. The temperature of the seal pot would be monitored at least once every 15 minutes and exceedances would be defined as any 3-hour average temperature which is 110C above the temperature measured during the performance test. Would this be acceptable?

A: Yes. The measurement of temperature would be an acceptable measure of equipment performance of the seal pot.

ADI Control #0000124:

Q: A company made physical changes to a boiler in 1988 to increase its capacity to burn bagasse, and in 1994 they began firing wood in the boiler. The boiler has an annual capacity factor for fuel oil of ten percent or less. Is the boiler an affected facility under Subpart Db?

A: Yes. The physical changes which were made to increase the use of bagasse also increased its capacity for burning wood, which increased the hourly emission rate of PM. The boiler has undergone a modification and is an affected facility subject to the Subpart Db emission standards for PM. The Subpart Db emission standards for NO_X and SO_2 do not apply to the boiler.

ADI Control #0000125

Q: A facility which manufactures polyethylene terephthalate (PET) resin using terephthalic acid and ethylene glycol as raw materials requested a waiver from testing three esterifier receiver tanks in the raw materials preparation section of the plant. Is a source test waiver appropriate?

A: Yes. A waiver was granted because testing of other similar emission points provides adequate assurance of compliance and because the tank emissions are very low when compared to the rest of the process.

ADI Control #0000126

Q: A company which has three natural-gas fired 12.0 MMBtu/hr steam generating units requests permission to keep records of fuel usage on a monthly basis rather than daily as required by Subpart Dc. A single gas meter will be used for the entire plant and the fuel usage for each unit will be prorated based on its design heat input capacity as a percentage of the total design heat input capacity for all natural gas-fired units at the plant. Is this an acceptable alternative fuel usage recordkeeping frequency?

A: Yes. The proposal to keep records for each steam generating unit on a monthly basis is acceptable.

ADI Control #0000127

Q: Is a company which proposes to make changes to a brown stock washer system exempt from the TRS standard due to technical issues and the costs associated with incinerating the exhaust emissions?

A: In order to make a determination as to whether the exemption allowed under Sec. 60.283(a)(1)(iv) is appropriate, additional information concerning the project will be needed.

ADI Control #0000128

Q1: Will EPA waive the requirement to monitor the nitrogen content of pipeline natural gas and allow an alternative STM standard test method for monitoring the sulfur content?

A1: Yes. Each of the turbines are fueled with pipeline natural gas which contains no fuel-bound nitrogen. EPA will approve the use of ASTM D 5504–94 or 5453–93 for sulfur analysis.

Q2: Will EPA allow semi-annual monitoring frequency for sulfur content?

A2: Yes, if the source has demonstrated low data variability and sulfur content results which are below the standard.

Q3: Will EPA approve the use of a CEM to monitor NO_X emissions on a source which uses water injection to control NO_X and a request that the source not be required to continuously correct the data to ISO standard ambient conditions?

A3: Yes, the use of a CEM is approved and the source does not have to correct the CEM data to ISO standards since the source demonstrated that their emissions are well below the standard.

Q4: Can a source use the NO_X CEM RA test to conduct the initial performance test?

A4: Yes, EPA approved the RA test for the NO_X CEM as an alternative to the initial performance test.

ADI Control #0000129

Q: Will EPA provide a conditional waiver for the initial performance test?

A: Yes, because the source is a peak loading station and conditions have not allowed the source to operate to perform the initial performance test by the deadline.

ADI Control #0000130

Q1: Does coke oven gas constitute ''coal'' as defined under Subpart Db?

A1: Yes. For the purposes of Subpart Db, coke is a coal-derived synthetic fuel,

and hence is regulated as coal under Subpart Db.

Q2: Does blast furnace gas constitute ''coal'' as defined under Subpart Db?

A2: No. Blast furnace gas is not derived from coal, and hence, is not regulated as coal under Subpart Db.

ADI Control #0100001

Q: Is an alternative sampling procedure proposed for a baghouse used to control particulate emissions from an electric arc furnace (EAF) acceptable?

A: Yes. Because the amount of particulate collected with this baghouse represents less than four percent of the total particulate collected by the two baghouses used to control EAF emissions, measuring the flow rate at the baghouse inlet would be an acceptable alternative to measuring the flow rate in each of the 14 exhaust stacks on the baghouse during performance testing.

ADI Control #0100002

Q: Is a relocated crusher at a facility subject to 40 CFR Part 60, Subpart OOO?

A: Because this crusher was originally constructed in 1973, it would be subject to New Source Performance Standards only if it has been modified or reconstructed after the applicability date of Subpart OOO (August 31, 1983). Because the determination request from the company addressed the issues of modification and reconstruction only from a subjective standpoint, it will be necessary to obtain additional information in order to resolve Subpart OOO applicability conclusively.

ADI Control #0100003

Q: Will EPA grant an extension of the deadline to complete certification testing of nitrogen oxides continuous emission monitoring systems installed on three combustion turbines?

A: An extension of the certification deadline under 40 CFR Part 60, Subpart GG is acceptable to Region 4 because market conditions do not currently justify operating these peaking turbines. However, to request an extension of the certification deadline under 40 CFR Part 75, the company must submit a petition to the Clean Air Markets Division at EPA Headquarters.

ADI Control #0100004

Q: Can a nitrogen oxides predictive emission monitoring system (PEMS) be used for demonstrating initial compliance and conducting ongoing monitoring on a boiler at a chemical company?

A: Yes. Based upon the results of a relative accuracy test audit conducted at three different boiler loads and the average nitrogen oxides emission rate reported by the PEMS for the initial 30-day compliance test, the PEMS can be used both for demonstrating initial compliance and for conducting ongoing monitoring.

ADI Control #0100005

Q: Is monitoring the hydrogen sulfide content of the fuel gas for two hydrogen reformer furnaces at a refinery using Draeger tubes an acceptable alternative to installing, certifying, and operating a hydrogen sulfide continuous emission monitoring system on the fuel gas line upstream of the furnaces?

A: Yes. Based upon historical data on the fuel gas hydrogen sulfide content and the fact that the company in question has an economic incentive to keep the sulfur content of the fuel gas low in order to avoid damaging the reformer catalyst, the proposed alternative will be adequate for monitoring the fuel gas hydrogen sulfide content.

ADI Control #0100006

Q: Under what conditions will firing a recovery boiler at a kraft pulp with only natural gas when the mill is shut down trigger the applicability of the nitrogen oxides emission standard in 40 CFR part 60, Subpart Db?

A: As long as the company complies with the annual capacity factor limit of ten percent or less for natural gas in its federally enforceable permit, the boiler will not be subject to the nitrogen oxides limit in Subpart Db. In addition to answering this basic applicability question, the determination provided input on a number of issues involving the deadline for initial testing and compliance demonstration procedures should the annual capacity factor for natural gas ever exceed 10 percent.

ADI Control #0100007

Q: Will EPA waive the requirement to conduct an initial performance test on two simple cycle combustion turbines if testing on two identical units at a facility indicate that emissions are less than 50 percent of the nitrogen oxides emission standard in 40 CFR part 60, Subpart GG?

A: Yes. Based upon the expectation that the variability in emissions between identical units will be low, waiving the requirement to conduct testing on a unit when the margin of compliance on an identical unit is high would be reasonable. The fact that nitrogen oxides continuous emission monitoring systems will be installed, certified, and operated on each turbine at the facility provides additional justification for waiving the requirement to conduct testing on all four units at the plant.

ADI Control #0100008

Q: Will EPA waive the requirement to monitor the amount of fuel burned each day in a boiler?

A: No. Fuel usage records are needed in order to verify that the company is not burning fuels to which an emission standard applies. Although the requirement to keep fuel usage records cannot be waived, a monthly fuel usage recordkeeping frequency was approved in this case because the only fuels currently burned in the boiler are natural gas and propane.

ADI Control #0100009

Q: Can a nitrogen oxides predictive emission monitoring system (PEMS) be used for demonstrating initial compliance and conducting ongoing monitoring on a package boiler at a kraft pulp mill?

A: Yes. Based upon the results of relative accuracy test audits conducted at three different boiler loads and the average nitrogen oxides emission rate reported by the PEMS for the initial 30-day compliance test, the PEMS can be used both for demonstrating initial compliance and for conducting ongoing monitoring.

ADI Control #0100010

Q: Can a nitrogen oxides predictive emission monitoring system (PEMS) be used for conducting ongoing monitoring on two boilers in South Carolina?

A: Based upon relative accuracy test audit (RATA) results, the PEMS for natural gas firing in Boiler No. 1 is acceptable, and the PEMS for natural gas firing in Boiler No. 2 will be acceptable if the company applies a bias correction factor of 1.072 to all nitrogen oxides results reported for this unit. The PEMS for oil firing cannot be approved for either unit because the company did not conduct RATAs that could be used to evaluate the accuracy of the PEMS when this fuel is fired.

ADI Control #0100011

Q: May Method 9 readings be used as an alternative to continuous opacity monitoring of a lime kiln where the COM does not provide accurate measurements because of steam interferences?

A: Yes. Method 9 readings may be used as an alternative to continuous opacity monitoring under specified requirements, which include daily readings and quarterly reporting.

ADI Control #0100012

Q: May a facility monitor the voltage and current of the third field of a three-

field wet electrostatic precipitator instead of each field?

A: No. A facility is required to monitor each field of the wet electrostatic precipitator.

ADI Control #0100013

Q: Will EPA approve the use of Method 9 visible emission readings in lieu of a COM for a Subpart Db boiler?

A: Yes. EPA approves the use of Method 9 instead of the installation of a COM due to the very clean fuel being required for use in the boiler and the limited period of operation allowed in the permit. Similar allowances have been approved by EPA in the past under similar circumstances.

ADI Control #0100014

Q: Will EPA approve under Subpart GG a custom fuel monitoring schedule for pipeline quality natural gas fuel being used at new gas turbines?

A: Yes. EPA approves the use of a custom fuel monitoring schedule based on the national policy of 1987 for stationary gas turbines burning natural gas fuel. The fuel quality indicates that compliance will be met at the turbines.

ADI Control #0100015

Q: Is a specific furnace at a foundry plant subject to NSPS Subpart AA?

A: No. At the time of installation of the ''C'' furnace there was an exemption provided for Electric Arc Furnaces located in foundries.

ADI Control #0100016

Q: Will EPA approve a boiler deration proposal from a company to limit the size of boilers at two facilities?

A: Yes. EPA Region III approves the deration proposal because it meets EPA's Policy on boiler deration for limiting the steam generation capacity of the boilers.

ADI Control #0100017

Q: Will EPA approve a custom fuel monitoring schedule under Subpart GG for Jet A fuel to be burned in certain gas turbines due to the small amount of time they are used and the fuel quality specifications?

A: Yes. EPA has the authority to approve custom fuel monitoring schedules under Subpart GG based on the operation of the turbines and the characteristics of the fuel supply.

ADI Control #0100018

Q: Will EPA approve an alternative monitoring procedure for the distillation column vent streams from a new Acetal Resin plant that involves monitoring valve positions and total gas flow? Will EPA approve alternative monitoring procedures for opacity and fuel quality at the company's new Subpart Dc boiler?

A: Yes, EPA has the authority to approve alternative monitoring procedures under the General Provisions of the NSPS program if the circumstances warrant it and EPA will approve alternatives under the company's conditions due to the physical infeasibility of vent gas monitoring in the manner prescribed in the rule and fuel quality considerations.

ADI Control #0100019

Q1: May a utility facility use acid rain program monitoring requirements to demonstrate compliance with 40 CFR part 60, Subpart GG at a 52-MW combustion turbine?

A1: Yes. You may use CEMs as required by the acid rain program to demonstrate compliance with NO_X and sulfur limits in 40 CFR part 60, Subpart GG.

Q2: May the facility use a custom monitoring schedule for sulfur content in fuel and waive the monitoring requirements for nitrogen content in fuel at a 22-MW combustion turbine?

A2: Yes. You may use the custom monitoring schedule as outlined in the August 14, 1987, memorandum from John Rasnic to all Regions. You may waive the monitoring of nitrogen content in the fuel when burning pipeline quality natural gas but not when burning ı2 distillate fuel oil.

ADI Control #0100020

Q1: Can a utility use CEMs for NO_X monitoring in lieu of the fuel monitoring requirements of 40 CFR part 60, Subpart GG?

A1: Yes. You can use CEMs as required by the acid rain program to demonstrate compliance with NO_X limits in 40 CFR part 60, Subpart GG.

Q2: Can the utility use the monitoring provisions of 40 CFR part 75 for sulfur content in fuel in lieu of the fuel monitoring requirements of 40 CFR part 60, Subpart GG?

A2: Yes. You can use the monitoring provisions of 40 CFR part 75 for sulfur content in fuel in lieu of the fuel monitoring requirements of 40 CFR part 60, Subpart GG.

ADI Control #0100021

Q: Due to weather conditions, a facility subject to Subpart LLL will not be able to test some control devices and maintain production levels required for testing by the deadline required by 40 CFR 63.7(b). Will EPA approve a 60 day extension of the deadline?

A: Yes. The request for an extension was approved.

ADI Control #0100022

Q: Does a brown stock washer qualify for an exemption from the TRS standard under sec. 60.283(a)(1)(iv)?

A: Due to the technical issues and costs associated with the brown stock washer system project, a temporary exemption from the Subpart BB standard for TRS can be granted.

ADI Control #0100023

Q: Will EPA waive the requirement to monitor the nitrogen content of the landfill gas burned in a turbine?

A: Yes. Based upon the results of samples collected and analyzed over a 12-week period, the landfill gas does not contain any fuel-bound nitrogen. Because fuel-bound nitrogen is not present in the landfill gas, and because any free nitrogen in the gas will not contribute appreciably to the formation of nitrogen oxides, it will not be necessary to monitor the nitrogen content of the landfill gas.

ADI Control #0100024

Q: Is it acceptable for a company to use a transfer efficiency value of 60 percent for the high volume low pressure (HVLP) spray equipment used in its metal furniture coating operation when determining compliance under Subpart EE?

A: Yes. It is acceptable provided that the operating pressure at the guns' air nozzles is no greater than 10 pounds per square inch. Based upon EPA's knowledge of the relative performance of various coating application technologies, it is likely that the Agency would have assigned HVLP equipment a transfer efficiency equal to or higher than the 60 percent value specified for manual electrostatic spray equipment in Subpart EE if HVLP equipment had been evaluated during the development of the standard.

ADI Control #0100025

Q1: Are small valves which are less than 0.5 inches in diameter and are associated with instrumentation systems considered valves under 40 CFR 60.482–7? Because valves which are less than 0.5 inches in diameter are not considered valves under 40 CFR part 63 Subpart H, should they be included in component counts under NSPS Subpart VV?

A1: Valves which are less than 0.5 inches in diameter and are associated with instrumentation systems are considered valves under NSPS Subpart VV. Although valves of less than 0.5 inches in diameter associated with instrumentation systems are not regulated as valves under 40 CFR part 63 Subpart H, they are considered to be

components of instrumentation systems, which are regulated by Subpart H. Because NSPS Subpart VV does not specify an instrumentation system as a separate piece of equipment regulated by the standard, valves of less than 0.5 inches in diameter associated with instrumentation systems are regulated by the Subpart VV standard as valves.

Q2: Is an in-line check valve subject to the requirements of Sec. 60.482–7(f) or is it considered a no detectable emissions valve?

A2: Since in-line check valves are enclosed within process piping for directional control and do not have the potential for fugitive emissions which are regulated by the standard, they may be considered exempt from the Subpart VV regulation as valves.

Q3: Subpart H of the MACT standards at 40 CFR 63.160(a) exempts equipment that is in organic hazardous air pollutant service for less than 300 hours per year. Is equipment in VOC service less than 300 hours per year required to be monitored under Subpart VV?

A3: Since NSPS Subpart VV does not include an exemption for equipment that is in organic hazardous air pollutant service for less than 300 hours per year, equipment in VOC service less than 300 hours per year is not exempt from monitoring requirements.

ADI Control #0100026

Q: Is an opacity monitoring approach based upon the collection of visible emissions data during periods of No. 6 oil firing an acceptable alternative to the installation of continuous opacity monitoring systems on two boilers whose primary fuel is natural gas?

A: Yes. Based upon the low annual capacity for oil in these units, the proposed opacity monitoring alternative is acceptable.

ADI Control #0100027

Q: Is an extension of the deadline for completing initial performance testing on a turbine unit?

A: Yes. Based upon numerous operating problems that the operator has experienced while firing oil, extending the deadline for completing testing for up to 720 operating hours following the resumption of oil firing will be acceptable. Basing the test extension on operating hours, rather than calendar days, is a better approach for this unit due to the limited operation on oil so far and the possibility that the operator may encounter additional operating problems when oil firing resumes.

ADI Control #0100028

Q: Is an opacity monitoring approach based upon the collection of visible emissions data during periods of No. 2 oil firing an acceptable alternative to the installation of a continuous opacity monitoring system on a boiler whose primary fuel is natural gas?

A: Yes. Based upon the low annual capacity for oil in this unit, the proposed opacity monitoring alternative is acceptable.

ADI Control #0100029

Q: Is an extension of the deadline for completing initial performance testing for several facilities at a plant in South Carolina acceptable?

A: Yes. The only emission unit subject to New Source Performance Standards is a boiler subject to Subpart Dc. Delaying the test for up to 30 days following the restart of the unit after the installation of a char removal system would be acceptable to Region 4. A decision regarding whether to extend the deadline for completing testing on other emission points subject to limits in a permit issued by South Carolina can be made at the discretion of the Department of Health and Environmental Control.

ADI Control #0100030

Q: Is an extension of the deadline for completing initial performance testing on a combined cycle unit in Florida acceptable?

A: Yes. It is acceptable to extend the deadline for completing the initial performance test until 30 days after the resumption of oil following the repairs in order to give the operator an opportunity to repair leaks in the water injection system used to control nitrogen oxides emissions during fuel oil combustion.

ADI Control #0100031

Q: Can the duration of visible emission observations be reduced from three hours to 90 minutes for a sand unloading and conveying operation?

A: Yes. Based upon the intermittent operation of this facility and the stringency of the applicable standard, reasonable assurance of compliance can be obtained by collecting 90 minutes of visible emissions data while the facility is in operation.

ADI Control #0100032

Q: Will EPA waive the requirement to monitor the opacity of a boiler fired with oil?

A: No. Although the annual capacity factor for oil fired in the boiler will be low, Subpart Db does not provide for an opacity monitoring exemption based upon annual capacity factors. Even though the requirement to monitor opacity cannot be waived, an alternative monitoring approach based upon the collection of visible emissions data during oil firing would be acceptable.

ADI Control #0100033

Q: Will EPA approve a custom fuel monitoring schedule for turbines at a facility?

A: Yes. Based on the fuel quality data submitted for the pipeline-quality natural gas fuel used by the turbines, EPA has approved a custom fuel monitoring schedule in accordance with EPA's National Policy.

ADI Control #0100034

Q: Can EPA waive the requirement for a CEM under Subpart J for loading rack vapors?

A: Yes. Provided certain circumstances exist, EPA can approve an Alternative Monitoring Plan submitted to EPA.

ADI Control #0100035

Q: Does a facility have to install a continuous emission monitor for monitoring H_2S vapors from a loading rack?

A: No. Under certain circumstances, EPA's Policy allows for approval of an alternative monitoring method for this pollutant from this emission source.

ADI Control #0100036

Q: Will EPA approve the definition of ''VOC used'' as ''VOC emitted'' for purposes of Subpart VVV?

A: Yes. In order to be consistent with past determinations on this issue for pultrusion processes where a lot of the styrene used in the process ends up in the final product, EPA will allow the facility to use the amount of unreacted styrene to calculate the VOC usage rate for purposes of the listed throughput exemption under Subpart VVV.

ADI Control #0100037

Q: Will EPA approve a facility's alternative monitoring plans for several refinery fuel gas streams at its petroleum refinery?

A: Yes. The alternative monitoring plans are approved in accordance with the Guidance entitled ''Alternative Monitoring Plan for NSPS Subpart J Refinery Fuel Gas: Conditions for Approval of the Alternative Monitoring Plan for Miscellaneous Refinery Fuel Gas Streams.''

ADI Control #0100038

Q: Do the changes made by the previous owner of a West Virginia refinery, pursuant to a RCRA Consent Order, trigger NSPS applicability under Subpart QQQ?

A: Yes, the changes made are, in some respects, construction of new affected

facilities and also the modification of other affected facilities through the completed projects.

Dated: May 30, 2001.

Michael Stahl,

Director, Office of Compliance.

[FR Doc. 01–14476 Filed 6–7–01; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[FRL–6994–6]

EPA Science Advisory Board; Request for Nominations for the Arsenic Rule Benefits Review Panel; and Notification of Public Advisory Committee Meetings and Request for Nominations for the Advisory Council on Clean Air Compliance Analysis (Council)

ACTION: Request for nominations to the Arsenic Rule Benefits Review Panel of the Environmental Protection Agency's (EPA) Science Advisory Board (SAB).

SUMMARY: The U.S. Environmental Protection Agency (EPA) Science Advisory Board is announcing the formation of an Arsenic Rule Benefits Review Panel (hereinafter, the ''Panel'') and soliciting nominations to this Panel. The EPA Science Advisory Board was established to provide independent scientific and technical advice, consultation, and recommendations to the EPA Administrator on the technical bases for EPA regulations. In this sense, the Board functions as a technical peer review panel.

Any interested person or organization may nominate qualified individuals for membership on the Panel. Nominees should be identified by name, occupation, position, address and telephone number. To be considered, all nominations must include a current resume providing the nominee's background, experience and qualifications.

Background

Following the January 22, 2001 **Federal Register** promulgation of the arsenic rule, a number of issues were raised to EPA by States, public water systems, and others regarding the adequacy of science and the basis for national economic analyses informing decisions about the rule. Because of the importance of the arsenic rule and the national debate surrounding it related to the science and economic analyses that inform the decision, EPA's Administrator publicly announced on March 20, 2001, that the Agency would take additional steps to reassess the scientific and economic issues associated with this rule, to gather more information, and to seek further public input on each of these important issues.

Consistent with that commitment, the EPA Science Advisory Board (SAB) will convene a panel of nationally recognized technical experts to review the estimates of the benefits associated with the final arsenic in drinking water rule.

An important aspect of forming any panel is the charge that is to be addressed during their review. At this time, the EPA charge to the subject panel has not been received. Once received, that charge will be placed on the Science Advisory Board website which can be found at *www.epa.gov/sab/.* Members of the public wishing to comment on the charge should send their comments to the Designated Federal Officer, Mr. Thomas Miller, as noted below. When the charge is placed on the SAB website, the date of its placement will be noted therein and comments on the charge will be accepted for ten calendar days following that date or the date for closing the nominations process which is the subject of this notice, whichever is later. In addition, the membership of the Panel itself will be posted at the same SAB website within 15 calendar days of closure of the nomination period.

The criteria for selecting Panel members are that Panel members be recognized experts in their fields; that Panel members be as impartial and objective as possible; that Panel members represent an array of backgrounds and perspectives (within the disciplines relevant to this review); and that the Panel members be available to participate fully in the review, which will be conducted over a relatively short time frame (i.e., within approximately 3 months). Panel members will be asked to attend at least one public meeting followed by at least one public teleconference meeting over the course of 3 months; they will be asked to participate in the discussion of key issues and assumptions at these meetings, and they will be asked to review and to help finalize the products and outputs of the Panel. The Panel will make recommendations to the Executive Committee (EC) of the SAB for approval of the Panel's report and transmittal to the Administrator.

Nominations should be submitted to Mr. Thomas O. Miller, Designated Federal Officer, EPA Science Advisory Board, U.S. Environmental Protection Agency (1400A), 1200 Pennsylvania Avenue, NW., Washington, DC 20460, telephone (202) 564–4558; FAX (202) 501–0582; or via e-mail at *miller.tom@epa.gov* no later than June 18, 2001. The Agency will not formally acknowledge or respond to nominations.

Advisory Council on Clean Air Compliance Analysis (the Council)

Pursuant to the Federal Advisory Committee Act, Public Law 92–463, notice is hereby given that the Advisory Council on Clean Air Compliance Analysis (the Council) of the EPA Science Advisory Board (SAB) will meet on the dates and times noted below. All times noted are Eastern Daylight Savings Time. All meetings are open to the public, however, seating is limited and available on a first come basis. *Important Notice:* Documents that are the subject of SAB reviews are normally available from the originating EPA office and are not available from the SAB Office—information concerning availability of documents from the relevant Program Office is included below.

1. Advisory Council on Clean Air Compliance Analysis (Council)—June 22, 2001 Teleconference

The Council will conduct a public teleconference meeting on Friday, June 22, 2001 between the hours of 1 pm and 3 pm (Eastern Daylight Savings Time). The meeting will be coordinated through a conference call connection in Room 6013 in the USEPA, Ariel Rios Building North, 1200 Pennsylvania Avenue, NW., Washington, DC 20004. The public is encouraged to attend the meeting in the conference room noted above, however, the public may also attend through a telephonic link if lines are available. Additional instructions about how to participate in the conference call can be obtained by calling Ms. Diana Pozun one week prior to the meeting (June 15, 2001) at (202) 564–4544, or via e-mail at *pozun.diana@epa.gov.*

Purpose of the Meeting

The purpose of this teleconference meeting is to begin the Council's process of providing advice to the Agency in developing the third in a series of statutorily mandated comprehensive analyses of the total costs and total benefits of programs implemented pursuant to the Clean Air Act. Section 812 of the Clean Air Act requires the EPA to periodically assess the effects of the 1990 Clean Air Act Amendments on the ''public health, economy and the environment of the United States'' and to report the findings and results of the assessments to Congress. Section 812 also

established the Advisory Council on Clean Air Compliance Analysis (the Council) and gave it the following mission: ''to review the data and methodology used to develop the 812 Study and to advise the EPA Administrator concerning the utility and relevance of the Study.'' EPA has to date completed two assessments and received the advice of the Council on them: The Benefits and Costs of the Clean Air Act: 1970 to 1990 (published, 1997) and The Benefits and Costs of the Clean Air Act, 1990 to 2010 (published 1999). For copies of these reports, please visit our website (*www.epa.gov/sab*) under the REPORTS subheading.

Council advice to the Agency for the third 812 Study will begin with the review of an ''analytical blueprint'' for the study. The purpose of this blueprint is to provide an opportunity for SAB and public review of the major goals, objectives, methodologies, and analytical choices for the study before it is implemented.

The purpose of the call is to provide Council members and consultants with the opportunity to: (1) Clarify the charge question (see below) related to the ''analytical blueprint'' for the third Section 812 Study; (2) request any supplemental materials from the Agency; (3) ask questions on materials already received from the Agency; and (4) and discuss preparations for a public meeting of the Council Meeting on Monday and Tuesday, July 9–10, 2001 in Washington, DC (see below for details on the July meeting).

Availability of Review Materials

Review materials for the meeting will include the following: ''Benefits and Costs of the Clean Air Act 1990–2020: Draft Analytical Plan for EPA's Second Prospective Analysis.'' The document will be available upon request from Mr. Jim DeMocker via telephone (202) 564–1673, fax (202) 564–1557, or email at *democker.jim@epa.gov.*

For Further Information

Any member of the public wishing further information concerning this meeting or wishing to submit brief oral comments must contact Dr. Angela Nugent, Designated Federal Officer, EPA Science Advisory Board (1400A), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone (202) 564–4562; FAX (202) 501–0582; or via e-mail at *nugent.angela@epa.gov.* Requests for oral comments must be *in writing* (e-mail, fax or mail) and received by Dr. Nugent no later than noon Eastern Daylight Savings Time on June 15, 2001.

2. Health and Ecological Effects Subcommittee (HEES) of the Advisory Council on Clean Air Compliance Analysis (Council)—June 25, 2001 Teleconference

The HEES, a subcommittee of the Council, will conduct a public teleconference meeting on June 25, 2001 between the hours of 11 am and 1 pm (Eastern Daylight Savings Time). The meeting will be coordinated through a conference call connection in Room 6013 in the USEPA, Ariel Rios Building North, 1200 Pennsylvania Avenue, NW., Washington, DC 20004. The public is encouraged to attend the meeting in the conference room noted above, however, the public may also attend through a telephonic link if lines are available. Additional instructions about how to participate in the conference call can be obtained by calling Ms. Diana Pozun one week prior to the meeting (June 22, 2001) at (202) 564–4544, or via e-mail at *pozun.diana@epa.gov*

Purpose of the Meeting

The HEES will review the Agency's proposed approach to assessment of health and ecological effects for the Section 812 Study and develop a draft response for the July 9–10, 2001 meeting of the Council to Agency charge questions on those issues.

Charge to the Subcommittee

To review the Agency's proposed analytical methodologies and data sources for the third Section 812 Study and provide advice prior to implementation of those methodologies. Topics for the AQMS's advice regarding analytical methodologies and data sources include: (1) Health effects modeling; (2) ecological and welfare effects modeling; and (3) assessment of the effects of hazardous air pollutants

Availability of Review Materials

Review materials for the meeting will include ''Benefits and Costs of the Clean Air Act 1990–2020: Draft Analytical Plan for EPA's Second Prospective Analysis.'' The document will be available upon request from Mr. Jim DeMocker via telephone (202) 564–1673, fax (202) 564–1557, or email at *democker.jim@epa.gov.*

For Further Information

Any member of the public wishing further information concerning this meeting or wishing to submit brief oral comments (10 minutes or less) must contact Dr. Angela Nugent, Designated Federal Officer, EPA Science Advisory Board (1400A), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone (202) 564–4562; FAX (202) 501–0323; or via e-mail at *nugent.angela@epa.gov.* Requests for oral comments must be *in writing* (e-mail, fax or mail) and received by Dr. Nugent no later than noon Eastern Daylight Savings Time on July 2, 2001.

3. Air Quality Modeling Subcommittee (AQMS) of the Advisory Council on Clean Air Compliance Analysis (Council)—July 2, 2001 Teleconference

The AQMS, a subcommittee of the Council, will conduct a public teleconference meeting on Monday, July 2, 2001 between the hours of 2 pm and 4 pm (Eastern Daylight Savings Time). The meeting will be coordinated through a conference call connection in Room 6013 in the USEPA, Ariel Rios Building North, 1200 Pennsylvania Avenue, NW., Washington, DC 20004. The public is encouraged to attend the meeting in the conference room noted above, however, the public may also attend through a telephonic link if lines are available. Additional instructions about how to participate in the conference call can be obtained by calling Ms. Diana Pozun one week prior to the meeting (June 22, 2001) at (202) 564–4544, or via e-mail at *pozun.diana@epa.gov*

Purpose of the Meeting

The AQMS will review the Agency's proposed approach to emission inventories and air quality modeling and develop a draft response for the July 9–10, 2001 meeting of the Council to Agency charge questions on those issues.

Charge to the Subcommittee

To review the Agency's proposed analytical methodologies and data sources for the third Section 812 Study and provide advice prior to implementation of those methodologies. Topics for the AQMS's advice regarding analytical methodologies and data sources include: (1) Emissions inventories and (2) air quality modeling.

Availability of Review Materials

Review materials for the meeting will include the following: ''Benefits and Costs of the Clean Air Act 1990–2020: Draft Analytical Plan for EPA's Second Prospective Analysis.'' The document will be available upon request from Mr. Jim DeMocker via telephone (202) 564–1673, fax (202) 564–1557, or email at *democker.jim@epa.gov.*

For Further Information

Any member of the public wishing further information concerning this meeting or wishing to submit brief oral

comments (10 minutes or less) must contact Dr. Angela Nugent, Designated Federal Officer, EPA Science Advisory Board (1400A), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; telephone (202) 564–4562; FAX (202) 501–0323; or via e-mail at *nugent.angela@epa.gov.* Requests for oral comments must be *in writing* (e-mail, fax or mail) and received by Dr. Nugent no later than noon Eastern Daylight Savings Time on July 2, 2001.

4. Special Panel of the Advisory Council on Clean Air Compliance Analysis (Council)—July 9–10, 2001

A special panel of the Council, which will include consultants expert in air quality modeling and assessment of health and ecological effects, will meet on Monday and Tuesday, July 9–10, 2001 in room 6013, USEPA, Ariel Rios Building North, 1200 Pennsylvania Avenue, NW, Washington, DC 20004. The meeting will begin by 8:30 a.m. and adjourn no later than 5:30 pm on July 9, 2001 and will begin by 8:30 am and adjourn no later than 3 pm on July 10, 2001.

Purpose of the Meeting

The special panel of the Council will review the major goals, objectives, methodologies, and analytical choices for the third 812 Study before it is implemented.

Charge to the Panel

To review the Agency's proposed analytical methodologies and data sources for the third Section 812 Study and provide advice prior to implementation of those methodologies. Topics for the Council's advice regarding analytical methodologies and data sources include: (1) Overall analytical scope and design; (2) scenario definition; (3) benefit and cost disaggregation; (4) cost estimation; (5) emissions inventories; (6) air quality modeling; (7) health effects modeling; (8) ecological and welfare effects modeling; (9) assessment of the effects of hazardous air pollutants; (10) economic valuation; (11) uncertainty characterization; and (12) results integration.

Availability of Review Materials

Review materials for the meeting will include ''Benefits and Costs of the Clean Air Act 1990–2020: Draft Analytical Plan for EPA's Second Prospective Analysis.'' The document will be available upon request from Mr. Jim DeMocker via telephone (202) 564–1673, fax (202) 564–1557, or email at *democker.jim@epa.gov.*

For Further Information

Any member of the public wishing further information concerning this meeting or wishing to submit brief oral comments (10 minutes or less) must contact Dr. Angela Nugent, Designated Federal Officer, EPA Science Advisory Board (1400A), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone (202) 564–4562; FAX (202) 501–0323; or via e-mail at *nugent.angela@epa.gov.* Requests for oral comments must be *in writing* (e-mail, fax or mail) and received by Dr. Nugent no later than noon Eastern Daylight Savings Time on July 2, 2001.

5. Council Contingent Teleconference—August 9, 2001

The Council, may, depending on progress achieved in developing its report from the July 9–10, 2001 meeting, convene in a public teleconference on Thursday, August 9, 2001 between 1 pm and 3 pm. The meeting will be coordinated through a conference call connection in Room 6013 in the U.S. EPA, Ariel Rios Building, 1200 Pennsylvania Avenue, NW., Washington, DC 20004. The public is encouraged to attend the meeting in the conference room noted above, however, a limited number of the public may also attend through a telephonic link. Additional instructions about how to participate in the meeting can be obtained by calling Ms. Diana Pozun. prior to the meeting (see contact information given above).

Purpose of the Meeting

The Council is scheduling this teleconference on a contingency basis. The teleconference will be convened only if, in the opinion of the Chair, it is needed to address issues that require further discussion prior to completion of the Committee's report. A decision as whether or not this teleconference will be convened will be made by close of business, July 30, 2001, 12 days prior to the tentatively scheduled date. The decision on the teleconference will be posted to the SAB website (www.epa.gov/sab); or members of the public may call or email Ms. Diana Pozun at (202) 564–4544, or via e-mail at *pozun.diana@epa.gov.*

Availability of Review Materials

If this teleconference is to be held, a list of the issues to be discussed, along with a draft meeting agenda, will be posted on the SAB website (*www.epa.gov/sab*) under the ''Agenda'' heading on or about April 13, 2001. If the meeting is canceled, a notice will be posted on the SAB website to that effect, as well.

For Further Information

To obtain information concerning this contingent teleconference, please contact Dr. Angela Nugent, Designated Federal Officer (DFO) (telephone (202) 564–4562; FAX (202) 501–0323; or via e-mail at *nugent.angela@epa.gov.* To obtain information about how to participate in this teleconference, please contact Ms. Diana Pozun (see contact information previously given).

Providing Oral or Written Comments at SAB Meetings

It is the policy of the EPA Science Advisory Board to accept written public comments of any length, and to accommodate oral public comments whenever possible. The EPA Science Advisory Board expects that public statements presented at its meetings will not be repetitive of previously submitted oral or written statements. *Oral Comments:* In general, each individual or group requesting an oral presentation at a face-to-face meeting will be limited to a total time of ten minutes. For teleconference meetings, opportunities for oral comment will usually be limited to no more than three minutes per speaker and no more than fifteen minutes total. Deadlines for getting on the public speaker list for a meeting are given above. Speakers should bring at least 35 copies of their comments and presentation slides for distribution to the reviewers and public at the meeting. *Written Comments:* Although the SAB accepts written comments until the date of the meeting (unless otherwise stated), written comments should be received in the SAB Staff Office at least one week prior to the meeting date so that the comments may be made available to the committee for their consideration. Comments should be supplied to the appropriate DFO at the address/contact information noted above in the following formats: One hard copy with original signature, and one electronic copy via e-mail (acceptable file format: WordPerfect, Word, or Rich Text files (in IBM–PC/Windows 95/98 format). Those providing written comments and who attend the meeting are also asked to bring 25 copies of their comments for public distribution.

Meeting Access

Individuals requiring special accommodation at these meetings, including wheelchair access to the conference room, should contact Dr. Nugent at least five business days prior

to the relevant meeting so that appropriate arrangements can be made.

6. Request for Nominations for the Advisory Council on Clean Air Compliance Analysis (the Council)

The U.S. Environmental Protection Agency (EPA) is soliciting nominations to the Council, or panels that provide the Council with detailed technical advice, for future reviews of the Agency's assessments under section 812 of the Clean Air Act Amendments of the effects of the 1990 Clean Air Act Amendments on the ''public health, economy and the environment of the United States.'' By Statute, the Council is composed of ''not less than nine members * * * in the fields of health and environmental effects of air pollution, economic analysis, environmental sciences, and other fields that the Administrator determines to be appropriate.'' Historically, the Council has been supported by two subcommittees, the Health and Ecological Effects Subcommittee and the Air Quality Modeling Subcommittees, which have advised the Council on technical issues. The EPA is especially seeking individuals with expertise in epidemiology related to air pollution effects, air quality modeling, and cost and benefit assessment as related to the effects of control of air pollution.

Any interested person or organization may nominate qualified individuals for membership on the subcommittee. Nominees should be identified by name, occupation, position, address and telephone number. To be considered, all nominations must include a current resume providing the nominee's background, experience and qualifications.

The criteria for selecting Council members or members of panels providing the Council with detailed technical advice, are that members be recognized experts in their fields; that members be as impartial and objective as possible; that members represent an array of backgrounds and perspectives (within their disciplines); and that members be available to participate fully in the review, which will be conducted over a relatively short time frame. Members will be asked to attend at least one public meeting followed by at least one public telephone conference meeting over the course of 3 months; they will be asked to participate in the discussion of key issues and assumptions at these meetings, and they will be asked to review and to help finalize the products and outputs of the Council or technical panel. Any technical panel will make recommendations to the Council for approval of the Board's report and transmittal to the Administrator.

Nominations should be submitted to Dr. Angela Nugent, Designated Federal Officer, EPA Science Advisory Board, U.S. Environmental Protection Agency (1400A), 1200 Pennsylvania Avenue, NW, Washington, DC 20460, telephone (202) 564–4562; FAX (202) 501–0323; or via e-mail at *nugent.angela@epa.gov* no later than Wednesday, August 1, 2001. The Agency will not formally acknowledge or respond to nominations.

General Information

Additional information concerning the EPA Science Advisory Board, its structure, function, and composition, may be found on the SAB Website (*http://www.epa.gov/sab*) and in EPA–SAB–01–002, Science Advisory Board FY 2000 Annual Staff Report: Making Science Real which is available on the SAB Website or from the SAB Publications Staff at (202) 564–4533 or via fax at (202) 501–0256. Committee rosters, draft Agendas and meeting calendars are also located on our website.

Dated: June 4, 2001.

John R. Fowle III,

Acting Staff Director, EPA Science Advisory Board.

[FR Doc. 01–14479 Filed 6–7–01; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–6618–8]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared pursuant to the Environmental Review Process (ERP), under section 309 of the Clean Air Act and section 102(2)(c) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at (202) 564–7167. An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in FR dated April 14, 2000 (65 FR 20157).

Draft EISs

ERP No. D–AFS–L65378–ID Rating EC2, Clean Slate Ecosystem Management Project, Aquatic and Terrestrial Restoration, Nez Perce National Forest, Salmon River Ranger District, Idaho County, ID.

Summary: EPA expressed concerns regarding purpose and need, alternatives, environmental monitoring, cumulative impacts, prescribed burning, and Clean Water Act TMDL protocols. EPA has requested inclusion of a more easy to follow statement of overriding purpose and need; the addition of a no-grazing alternative that includes active habitat restoration; the addition of specific and enforceable standards; thresholds and responsible parties for environmental monitoring; additional detail on implementation and contingencies for the prescribed burning program; additional analysis of cumulative impacts, and more detail on the process to be used for addressing TMDL protocols.

ERP No. D–BLM–G65078–NM Rating LO, San Felipe Pueblo Land Exchange, Involves Exchanges Federal Lands to Private Lands, Acquisition, Sandoval and Santa Fe Cos. NM.

Summary: EPA has no objection to the proposed plan of action.

ERP No. D–BLM–K65330–CA Rating LO, Northern and Eastern Colorado Desert Plan (Plan), Implementation, Comprehensive Framework for Managing Species and Habitats (BLM), Joshua Tree National Park (JTNP) and Chocolate Mountains Aerial Gunnery Range, California Desert, Riverside, Imperial and San Bernardino Counties, CA.

Summary: EPA has no objections to the proposed plan.

ERP No. D–FHW–F40393–MI Rating EC2, I–96/Airport Area Access Study, Transportation Improvements, Surrounding the Gerald R. Ford International Airport, Kent County, MI.

Summary: EPA expressed concerns regarding wetlands, woodlands and water quality impacts to Thornapple River, Martin and Beck Drain and Little Plaster Creek.

ERP No. D–FHW–F40394–MI Rating EO2, I–94/Rehabilitation Project, Transportation Improvements to a 6.7 mile portion of I–94 from east I–96 west end to Conner Avenue on the east end, Funding and NPDES Permit, City of Detroit, Wayne County, MI.

Summary: EPA expressed environmental objections because of issues in the following areas: scope of analysis, purpose and need, alternatives analysis, air quality, noise, pedestrian and bicyclist impacts, costs, and cumulative impacts.

ERP No. D–FHW–G40160–OK Rating LO, I–40 Crosstown Expressway Transportation Improvements, From I–235/I–35 Interchange West to Meridan Avenue, Funding, Oklahoma City, OK.

Summary: EPA has no objection to the selection of the preferred alternative. EPA however asks that additional information on cultural resource

mitigation, SHPO coordination, and hazardous waste site baseline data be incorporated in the FEIS to strengthen the document.

ERP No. D–FRC–E08021–00 Rating EC2, Florida Gas Transmission (FGT) Phase V Expansion Project, FGT Natural Gas Pipeline and Associated Above Ground Facilities, Construction and Operation, Approvals and Permit Issuance, several counties of FL, AL and MS.

Summary: EPA has environmental concerns about the proposed project. In particular, air quality, wetlands impact, water quality, noise, endangered species and Environmental Justice issues warrant further discussion as the project progresses.

ERP No. D–NOA–L91012–WA Rating EO2, Anadromous Fish Agreements and Habitat Conservation Plans for the Welss, Rocky Reach, and Rock Island Hydroelectric Projects, Implementation, Incidental Take Permits, Chelan and Douglas Counties, WA.

Summary: EPA objects to selection of Alternative 3 as the preferred alternative. The proposed framework for the HCPs fails to demonstrate that salmon and fish species of concern would be protected and restored during the next 50 years. Specific problems with the framework and accompanying analyses include Columbia River bull trout not being included in the HCP or extensively analyzed, development of biological information being deferred until the writing of the Biological Opinion, a lack of monitoring methodology, and inadequate water quality information. EPA recommends that NMFS invite USF&WS to become a cooperating agency to accommodate inclusion of Columbia River bull trout in the context of the HCP and that it address concerns about inadequate information and analyses described above.

ERP No. D–NRS–D28013–WV Rating EC2, Upper Tygart Valley River Watershed Plan, Water Supply Project, Approval and Funding, Randolph and Pocahontas Counties, WV.

Summary: EPA expressed environmental concerns regarding loss of native trout habitat and wetlands and suggested that more information be provided on stream and wetland mitigation.

ERP No. DA–FHW–F40347–IL Rating EO2, FAP Route 340 (I–355 South Extension), Interstate Route 55 to Interstate Route 80, Additional Information for the Tollroad/Freeway Alternative, Funding, US Coast Guard Permit and COE Section 404 Permit, Cook, DuPage and Will Counties, IL.

Summary: EPA raised objections to the selection of alternatives. EPA's objections would be resolved if an additional Supplemental EIS were to be issued with a full environmental impact assessment of the Lemont Bypass Alternative. Our Section 404 objections would be resolved if sufficient wetlands impacts information on the Lemont Bypass Alternative is submitted to permit a finding of compliance with the Section 404(b)(1) Guidelines.

Final EISs

ERP No. F–COE–K36107–CA Bolsa Chica Project, Construction/Road Construction, Restoration and Flood Control Improvement, Section 10/404 Permits and Land Use Plan, City of Huntington Beach, Orange County, CA.

Summary: No formal comment letter was sent to the preparing agency.

ERP No. F–FHW–E40739–NC US 17 New Bern Bypass Construction, Jones-Craven County Line to NC–1438 near Vanceboro, Funding, Section 404 and U.S. Coast Guard Bridge Permit, Craven County, NC.

Summary: EPA's review indicates that all earlier concerns have been addressed satisfactorily. Adverse community, cultural and natural environmental resource impacts have been minimized substantially. The 4-lane highway improvement project on new alignment includes commitments for good mitigation of identified wetlands losses, stormwater runoff control, and habitat impacts.

ERP No. F–IBR–K39049–CA Coachella Canal Lining Water Project, Revised and Updated Information, Approval of the Transfers and Exchanges of Conserved Coachella Canal Water, Construction, Operation and Funding, Riverside and Imperial Counties, CA.

Summary: EPA recognized the commitment to mitigation for biological resources, cumulative impacts, safety, and large mammals. We recommended the ROD include additional information on consultation with tribal governments on cultural resources and local socioeconomic effects from loss of canal seepage water.

ERP No. FS–COE–K36083–CA Guadalupe River Flood Control and Adjacent Streams Investigation, Proposed Modifications to the Guadalupe River Project, Downtown San Jose, Santa Clara County, CA.

Summary: EPA found the FGRER/FSEIS adequately addresses most of the issues raised in our comment letter on the DSEIS. We reiterated our support for additional measures to control mercury impacts through sediment control traps and mitigation measures which would remove ''hard'' engineered flood control structures in other parts of the basin. EPA expressed continued concern with the use of invert stabilization mechanisms.

Dated: June 4, 2001.

Joseph C. Montgomery,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 01–14513 Filed 6–7–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–6618–7]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7167 or www.epa.gov/oeca/ofa

Weekly receipt of Environmental Impact Statements

Filed May 29, 2001 Through June 01, 2001

Pursuant to 40 CFR 1506.9.

EIS No. 010194, Draft EIS, FHW, AL, Memphis to Atlanta Corridor Study (DPS–A002(002)), Proposal to Build Highway from the Mississippi/Alabama State Line to Interstate 65, Funding and COE Section 404 Permit, Colbert, Franklin, Lauderdale, Lawrence, Limestone and Morgan Counties, AL, Comment Period Ends: July 30, 2001, Contact: Joe D. Wilkerson (334) 223–7370.

EIS No. 010195, Draft EIS, FHW, LA, I–49 Connector, Construction from Evangeline Thruway US–90 and US–197 in Urbanized Lafayette, Funding, COE Section 10 and 404 Permits, Parish of Lafayette, LA, Comment Period Ends: July 23, 2001, Contact: Bill Farr (225) 757–7615.

EIS No. 010196, Draft EIS, FHW, FL, I–4 Corridor Improvements, Upgrading the Safety and Mobility of the existing I–4, from west of FL–528 (Bee Line Expressway) interchange in Orange County to east of FL–472 interchange in Volusia County, Funding, COE Section 10 and 404 Permits, NPDES Permit, Orange, Seminole, and Volusia Counties, FL, Comment Period Ends: July 23, 2001, Contact: Donald Davis (850) 942–9650.

EIS No. 010197, Draft EIS, BOP, FL, GA, MS, AL, Criminal Alien Requirement (CAR) II, To Contract for a Private Contractor-Owned/Contractor-Operated Correctional Facility in Florida, Mississippi, Georgia and Alabama to House Adult-Male and Non-US Citizen, AL, FL, GA and/or MS, Comment Period Ends Due: July

23, 2001, Contact: David J. Dorworth (202) 514–6470.

EIS No. 010198, Draft EIS, GSA, NY, U.S. Mission to the United Nations (USUN), Demolition of Current USUN and the Construction of New Facility on the Same Site, Located at 799 United Nations Plaza, New York, NY, Comment Period Ends: July 23, 2001, Contact: Peter Sneed (212) 264–3581.

EIS No. 010199, Final EIS, RUS, KY, Jackson County Lake Project, Implementation, To Provide Adequate Water Supplies for the Projected Residential, Commercial and Industrial Needs, Funding and Possible COE Section 10 and 404 Permits, Jackson County, KY, Wait Period Ends: July 09, 2001, Contact: Mark S. Plank (202) 720–1649.

EIS No. 010200, Final EIS, IBR, CA, Grassland Bypass Project (2001 Use Agreement), To Implement the New Use Agreement for the period from October 1, 2001 through December 21, 2009, San Joaquin River and Merced River, Fresno, Merced and Stanislaus Counties, CA, Wait Period Ends: July 09, 2001, Contact: Michael Delamore (559) 487–5039.

EIS No. 010201, Final EIS, AFS, NV, CA, Northern Sierra Amendment to the Toiyabe Land and Resource Management, To Unify and Revise Management Direction, Humboldt-Toiyabe National Forest, Carson Ranger District, Stanislaus National Forest, Lake Tahoe Basin Management Unit, Douglas and Washoe Counties, NV and Alpine and Toulomne Counties, CA, Wait Period Ends: July 09, 2001, Contact: Dave Loomis (775) 882–2766.

EIS No. 010202, Final Supplement, COE, KY, Lower Cumberland and Tennessee Rivers Navigation Improvements, Kentucky Lock Addition, Implementation, Nashville District, Marshall and Livingston Counties, KY, Wait Period Ends: July 09, 2001, Contact: Tim Higgs (615) 736–7863.

EIS No. 010203, Final EIS, AFS, CA, Fuels Reduction for Community Protection Phase 1 Project on the Six Rivers National Forest, Proposes to Reduce Fuels High Severity Burned Stands, Lower Trinity Ranger District, Humboldt and Trinity Counties, CA, Wait Period Ends: July 09, 2001, Contact: David Webb (707) 457–3131.

Amended Notices

EIS No. 010128, Draft EIS, FHW, MT, Montana State Primary Route 78 (P–78), Reconstruction, Widening and Realignment, from the junction with State Secondary Route 419 (S–419) which is just South of Abarokee, to the Southern end of the Yellowstone River Bridge which is just south of Columbus, MT, Due: June 25, 2001, Contact: Dale W. Paulson (406) 449–5302. Revision of FR Notice Published on 04/27/2001: CEQ Review Period Ending 06/11/2001 has been Extended to 06/25/2001.

EIS No. 010172, Draft EIS, FHW, MD, MD–210 (Indian Head Highway) Multi-Modal Study, MD–210 Improvements between I–95/I–495 (Capitol Beltway) and MD–228 Funding and US COE Section 404 Permit Issuance, Prince George's County, MD, Due: July 23, 2001, Contact: Nelson Castellanos (410) 962–4342. Revision of FR notice published on 05/18/2001: CEQ Due Date Corrected from 09/23/2001 to 07/23/2001.

Dated: June 4, 2001.

Joseph C. Montgomery,

Director, NEPA Compliance Division, Office of Federal Activities

[FR Doc. 01–14512 Filed 6–7–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6992–6]

Notice to Existing Assistance Agreement Recipients Funded With Fiscal Year (FY) 2000 or 2001 Appropriations: New Requirements Regarding Litigation and Lobbying Certification

ACTION: Notice.

AGENCY: Environmental Protection Agency.

SUMMARY: The Office of Management and Budget (OMB) Circulars A–21, A–87, and A–122, which establish the principles for determining allowable costs under Federal assistance agreements, prohibit the use of Federal assistance funds for certain lobbying and litigation costs.

In addition, Section 424 of the Departments of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Act, 2001, Public Law 106–277, requires that: ''A chief executive officer of any entity receiving funds under this Act shall certify that none of the funds have been used to engage in the lobbying of the Federal Government or in litigation against the United States unless authorized under existing law.'' Section 426 of the Department of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Act, 2000, Public Law 106–74, contains a similar provision. This requirement applies to not-for-profit institutions, educational institutions, state, local or tribal governments and other entities receiving assistance awards under EPA's FY 2000 and 2001 Appropriations Acts.

The Paperwork Reduction Act (PRA), 44 U.S.C.A. 3500 et seq., requires that a Federal agency intending to request information from ten or more persons must obtain OMB approval before requesting that information. The appropriations act provisions described above impose additional information collection requirements on EPA assistance agreements. Therefore, EPA is currently seeking OMB approval of an information collection request for a certification document to be distributed and signed by a chief executive officer representing each entity. The certification document will not be disseminated until it has been approved by OMB.

Even though OMB has not yet approved the information collection request for the certification document, the mandates in the appropriations acts remain in effect because they are imposed directly by statute. Thus, recipients with assistance agreements funded with FY 2000 or FY 2001 appropriations must comply with this certification requirement. However, a particular format is not required until that form is approved by OMB. Until that time, each entity may provide this certification in any reasonable manner of choice. The certification must be submitted to EPA after the funds received under those appropriations have been expended.

FOR FURTHER INFORMATION CONTACT: William Hedling, U.S. Environmental Protection Agency, Office of Grants and Debarment, 1200 Pennsylvania Avenue, NW., Washington, DC 20460, phone: (202) 564–5377, FAX: (202) 565–2470, or e-mail at *www.hedling.william@epa.gov.*

Howard F. Corcoran,

Director Office of Grants & Debarment.

[FR Doc. 01–14483 Filed 6–7–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6993–2]

Science Advisory Board; Notification of Public Advisory Committee Meetings

Pursuant to the Federal Advisory Committee Act, Public Law 92–463, notice is hereby given of four meetings

of the Surface Impoundments Study Subcommittee (SISS) of the US EPA Science Advisory Board's (SAB) Environmental Engineering Committee (EEC). The meetings are open to the public, however, seating is limited and available on a first come basis. *Important Notice:* Documents that are the subject of SAB reviews are normally available from the originating EPA office and are not available from the SAB Office—information concerning availability of documents from the relevant Program Office is included below.

1. Surface Impoundments Study Subcommittee (SISS)—First Teleconference Meeting—June 26, 2001

The Surface Impoundments Study Subcommittee (SISS) will meet by conference call from noon–2 pm Eastern time on June 26, 2001. Members of the public wishing to participate in the teleconference must make arrangements with Ms. Mary Winston by noon the Wednesday *before* the meeting. Instructions about how to participate in the conference call can be obtained by calling Ms. Mary Winston, Management Assistant, at (202) 564–4538, or via e-mail at: *winston.mary@epa.gov.*

The SISS welcomes written public comment and will accept oral comments during a portion of this conference call. The comment period will be limited to approximately 30 minutes in total with about five minutes allowed for per speaker. Additional opportunities for public comment will provided at the July 19 and August 27 conference call meetings as well as the September 17–19, 2001 face-to-face meeting.

Purpose of the Meeting—The purpose of the conference call meeting is to allow the Committee and the Agency to discuss and refine, if necessary, the charge for the review of the Surface Impoundments Study and to make plans for the face-to-face meeting on September 17–19, 2001.

Availability of Materials and Contact Information—See below.

2. Surface Impoundments Study Subcommittee (SISS)—Teleconference Meeting—July 19, 2001

The Surface Impoundments Study Subcommittee (SISS) will meet by conference call from 1–3 pm Eastern time on July 19, 2001. Members of the public wishing to participate in the teleconference must make arrangements with Ms. Mary Winston by noon the Wednesday *before* the meeting. Instructions about how to participate in the conference call can be obtained by calling Ms. Mary Winston, Management Assistant, at (202) 564–4538, or via e-mail at: *winston.mary@epa.gov.*

The SISS welcomes written public comment and will accept oral comments during a portion of this conference call. The comment period will be limited to approximately 30 minutes in total with about five minutes allowed for per speaker. Additional opportunities for public comment will be provided at the August 27 conference call meeting as well as the September 17–19, 2001 face-to-face meeting.

Purpose of the Meeting—The purpose of the conference call meeting is to allow the Subcommittee and the Agency to continue preparations for the face-to-face meeting. The chair plans to make writing assignments to the panelists and confirm that they have the materials necessary to complete them.

Availability of Materials and Contact Information—See below.

3. Surface Impoundments Study Subcommittee (SISS)—Teleconference Meeting—August 27, 2001

The Surface Impoundments Study Subcommittee (SISS) will meet by conference call from 1–3 pm Eastern time on August 27, 2001. Members of the public wishing to participate in the teleconference must make arrangements with Ms. Mary Winston by noon the Wednesday *before* the meeting. Instructions about how to participate in the conference call can be obtained by calling Ms. Mary Winston, Management Assistant, at (202) 564–4538, or via e-mail at: *winston.mary@epa.gov.*

The SISS welcomes written public comment and will accept oral comments during a portion of this conference call. The comment period will be limited to approximately 30 minutes in total with about five minutes allowed for per speaker. Additional opportunities for public comment will provided at the September 17–19, 2001 face-to-face meeting.

Purpose of the Meeting—The purpose of the conference call meeting is to allow the Subcommittee and the Agency to complete preparations for the face-to-face meeting. Panelists will discuss their preliminary, individual writings and accept comments on them.

Availability of Materials and Contact Information—See below.

4. Surface Impoundments Study Subcommittee (SISS)—September 17–19, 2001

The Surface Impoundments Study Subcommittee (SISS) will meet Monday September 17 through Wednesday September 19, 2001, room 6530 of the Ariel Rios Building, 1200 Pennsylvania Ave., NW., Washington, DC. The meeting will convene at 9:30 Eastern time on Monday September 17 and will adjourn no later than 3:00 pm Wednesday September 19, 2001.

Purpose of the Meeting—The Subcommittee will review the Office of Solid Waste's Surface Impoundments Study and plans to prepare a draft report of the consensus findings, conclusions and recommendations resulting from that review. The Subcommittee may schedule a subsequent public conference call meeting to approve final language of its draft report before submitting it to the Environmental Engineering Committee for consideration. If so, that will be announced separately.

Background: Under the Resource Conservation and Recovery Act (RCRA), EPA allowed land placement of ''decharacterized'' wastes that were formerly characteristic hazardous wastes managed in wastewater systems, but had been treated or diluted to remove the characteristic hazard. The Land Disposal Program Flexibility Act of 1996 (LDPFA) required that EPA study the two types of land placement of these wastes: underground injection, and placement (storage, treatment or disposal) in surface impoundments. This peer review concerns only the surface impoundment waste management technique.

The study of surface impoundments is also the subject of other regulatory and judicial developments. For certain types of facilities EPA was required to study human health risks from air inhalation of 105 chemical constituents present in surface impoundments.

Industrial Surface Impoundments in the United States is the report that discusses EPA's estimated risks to human health and the environment that may be posed by managing industrial nonhazardous wastes in surface impoundments. It provides estimates of cancer and non-cancer human health risks for individuals (receptors) who may be exposed to releases from surface impoundments used to manage wastewaters and wastewater treatment sludges, a screening analysis of other indirect pathway human health risks, and a screening analysis of the potential risks to ecological receptors. EPA will use the risk results, along with the analysis of existing regulatory and nonregulatory programs designed to address the risks (described in Chapter 4 of the report) to decide whether, and if so, how, to apply the land disposal restrictions or take other appropriate actions to address risks found.

In 1997 a subcommittee of the Environmental Engineering Committee

Subcommittee reviewed the draft structure for this study. The Subcommittee commented on: a) the technical merits of the overall study structure; b) the technical merits of the proposed risk assessment; and c) the involvement of technical experts, affected facilities and the public at critical points in the study's design and implementation. This report (EPA–SAB–EEC–98–009) can be found in the Fiscal Year 1998 Reports section of the SAB's website (*www.epa.gov/sab*).

Charge to the Committee—The full charge will be posted at the SAB's website (www.epa.gov/sab). In summary, the Subcommittee is charged to address the following questions:

(1)(a) Does the Science Advisory Board believe that the general methodology we chose for developing our risk analysis was appropriate for the policy questions posed in the statute and consent decree.

(b) Regarding the overall study implementation, from design through sample selection, data collection and analysis, what areas of strength do you see in the overall methodology, and what areas of potential improvement or additional analysis do you recommend?

(c) Did EPA adequately characterize the risks? Are the risk analysis and findings transparent? That is, are they explicit in:

- Describing the assessment approach, assumptions, extrapolations and use of models
- Describing plausible alternative assumptions
- Identifying data gaps
- Distinguishing science from policy
- Describing uncertainty, and
- Describing the relative strength of the assessment?

(d) Please provide your assessment of the accuracy of EPA's overall study conclusions regarding risks to human health and the environment. Were the conclusions either false positive or false negative conclusions (finding risks of greater or lesser magnitude than the risks that likely exist)?

(2)(a) Should EPA have performed a more in-depth evaluation of abnormal operating condition events? If so, what methods or approaches would the SAB recommend regarding collecting more reliable data, and modeling the probability and impacts of such events?

(3)(a) For the indirect human health and ecological screening-level analyses, in the SAB's view, do the results point to areas of potential future research? If so, do you have recommendations on prioritizing future studies in these areas?

(b) Based on the screening-level estimates we developed for other indirect and ecological risks, did it appear that we overlooked potential problem areas?

(c) Did we clearly describe and properly characterize the other indirect human health and ecological risk analyses?

(4)(a) Is it likely that EPA's data imputation protocol, or ''surrogate data protocol'' for imputing waste composition data markedly affected the ultimate conclusions regarding potential risks? If so, in what direction did the protocol probably bias the conclusions?

(b) Should EPA have used any other approaches for qualifying or presenting the data?

(c) Was using the assumption that a chemical could be present up to the detection limit, when it was reported as being present below a detection limit, a reasonable concentration to choose for risk screening purposes?

(d) Did the EPA-generated default detection limit protocol provide reasonable approximations of likely detection limits encountered in the field by the facilities, when the detection limits were not reported in the laboratory analysis?

(e) Do the results that are based on imputed/detection limit data suggest that further analysis is needed?

(5)(a) Although there are limitations of performing the comparison of survey and field sampling waste composition data, what is the SAB's view on EPA's conclusions about the accuracy of the reported survey data on chemical constituent concentrations/quantities?

(b) What is the SAB's view on EPA's conclusion on the potential incomplete reporting of chemical constituents present?

(c) Would the SAB recommend alternate approaches, in order to obtain the best possible information regarding the exact chemical constituents present, given the same budget and time constraints?

(6)(a) Would the SAB recommend another approach for representing the groundwater source term, for example, performing a bounding analysis, using the sludge data, where available, to represent an upper bound of the groundwater source term, and using wastewater data as the lower bound, for those chemical constituents for which this situation may be an issue?

(b) Compared to other sources of uncertainty in the groundwater and groundwater to surface water pathway analyses, how large a source of uncertainty does the decision to use wastewater composition data appear to introduce into the overall study conclusions?

Availability of Materials—The background materials provided to the Subcommittee are available at *http://www.epa.gov/epaoswer/hazwaste/ldr/icr/ldr-impd.htm*. A limited number of paper copies can be obtained by contacting Shannon Sturgeon, U.S. Environmental Protection Agency, Office of Solid Waste (5307W), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Ms. Sturgeon may also be contacted at 703 605 0509 or via e-mail at *sturgeon.sharon@epa.gov*. The draft meeting agenda may be obtained from Ms. Mary Winston, Management Assistant, at (202) 564–4538, or via e-mail *at:winston.mary@epa.gov* approximately two weeks before the meeting.

FOR FURTHER INFORMATION: Any member of the public wishing further information concerning this meeting or wishing to submit brief oral comments (10 minutes or less) must contact Ms. Kathleen White, Designated Federal Officer, Science Advisory Board (1400A), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone (202) 564–4559; fax (202) 501–0582; or via e-mail at *conway.kathleen@epa.gov*. Requests for oral comments must be *in writing* (e-mail, fax or mail) and received by Ms. White no later than noon Eastern Standard Time on the Wednesday before the scheduled meeting.

Providing Oral or Written Comments at SAB Meetings

It is the policy of the Science Advisory Board to accept written public comments of any length, and to accommodate oral public comments whenever possible. The Science Advisory Board expects that public statements presented at its meetings will not be repetitive of previously submitted oral or written statements. *Oral Comments:* In general, each individual or group requesting an oral presentation at a face-to-face meeting will be limited to a total time of ten minutes. For these teleconference meetings, opportunities for oral comment have been expanded to no more than five minutes per speaker and no more than thirty minutes total. Deadlines for getting on the public speaker list for a meeting are given above. Speakers should bring at least 35 copies of their comments and presentation slides for distribution to the reviewers and public at the meeting. *Written Comments:* Although the SAB accepts written comments until the date

of the meeting (unless otherwise stated), written comments should be received in the SAB Staff Office at least one week prior to the meeting date so that the comments may be made available to the committee for their consideration. Comments should be supplied to Ms. White at the address/contact information noted above in the following formats: one hard copy with original signature, and one electronic copy via e-mail (acceptable file format: WordPerfect, Word, or Rich Text files (in IBM-PC/Windows 95/98 format). Those providing written comments and who attend the meeting are also asked to bring 25 copies of their comments for public distribution.

General Information—Additional information concerning the Science Advisory Board, its structure, function, and composition, may be found on the SAB Website (*http://www.epa.gov/sab*) and in The FY2000 Annual Report of the Staff Director which is available from the SAB Publications Staff at (202) 564–4533 or via fax at (202) 501–0256. Committee rosters, draft Agendas and meeting calendars are also located on our website.

Meeting Access—Individuals requiring special accommodation at this meeting, including wheelchair access to the conference room, should contact Ms. Winston at least five business days prior to the meeting so that appropriate arrangements can be made.

Dated: May 31, 2001.

John R. Fowle, III,

Acting Staff Director, Science Advisory Board.

[FR Doc. 01–14475 Filed 6–7–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPPTS–59376; FRL–6787–1]

Approval of Test Marketing Exemption for a Certain New Chemical With Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's approval of an application for test marketing exemption (TME) under section 5(h)(1) of the Toxic Substances Control Act (TSCA) and 40 CFR 720.38. EPA has designated this application as TME–01–0010. The test marketing conditions are described in the TME application and in this notice.

DATES: Approval of this TME is effective May 31, 2001. Written comments will be received until June 25, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit III. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPPTS–59376 and the TME number TME–01–0010 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: *For general information contact*: Barbara Cunningham, Director, Office of Program Management and Evaluation (7401), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 554–1404; e-mail address: TSCA-Hotline@epa.gov.

For technical information contact: Andrea Conrath, New Chemicals Prenotice Branch, Chemical Control Division (7405), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 260–2721; e-mail address: conrath.andrea@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Does this Action Apply to Me?

This action is directed in particular to the chemical manufacturer and/or importer who submitted the TME to EPA. This action may, however, be of interest to the public in general. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

II. How Can I Get Additional Information, Including Copies of this Document or Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**— Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number OPPTS–59376. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the TSCA Nonconfidential Information Center, North East Mall Rm. B–607, Waterside Mall, 401 M St., SW., Washington, DC. The Center is open from noon to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number of the Center is (202) 260–7099.

III. How and to Whom Do I Submit Comments?

The notice of receipt was published late in the 45–day review period; however, an opportunity to submit comments is being offered at this time. You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPPTS–59376 in the subject line on the first page of your response. The complete nonconfidential document is available in the TSCA Nonconfidential Information Center at the address in Unit II.B. between noon and 4 p.m., Monday through Friday, excluding holidays. EPA may modify or revoke the test marketing exemption if comments are received which cast significant doubt on its finding that the test marketing activities will not present an unreasonable risk of injury.

1. *By mail*. Submit your comments to: Document Control Office (7407), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier*. Deliver your comments to: OPPT Document Control Office (DCO) in East Tower Rm. G–099, Waterside Mall, 401 M St., SW., Washington, DC. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 260–7093.

3. *Electronically*. You may submit your comments electronically by e-mail to: oppt.ncic@epa.gov or mail your computer disk to the address identified above. Do not submit any information

electronically that you consider to be CBI. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on standard disks in WordPerfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number OPPTS–59376. Electronic comments may also be filed online at many Federal Depository Libraries.

IV. How Should I Handle CBI Information That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the technical person identified under **FOR FURTHER INFORMATION CONTACT**.

V. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Offer alternative ways to improve the proposed rule or collection activity.

7. Make sure to submit your comments by the deadline in this document.

8. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

VI. What is the Agency's Authority for Taking this Action?

Section 5(h)(1) of TSCA and 40 CFR 720.38 authorizes EPA to exempt persons from premanufacture notification (PMN) requirements and permit them to manufacture or import new chemical substances for test marketing purposes, if the Agency finds that the manufacture, processing, distribution in commerce, use, and disposal of the substances for test marketing purposes will not present an unreasonable risk of injury to health or the environment. EPA may impose restrictions on test marketing activities and may modify or revoke a test marketing exemption upon receipt of new information which casts significant doubt on its finding that the test marketing activity will not present an unreasonable risk of injury.

VII. What Action is the Agency Taking?

EPA has approved the above-referenced TME. EPA has determined that test marketing the new chemical substance, under the conditions set out in the TME application and in this notice, will not present any unreasonable risk of injury to health or the environment.

VIII. What Restrictions Apply to this TME?

The test market time period, production volume, number of customers, and use must not exceed specifications in the application and this notice. All other conditions and restrictions described in the application and in this notice must also be met.

TME–01–0010.

Date of Receipt: April 11, 2001.

Notice of Receipt: May 18, 2001 (66 FR 27651) (FRL–6782–3).

Applicant: Westvaco Corporation.

Chemical: (G) Butyl acrylate, polymer with styrene and methylamino chloride compounds.

Use: Binding agent in paper coatings.

Production Volume: Confidential.

Number of Customers: 8.

Test Marketing Period: 365 days, commencing on first day of commercial manufacture.

The following additional restrictions apply to this TME. A bill of lading accompanying each shipment must state that the use of the substance is restricted to that approved in the TME. In addition, the applicant shall maintain the following records until 5 years after the date they are created, and shall make them available for inspection or copying in accordance with section 11 of TSCA:

1. Records of the quantity of the TME substance produced and the date of manufacture.

2. Records of dates of the shipments to each customer and the quantities supplied in each shipment.

3. Copies of the bill of lading that accompanies each shipment of the TME substance.

IX. What was EPA's Risk Assessment for this TME?

The Agency has not taken action to control exposures to or releases of this substance. EPA identified a concern for potential lung effects from inhalation exposure to workers handling this TME substance, based upon data for structurally similar analogs, namely high molecular weight polymers and cationic polymers. However, EPA decided not to regulate the TME substance at this time, based on mitigation of exposure through expected use of appropriate personal protective equipment, as described on the company's Material Safety Data Sheet (MSDS) for this chemical. EPA also identified aquatic toxicity concerns for this chemical, again based upon analog data as described above. However, this concern is mitigated as there are no releases to water expected, and minimal environmental releases overall. Therefore, the test market activities will not present an unreasonable risk of injury to human health or the environment.

X. Can EPA Change Its Decision on this TME in the Future?

Yes. The Agency reserves the right to rescind approval or modify the conditions and restrictions of an exemption should any new information that comes to its attention cast significant doubt on its finding that the test marketing activities will not present any unreasonable risk of injury to human health or the environment.

List of Subjects

Environmental protection, Test marketing exemptions.

Dated: May 31, 2001.

Rebecca S. Cool,

Chief, New Chemicals Prenotice Branch, Office of Pollution Prevention and Toxics.

[FR Doc. 01–14485 Filed 6–7–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPPTS–59377; FRL–6787–2]

Approval of Test Marketing Exemption for a Certain New Chemical

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's approval of an application for test marketing exemption (TME) under section 5(h)(1) of the Toxic Substances Control Act (TSCA) and 40 CFR 720.38. EPA has designated this application as TME–01–11. The test marketing conditions are described in the TME application and in this notice.

DATES: Approval of this TME is effective May 31, 2001.

FOR FURTHER INFORMATION CONTACT: *For general information contact*: Barbara Cunningham, Director, Office of Program Management and Evaluation, Office of Pollution Prevention and Toxics (7401), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 554–1404; e-mail address: TSCA-Hotline@epa.gov.

For technical information contact: Adella Watson, New Chemicals Prenotice Branch, Chemical Control Division (7405), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 260–3752; e-mail address: watson.adella]@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Does this Action Apply to Me?

This action is directed in particular to the chemical manufacturer and/or importer who submitted the TME to EPA. This action may, however, be of interest to the public in general. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

II. How Can I Get Additional Information, Including Copies of this Document or Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations, '' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number OPPTS–59377. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as Confidential Business Information CBI. This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the TSCA Nonconfidential Information Center, North East Mall Rm. B–607, Waterside Mall, 401 M St., SW., Washington, DC. The Center is open from noon to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number of the Center is (202) 260–7099.

III. What is the Agency's Authority for Taking this Action?

Section 5(h)(1) of TSCA and 40 CFR 720.38 authorizes EPA to exempt persons from premanufacture notification (PMN) requirements and permit them to manufacture or import new chemical substances for test marketing purposes, if the Agency finds that the manufacture, processing, distribution in commerce, use, and disposal of the substances for test marketing purposes will not present an unreasonable risk of injury to health or the environment. EPA may impose restrictions on test marketing activities and may modify or revoke a test marketing exemption upon receipt of new information which casts significant doubt on its finding that the test marketing activity will not present an unreasonable risk of injury.

IV. What Action is the Agency Taking?

EPA approves the above-referenced TME. EPA has determined that test marketing the new chemical substance, under the conditions set out in the TME application and in this notice, will not present any unreasonable risk of injury to health or the environment.

V. What Restrictions Apply to this TME?

The test market time period, production volume, number of customers, and use must not exceed specifications in the application and this notice. All other conditions and restrictions described in the application and in this notice must also be met.

TME–01–11.

Date of Receipt: April 19, 2001.

Notice of Receipt: May 18, 2001 (66 FR 27656) (FRL–6783–9).

Applicant: CBI.

Chemical: (G) Modified melamine.

Use: (G) Component of coating with open use.

Production Volume: 40,000 kg/yr.

Number of Customers: CBI.

Test Marketing Period: 365 days, commencing on first day of commerical manufacture.

The following additional restrictions apply to this TME. A bill of lading accompanying each shipment must state that the use of the substance is restricted to that approved in the TME. In addition, the applicant shall maintain the following records until 5 years after the date they are created, and shall make them available for inspection or copying in accordance with section 11 of TSCA:

1. Records of the quantity of the TME substance produced and the date of manufacture.

2. Records of dates of the shipments to each customer and the quantities supplied in each shipment.

3. Copies of the bill of lading that accompanies each shipment of the TME substance.

VI. What was EPA's Risk Assessment for this TME?

EPA identified no significant health or environmental concerns for the test market substance. Therefore, the test market activities will not present any unreasonable risk of injury to human health or the environment.

VII. Can EPA Change Its Decision on this TME in the Future?

Yes. The Agency reserves the right to rescind approval or modify the conditions and restrictions of an exemption should any new information that comes to its attention cast significant doubt on its finding that the test marketing activities will not present any unreasonable risk of injury to human health or the environment.

List of Subjects

Environmental protection, Test marketing exemptions.

Dated: May 31, 2001.

Rebecca S. Cool,

Chief, New Chemicals Prenotice Branch, Office of Pollution Prevention and Toxics.

[FR Doc. 01–14486 Filed 6–7–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[CWA–HQ–2001–6001; FRL –6994–2]

Clean Water Act Class II: Proposed Administrative Settlement, Penalty Assessment and Opportunity To Comment Regarding WorldCom, Inc.

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has entered into a consent agreement with WorldCom, Inc. to resolve violations of the Clean Water Act (''CWA''), and its implementing regulations. WorldCom failed to prepare Spill Prevention Control and Countermeasure (''SPCC'') plans for seventy-five facilities where they stored diesel oil in above ground tanks. EPA, as authorized by CWA section 311(b)(6), 33 U.S.C. 1321(b)(6), has assessed a civil penalty for these violations. The Administrator, as required by CWA section 311(b)(6)(C), 33 U.S.C. 1321(b)(6)(C), is hereby providing public notice of, and an opportunity for interested persons to comment on, this consent agreement and proposed final order.

DATES: Comments are due on or before July 9, 2001.

ADDRESSES: Mail written comments to the Enforcement & Compliance Docket and Information Center (2201A), Docket Number EC–2001–005, Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Mail Code 2201A, Washington, DC 20460. (Comments may be submitted on disk in WordPerfect 8.0 or earlier versions.) Written comments may be delivered in person to: Enforcement and Compliance Docket Information Center, U.S. Environmental Protection Agency, Rm. 4033, Ariel Rios Bldg., 1200 Pennsylvania Avenue, NW., Washington, DC. Submit comments electronically to *docket.oeca@epa.gov.* Electronic comments may be filed online at many Federal Depository Libraries.

The consent agreement, the proposed final order, and public comments, if any, may be reviewed at the Enforcement and Compliance Docket Information Center, U.S. Environmental Protection Agency, Rm. 4033, Ariel Rios Bldg., 1200 Pennsylvania Avenue, NW., Washington, DC. Persons interested in reviewing these materials must make arrangements in advance by calling the docket clerk at 202–564–2614. A reasonable fee may be charged by EPA for copying docket materials.

FOR FURTHER INFORMATION CONTACT: Beth Cavalier, Multimedia Enforcement Division (2248–A), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone (202) 564–3271; fax: (202) 564–9001; e-mail: cavalier.beth@epa.gov.

SUPPLEMENTARY INFORMATION:

Electronic Copies: Electronic copies of this document are available from the EPA Home Page under the link ''Laws and Regulations'' at the **Federal Register**—Environmental Documents entry (http://www.epa.gov/fedrgstr).

I. Background

WorldCom, Inc., a telecommunications company incorporated in the State of Georgia and located at 500 Clinton Center Drive, Clinton, Mississippi 39056, failed to prepare SPCC plans for seventy-five facilities. WorldCom, Inc. disclosed, pursuant to the EPA ''Incentives for Self-Policing: Discovery, Disclosures, Correction and Prevention of Violations'' (''Audit Policy''), 60 FR 66706 (December 22, 1995), that they failed to prepare SPCC plans for seventy-five facilities where they stored diesel oil in above ground storage tanks, in violation of the CWA section 311(b)(3) and 40 CFR Part 112. EPA determined that WorldCom met the criteria set out in the Audit Policy for a 100% waiver of the gravity component of the penalty. As a result, EPA waived the gravity based penalty ($137,500) and proposed a settlement penalty amount of eighty-one thousand, three hundred and six ($81,306). This is the amount of the economic benefit gained by WorldCom, attributable to their delayed compliance with the SPCC regulations. WorldCom, Inc. has agreed to pay this amount in civil penalties. EPA and WorldCom negotiated and signed an administrative consent agreement, following the Consolidated Rules of Procedure, 40 CFR 22.13, on June 1, 2001 (*In Re: WorldCom, Inc.,* Docket No. CWA–HQ–2001–6001). This consent agreement is subject to public notice and comment under CWA section 311(b)(6), 33 U.S.C. 1321(b)(6).

Under CWA section 311(b)(6)(A), 33 U.S.C. 1321 (b)(6)(A), any owner, operator, or person in charge of a vessel, onshore facility, or offshore facility from which oil is discharged in violation of the CWA section 311 (b)(3), 33 U.S.C. 1321 (b)(3), or who fails or refuses to comply with any regulations that have been issued under CWA section 311 (j), 33 U.S.C. 1321(j), may be assessed an administrative civil penalty of up to $137,500 by EPA. Class II proceedings under CWA section 311(b)(6) are conducted in accordance with 40 CFR part 22.

The procedures by which the public may comment on a proposed Class II penalty order, or participate in a Clean Water Act Class II penalty proceeding, are set forth in 40 CFR 22.45. The deadline for submitting public comment on this proposed final order is July 9, 2001. All comments will be transferred to the Environmental Appeals Board (''EAB'') of EPA for consideration. The powers and duties of the EAB are outlined in 40 CFR 22.04(a).

Pursuant to CWA section 311(b)(6)(C), EPA will not issue an order in this proceeding prior to the close of the public comment period.

List of Subjects

Environmental protection.

Dated: June 1, 2001.

David A. Nielsen,

Director, Multimedia Enforcement Division, Office of Enforcement and Compliance Assurance.

[FR Doc. 01–14481 Filed 6–7–01; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). Currently, the FDIC is soliciting comments concerning the following collections of information titled: (1) Recordkeeping and Disclosure Requirements in Connection with Regulation Z (Truth in Lending); (2) Recordkeeping and Disclosure Requirements in Connection with Regulation M (Consumer Leasing); (3) Recordkeeping and Disclosure

Requirements in Connection with Regulation E (Electronic Fund Transfers), and (4) Recordkeeping and Disclosure Requirements in Connection with Regulation B (Equal Credit Opportunity).

DATES: Comments must be submitted on or before August 7, 2001.

ADDRESSES: Interested parties are invited to submit written comments to Tamara R. Manly, Management Analyst (Regulatory Analysis), (202) 898–7453, Office of the Executive Secretary, Room F–4058, Attention: Comments/OES, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429. All comments should refer to the OMB control number. Comments may be hand-delivered to the guard station at the rear of the 17th Street Building (located on F Street), on business days between 7 a.m. and 5 p.m. [FAX number (202) 898–3838; Internet address: comments @ fdic.gov].

A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Alexander Hunt, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 3208, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Tamara R. Manly, at the address identified above.

SUPPLEMENTARY INFORMATION:

Proposal to renew the following currently approved collections of information:

1. *Title:* Recordkeeping and Disclosure Requirements in Connection with Regulation Z (Truth in Lending).

OMB Number: 3064–0082.

Frequency of Response: On occasion.

Affected Public: Any businesses or individuals that regularly offer or extend consumer credit.

Estimated Number of Respondents: 5,662.

Estimated Time per Response: 787 hours.

Total Annual Burden: 4,455,994 hours.

General Description of Collection: Regulation Z (12 CFR part 226), issued by the Board of Governors of the Federal Reserve System, prescribes uniform methods of computing the cost of credit, disclosure of credit terms, and procedures for resolving billing errors on certain credit accounts.

2. *Title:* Recordkeeping and Disclosure Requirements in Connection with Regulation M (Consumer Leasing).

OMB Number: 3064–0083.

Frequency of Response: On occasion.

Affected Public: Any businesses engaging in consumer leasing.

Estimated Number of Respondents: 5,662.

Estimated Time per Response: 4 hours.

Total Annual Burden: 22,648 hours.

General Description of Collection: Regulation M (12 CFR part 2123), issued by the Board of Governors of the Federal Reserve System, implements the consumer leasing provisions of the Truth in Lending Act.

3. *Title:* Recordkeeping and Disclosure Requirements in Connection with Regulation E (Electronic Fund Transfers).

OMB Number: 3064–0084.

Frequency of Response: On occasion.

Affected Public: Any users of the electronic fund transfer system.

Estimated Number of Respondents: 5,662.

Estimated Time per Response: 120.4 hours.

Total Annual Burden: 681,705 hours.

General Description of Collection: Regulation E (12 CFR part 205), issued by the Board of Governors of the Federal Reserve System, establishes the rights, liabilities, and responsibilities of consumers who use electronic fund transfer services and of financial institutions that offer these services.

4. *Title:* Recordkeeping and Disclosure Requirements in Connection with Regulation B (Equal Credit Opportunity).

OMB Number: 3064–0085.

Frequency of Response: On occasion.

Affected Public: Any financial institution engaging in credit transactions.

Estimated Number of Respondents: 5,662.

Estimated Time per Response: 43 hours.

Total Annual burden: 243,466 hours.

General Description of Collection: Regulation B (12 CFR part 202), issued by the Board of Governors of the Federal Reserve System, prohibits creditors from discriminating against applicants on any of the bases specified by the Equal Credit Opportunity Act, establishes guidelines for gathering and evaluating credit information, and requires creditors to give applicants a written notification of rejection of an application.

Request for Comment

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the collection should be modified prior to submission to OMB for review and approval. Comments submitted in response to this notice also will be summarized or included in the FDIC's requests to OMB for renewal of these collections. All comments will become a matter of public record.

Dated at Washington, DC, this 4th day of June, 2001.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 01–14442 Filed 6–7–01; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meeting; Notice of Agency Meeting

Pursuant to the provisions of the ''Government in the Sunshine Act'' (5 U.S.C. 552b), notice is hereby given that at 11:05 a.m. on Tuesday, June 5, 2001, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters relating to the Corporation's corporate and supervisory activities.

In calling the meeting, the Board determined, on motion of Director Ellen S. Seidman (Director, Office of Thrift Supervision), seconded by Director John M. Reich (Appointive), concurred in by Director John D. Hawke, Jr. (Comptroller of the Currency), and Chairman Donna Tanoue, that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no notice earlier than June 1, 2001, of the meeting was practicable, that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(2), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the ''Government in the Sunshine Act'' (5 U.S.C. 552b(c)(2), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

The meeting was held in the Board Room of the FDIC Building located at 550–17th Street, NW., Washington, DC.

Dated: June 5, 2001.

Federal Deposit Insurance Corporation.

James D. LaPierre,

Deputy Executive Secretary.

[FR Doc. 01–14568 Filed 6–6–01; 10:21 am]

BILLING CODE 6714–01–M

FEDERAL EMERGENCY MANAGEMENT AGENCY

Cooperating Technical Partners

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice of cooperating technical partners flood hazard mapping initiative (formerly known as Cooperating Technical Communities).

SUMMARY: We (FEMA) give notice of the Cooperating Technical Partners initiative that will recognize and encourage participation by states, regional agencies, and communities in the flood hazard mapping process.

DATES: Funding available May 4, 2001 for FY 2001.

FOR FURTHER INFORMATION CONTACT: Your FEMA Regional Cooperating Technical Partners Coordinator. We list contact names for the coordinators under Section (h) of this document.

SUPPLEMENTARY INFORMATION: (a) *Background.* Throughout this notice, the terms ''we,'' ''our,'' and ''us,'' refers to FEMA. The term ''Partner'' (upper case ''P'') or ''CTP'' refers to a participant in the CTP initiative. We administer the National Flood Insurance Program (NFIP) and under section 1360 of the National Flood Insurance Act of 1968, as amended (42 U.S.C. 4101), we establish and update flood-risk zone data in floodplain areas. In the identification of flood-prone areas, we may consult with, receive information from, and enter into agreements or other arrangements with the head of any State, regional, or local agency in order to identify these floodplain areas.

We are implementing the Cooperating Technical Partners (CTP) concept as part of our Flood Map Modernization plan *(http://www.fema.gov/library/mapmod.pdf).* The initiative was formerly known as Cooperating Technical Communities. The CTP initiative will formally recognize and encourage the ongoing contributions that our mapping partners—States, regional agencies, and communities—make in assisting us in providing timely and accurate flood hazard information. The participating entity will enter into a partnership agreement with us to develop or maintain all or a component of its flood hazard maps.

CTP collaborations will maximize the effectiveness of the limited local and Federal funding available for flood mapping, while maintaining consistent national standards. Through these partnerships, the integration of locally funded or developed flood and mapping data in the flood mapping process will enable contributing partners to expand the scope of our flood mapping efforts. We expect that this will result in enhanced responsibility for the maps by the partners and, in turn, heightened local awareness of flood risks, more effective floodplain management, and more accurate maps. The Cooperating Technical Partners initiative includes both locally funded and FEMA-funded activities.

Under the initiative, the Partner and we will enter a general overall agreement (CTP Agreement) that recognizes the fundamental importance of flood hazard identification, as well as flood insurance and floodplain management. Then, as the CTP and we identify specific flood mapping activities to undertake, the CTP and we will develop and enter into Mapping Activity Agreements under the umbrella of the overall CTP Agreement.

We envision that most Mapping Activity Agreements will be collaborative efforts where both the CTP and FEMA contribute data and units of work to maximize the extent, accuracy, and utility of flood studies to best meet local and Federal needs, while minimizing costs for all parties. Federal funding will be limited even if we can allocate supplemental map modernization funding. In any event, we will allocate funding within the context of our flood study prioritization process.

Additional Guidance is available at *http://www.fema.gov/mit/tsd/CPT_main.htm.*

(b) Availability *of Fiscal Year 2001 Funds.* We have set aside approximately $8 million nation-wide for use by all FEMA Regional offices to fund CTP mapping activities in Fiscal Year 2001. We base the selection of CTP participants on floodplain mapping needs and on the partners' interest, contributions, and their capability to perform the types of eligible activities that we identified for the CTP initiative. Funding will be provided to eligible CTP applicants through the Cooperative Agreement process in accordance with Title 44 of the Code of Federal Regulations (CFR), part 13. Request for Federal Assistance (RFA) packages will be mailed to potential applicants from the FEMA Regional offices upon publication of this notice.

(c) *Eligibility.* We intend the cooperative agreements awarded in this effort to supplement and not supplant on-going mapping efforts by the community, regional agency, or State. The FEMA funds would be in addition to the partner's current flood hazard mapping effort. Our Regional Offices will select partners based on the following criteria:

(1) The CTP applicant must have existing processes or systems in place that support mapping or data collection activities that contribute to flood hazard identification. These ongoing processes or systems must be supported by non-federal funding.

(2) The CTP applicant must have demonstrated the capability and commitment to perform the mapping activities for which it is applying. This capability may be indicated through (but not limited to) a FEMA Regional Office review of both previously prepared map products and of the Partner's existing processes or systems for the production of map products that are intended by the Partner to be utilized for CTP activities.

(3) The CTP applicant must be a community participating in the NFIP, and be in good standing in the program as determined by our Regional Office, or be a State or regional agency that serves communities that participate in the NFIP.

(4) The CTP applicant that will be receiving funds under a cooperative agreement must be able to perform the financial management activities required as part of the cooperative agreement (i.e., account for federal funds, prepare required performance and financial reports). Our regional offices will assist the communities with these financial management activities. FEMA-funded activities must meet the requirements of 44 CFR part 13, Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments. Part 13 sets forth requirements for proper grant administration and management including, but not limited to, record-keeping, allowable costs, and the processes for use of contractors.

(5) The CTP applicant must have in-house staff capabilities in the appropriate technical area for the given activity. If a portion of the activities is contracted, the CTP partner must have in-house staff capability to monitor the contractor as well as review and approve the products. For these purposes, ''capability'' means demonstrated experience in the performance of, or management through contracting of, similar activities.

(6) The CTP that will be utilizing a contractor to perform FEMA-funded activities must ensure that those contractors meet the requirements of 44 CFR part 13, Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments. Within part 13, § 13.36 covers procurement standards that must be followed for any mapping related activities for which the CTP wishes to contract with another party. Items in this Part include, but are not limited to, contract administration and record keeping, notification requirements, review procedures, competition, methods of procurement, cost and pricing analysis. If desired, FEMA will provide assistance on developing selection criteria for contracted tasks. All work must meet the standards requirements and certification requirements described in sections (e) and (f) of this document.

We will continue to evaluate these criteria and will further enhance them in subsequent years as necessary.

(d) *Activities.* All of the eligible activities listed below contain the following benefits for both the CTP partner and for FEMA:

- Local capabilities in hazard identification and risk assessment—the building blocks for disaster resistance—will be enhanced through FEMA technical assistance, experience, standards, and funding;
- The data, methods, and mapping used for local, regional, and state permitting processes will also be used for NFIP mapping, to the extent possible;
- Close coordination and involvement in the flood hazard mapping process will result in more efficient local floodplain management by the CTC;
- The program has the potential to interject a tailored, local focus into a national program where unique conditions may exist that necessitate special approaches to flood hazard identification.
- By incorporating local knowledge and expertise, we expect that National Flood Insurance Program flood hazard maps will be more accurate and can be updated faster than current procedures allow.

Mapping Activity Statements will support the development of flood hazard mapping or a component of the production and maintenance of flood hazard mapping. We will collaborate with the CTP on these mapping activities. We may provide technical assistance, support, and data to the CTP and in some cases funding may also be available. The following mapping activities may receive funding in Fiscal Year 20001 through a cooperative agreement with us:

Activity	Partner	Description
Refinement of Approximate Zone A Boundaries	Community/Regional State Agency	The CTP works with FEMA to perform analyses to refine Zone A boundaries. Emphasis placed on automation techniques.
Hydrologic & Hydraulic (H&H) Modeling and Floodplain Mapping.	Community/Regional State Agency	The CTP develops digital engineering data and floodplain mapping using GIS-based or traditional H&H modeling.
DFIRM Preparation	Community/Regional/State Agency	The CTP digitizes the effective FIRM into a DFIRM.
Redelineation of Detailed Flood Hazard Information Using Updated Topographic Data.	Community/Regional/State Agency	The CTP redelineates the effective flood hazard information using more up-to-date topographic data. GIS is used, where available.

While no funding will be provided to CTPs for the following mapping activities, we may provide technical assistance, support, and data to the CTP:

Activity	Partner	Description
Base Map Inventory	Regional or State Agency	The CTP performs an investigation and provides an inventory of base maps meeting FEMA's specifications for NFIP communities in the state.
Digital Base Map Data Sharing	Community/Regional/State Agency	The CTP supplies a base map for DFIRM production. The base map will comply with FEMA's minimum accuracy requirements and be distributable by FEMA to the public (hardcopy and electronic formats).
DFIRM Maintenance	Community/Regional/State Agency	The CTP assumes responsibility for long-term, periodic maintenance of the DFIRM. This can include base map and/or flood information.
Hydrologic and Hydraulic Review Agreement—*This activity is currently being considered as a pilot activity.	Community/Regional/State Agency	The CTP evaluates H&H studies prepared for flood data updates and/or 44 CFR Part 65 map revisions. The review will focus on compliance with the technical and regulatory requirements contained in FEMA's various flood mapping guidelines and specifications, the pertinent NFIP flood mapping regulations, as well as standard accepted engineering practices.
Analysis of Community Mapping Needs (to support FEMA's Mapping Needs Update Support System (MNUSS)).	Regional/State Agency	The CTP performs a detailed community-by-community investigation and assessment of every NFIP community's mapping needs, including flood data updates, map maintenance, and includes unmapped communities.

Activity	Partner	Description
Technical Standards Agreement	Community/Regional/State Agency	Adoption of specific technical standards or processes appropriate for local conditions for NFIP flood mapping purposes.

(e) *Standards.* Unless otherwise indicated in specific Mapping Activity Statements, all flood hazard identification activities will be accomplished according to the relevant portions of 44 CFR parts 59–77, as well as the technical standards contained in FEMA's *Guidelines and Specifications for Study Contractors* (FEMA 37) dated 1/95 and FEMA's *Guidelines and Specifications for Flood Map Production Coordination Contractors* dated 2/17/99, and all subsequent revision to these documents.

(f) *Certification.* All data generated under CTP Mapping Activity Statements must meet the applicable certification requirements for the identification and publication of flood hazard information in Flood Insurance Rate Map (FIRM) form as indicated in 44 CFR, part 65, Identification and Mapping of Special Hazard Areas. For those States that have adopted more stringent mapping requirements that have been sanctioned by FEMA, all Mapping Activity Statements must be reviewed, coordinated with, and concurred upon by the State and all map products must meet State certification requirements.

(g) *Evaluation Criteria.* The performance of each CTP will be evaluated upon completion of the period of performance for each Mapping Activity Statement. This evaluation will determine the adequacy of the performance by the CTP and the eligibility for future Mapping Activity Statements to be initiated. Insufficient performance by the CTP may result in cancellation of FEMA funding at any point during the period of performance for a Mapping Activity Statement. Evaluation will be based upon the following criteria:

(1) The continued maintenance, (funded/supported by the CTP), for existing and/or future processes or systems in place to support mapping or data collection activities that contribute to flood hazard identification, e.g., continued data collection for changing flood hazards and related development, continued upgrades to data collection or mapping capabilities to incorporate new technologies, preparation of multi-year mapping or data collection plans, etc.

(2) The demonstrated commitment by the CTP for existing and continued support of flood hazard identification and mapping activities conducted with and by FEMA.

(3) Adherence to timeliness and completeness of report submittal to the Regional Office.

(4) Adherence to timeliness and completeness of mapping product submittal to the Regional Office.

(5) Quality of product(s) submitted to the Regional Office.

(6) Ability to cooperate and coordinate with the FEMA Regional Office, the Technical Services Division of the Mitigation Directorate in Washington, and/or FEMA's Mapping Coordination Contractor during all phases of the Mapping Activity as needed.

(h) *Cooperating Technical Partners Regional Contacts.*

Region 1: (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont), Dean Savramis, 442 J.W. McCormack POCH, Boston, MA 02109, Telephone: (617) 223–9564, (e-mail) *dean.savramis@fema.gov.*

Region 2: (New Jersey, New York, Puerto Rico, Virgin Islands), Paul Weberg, 26 Federal Plaza, Room 1337, New York, NY 10278, (212) 225–7229, (e-mail) *paul.weberg@fema.gov.*

Region 3: (Delaware, Maryland, Pennsylvania, Virginia, West Virginia, District of Columbia), Erik Rourke, 615 Chestnut Street, 6th Floor, Philadelphia, PA 19106, (215) 931–5665, (e-mail) *erik.rourke@fema.gov.*

Region 4: (Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee), Laura Algeo, 3003 Chamblee Tucker Rd., Atlanta, GA 30341, Telephone: (770) 220–5515, (e-mail) *laura.algeo@fema.gov.*

Region 5: (Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin), Ken Hinterlong, 536 S. Clark Street, 6th Floor, Chicago, IL 60605, Telephone: (312) 408–5529, (e-mail) *ken.hinterlong@fema.gov.*

Region 6: (Arkansas, Louisiana, New Mexico, Oklahoma, and Texas), Jack Quarles, FRC 800 North Loop 288, Denton, TX 76210, Telephone: (817) 898–5156, (e-mail) *jack.quarles@fema.gov.*

Region 7: (Iowa, Kansas, Missouri, and Nebraska), Bob Franke, 2323 Grand Avenue, Suite 900, Kansas City, MO 64108, Telephone: (816) 283–7073, (e-mail) *bob.franke@fema.gov*

Region 8: (Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming), John Liou, Denver Federal Center, Bldg. 710, Box 25267, Denver, CO 80225, Telephone: (303) 235–4836, (e-mail) *john.liou@fema.gov.*

Region 9: (Arizona, California, Hawaii, Nevada, American Samoa, Guam), Les Sakumoto, Bldg. 105, Presidio of San Francisco, San Francisco, CA 94129, Telephone: (415) 923–7183, (e-mail) *leslie.sakumoto@fema.gov.*

Region 10: (Alaska, Idaho, and Oregon, Washington), Larry Basich, Federal Regional Center, 130–228th Street, Bothell, WA 98021, Telephone: (425) 487–4703, (e-mail) *lawrence.basich@fema.gov.*

Dated: June 4, 2001.

Margaret E. Lawless,

Acting Executive Associate Director for Mitigation.

[FR Doc. 01–14440 Filed 6–7–01; 8:45 am]

BILLING CODE 6718–04–U

FEDERAL EMERGENCY MANAGEMENT AGENCY

Privacy Act of 1974: Flood Map Customer Records

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice of a new system of records.

SUMMARY: In accordance with the Privacy Act of 1974 (5 U.S.C. 552a), we (FEMA) give notice that we are establishing a new system of records under the authority of the Flood Insurance Act of 1968 as amended, 42 U.S.C. 4100, et seq. That Act established the National Flood Insurance Program (NFIP), a critical component of which is the identification and mapping of the nation's floodplains to provide the data necessary for community floodplain management programs and to actuarially rate flood insurance. Pursuant to statute, we distribute conventional and digital flood map products without charge to federal, state and municipal governments. We charge all other users for our products and services. This system of records will enable us, through the NFIP Flood Map Store, to fill written, telephonic and electronic orders from these users for the various map products; to cumulate and retrieve their order information; and to disseminate new product information to them.

DATES: This new system of records takes effect July 18, 2001. We will accept public comments until July 18, 2001.

ADDRESSES: We invite your comments on this system of records. Please address to the Rules Docket Clerk, Office of the General Counsel, Federal Emergency Management Agency, Room 840, 500 C Street, SW, Washington, DC 20472; (telefax) (202)–646–4536, or (email) *rules@fema.gov.*

FOR FURTHER INFORMATION CONTACT: Eileen Leshan, FOIA/Privacy Act Specialist, Federal Emergency Management Agency, Room 840, 500 C Street, SW, Washington, DC 20472, (telephone) (202)–646–4115, (telefax) (202)–646–4536, or (email) Eileen.Leshan@fema.gov.

SUPPLEMENTARY INFORMATION: We published a notice of Fee Schedule for Processing Requests for Map Changes, for Flood Insurance Study Backup Data, and for National Flood Insurance Program Map and Insurance Products on May 3, 2000, 65 FR 25726.

The new systems of records report, required by 5 U.S.C. 552a(r), is being simultaneously submitted to the Committee on Government Operations of the House of Representatives, the Committee on Governmental Affairs of the Senate, and the Office of Management and Budget, pursuant to Appendix 1 to OMB Circular A–130.

Accordingly, we add FEMA/MIT–7 of the FEMA Privacy Act systems of records to read as follows:

FEMA/MIT–7

SYSTEM NAME:

Flood Map Customer Records.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Offices of the map sales servicing agent under contract with the Federal Emergency Management Agency, Washington, DC 20472.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who purchase flood-related map products or whose requests have been forwarded to the map sales servicing contractor. The system also contains records concerning individuals in their entrepreneurial capacity, corporations and other business entities whose records are not subject to the Privacy Act.

CATEGORIES OF RECORDS IN THE SYSTEM:

Electronic database contains name, address, phone number, credit card number and expiration date, account number, order number, product requested and appropriate accounting entries. Information from paper orders is entered into database and paper orders are destroyed after three months.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The National Flood Insurance Act of 1968, as amended, and the Flood Disaster Protection Act of 1973, as amended, 42 U.S.C. 4001 *et seq.,* 5 U.S.C 301, Reorganization Plan No. 3 of 1978 and E.O. 12127.

PURPOSE(S):

The primary use of the records is for reference by the map sales servicing contractor in processing customer inquiries, orders and complaints. The contractor must comply with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a.

ROUTINE USE OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to use of the records by a contractor engaged to assist the Agency in performing a contract service related to this system of records and who requires access to the records in order to perform the activity, disclosure of records outside FEMA or the map sales contractor may be made to:

(1) The U.S. Department of Justice or a court or adjudicative body when (a) the United States, FEMA, a component of FEMA, the map sales servicing contractor or, when represented by the Government, an employee of FEMA is a party to litigation or anticipated litigation or has an interest in such litigation, and (b) FEMA determines that the disclosure is relevant or necessary to the litigation and is compatible with the purpose for which the records were compiled;

(2) An appropriate Federal, State, local or foreign agency responsible for investigating, prosecuting, enforcing, or implementing a statute, regulation, rule or order, where FEMA becomes aware of an indication of a violation or potential violation of civil or criminal law or regulation;

(3) A Congressional office when disclosure from the record of an individual is necessary to respond to an inquiry the individual has made to the Congressional office.

(4) To the National Archives and Records Administration for the purpose of conducting records management studies under the authority of 44 U.S.C. 2904 and 2906.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

Disclosures under 5 U.S.C. 552a(b)(12): Disclosures may be made from this system to a ''consumer reporting agency'' as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f)) or the Federal Claims Collection Act of 1966 (31 U.S.C. 3701(a)(3)).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records in this system are temporarily stored in a database (i.e., on computer hard drives and computer disks) and subsequently archived in magnetic media. Paper printouts of these data may be made as necessary. Paper copies of customer orders are stored in manual files and destroyed after three months.

RETRIEVABILITY:

Retrievable by name of organization, individual, account number or order number.

SAFEGUARDS:

Records are maintained by the FEMA map sales servicing contractor in areas occupied by contractor personnel during working hours with the building locked and secured by alarm during off hours. In addition, the risk of unauthorized access to or disclosure of personal data in the proposed system is minimized through the use of passwords and security profiles and permissions to enter the computer system in which data are maintained. The computerized records and paper records are stored in secured areas that are accessible only to employees who require the information in performing their official duties. Paper documents are stored either in lockable file cabinets within locked rooms or in otherwise secured areas. All personnel with access to records are screened, cleared and trained.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the retention and disposition schedules set forth in FEMA Manual 5400 (August 1989), ''Records Management: Disposition, Retention and Files Plan.'' Means of disposal are appropriate to the storage medium (e.g., erasure of disks, shredding of paper records, etc.).

SYSTEM MANAGER AND ADDRESS:

Project Officer, Map Service Center, Technical Services Division, Mitigation Directorate, Federal Emergency Management Agency, Washington, DC 20472.

NOTIFICATION AND RECORDS ACCESS PROCEDURES:

Inquires should be addressed to the System Manager following procedures set forth at 44 CFR part 6, subpart C.

CONTESTING RECORDS PROCEDURE:

A petition for amendment should be addressed to the System Manager and must meet the content requirements set forth at 44 CFR part 6, subpart D.

RECORD SOURCE CATEGORIES:

Customers on whom record(s) are maintained.

SYSTEM EXEMPTIONS FROM CERTAIN PROVISIONS OF THE ACT.

None.

Dated: June 4, 2001.

Margaret Lawless,

Acting Executive Associate Director for Mitigation

[FR Doc. 01–14441 Filed 6–7–01; 8:45 am]

BILLING CODE 6718–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Public Health and Science; Announcement of Anticipated Availability of Funds for Family Planning Services Grants

AGENCY: Office of Population Affairs, OPHS, HHS.

ACTION: Notice.

SUMMARY: The Office of Population Affairs (OPA) announces the anticipated availability of funds for Fiscal Year (FY) 2002 family planning services grants under the authority of Title X of the Public Health Service Act and solicits applications for competing grants awards to serve the areas and/or populations set out below. Only applications which propose to serve the populations and/or areas listed in Table I will be accepted for review and possible funding. A description of Title X Family Planning Program can be found at OMB Catalog of Federal Domestic Assistance 93.217.

DATES: Application and funding dates vary. See **SUPPLEMENTARY INFORMATION** below.

ADDRESSES: Applications for grants in DHHS Regions I–X should be sent to: Office of Grants Management for Family Planning Services, 1301 Young Street, Suite 766, Dallas, TX 75202.

FOR FURTHER INFORMATION CONTACT:

Administrative and Budgetary Requirements

Regions I–X: Maudeen Pickett, Office of Grants Management for Family Planning Services, 214–767–3401,

Program Requirements

Regional Program Consultants for Family Planning: Region I (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont)—Suzanne Theroux, 617–565–1063; Region II (New Jersey, New York, Puerto Rico, Virgin Islands)—Lucille Katz, 212–264–3935; Region III (Delaware, Washington, DC, Maryland, Pennsylvania, Virginia, West Virginia)—Louis Belmonte, 215–861–4641; Region IV (Kentucky, Mississippi, North Carolina, Tennessee, Alabama, Florida, Georgia, South Carolina)—Cristino Rodriguez, 404–562–7900; Region V (Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin)—Janice Ely, 312–886–3864; Region VI (Arkansas, Louisiana, New Mexico, Oklahoma, Texas)—Evelyn Glass, 214–767–3088; Region VII (Iowa, Kansas, Missouri, Nebraska)—Elizabeth Curtis, 816–426–2924; Region VIII (Colorado Montana, North Dakota, South Dakota, Utah, Wyoming)—Christy Crosser, 303–884–7849 or Jil Leslie, 303–844–7856; Region IX (Arizona, California, Hawaii, Nevada, Commonwealth of the Northern Mariana Islands, American Samoa, Guam, Republic of Palau, Federal States of Micronesia, Republic of the Marshall Islands)—Nadine Simons, 415–437–7984; Region X (Alaska, Idaho, Oregon, Washington)—Janet Wildeboor, 206–615–2776.

SUPPLEMENTARY INFORMATION:

Definitions

For the purposes of this announcement, the following definitions apply:

Application/Proposal (used interchangeably)—a request for financial support of a project submitted to OPA on specified forms and in accordance with instructions provided.

Grant—financial assistance in the form of money, awarded by the Federal Government to an eligible recipient (a *grantee* or *recipient* is the entity that receives a Federal grant and assumes the legal and financial responsibility and accountability for the awarded funds and performance of activities approved for funding).

Project—those activities described in the grant application and supported under the approved budget.

Eligible Applicants—any public or private nonprofit entity located in a state (which includes the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, the U.S. Outlying Islands [Midway, Wake *et al.*], the Marshall Islands, the Federated States of Micronesia and the Republic of Palau) is eligible to apply for a Title X family planning services grant.

Title X of the Public Health Service Act, 42 U.S.C. 300, *et seq.* authorizes the Secretary of Health and Human Services (HHS) to award grants to public or private nonprofit organizations to establish and operate voluntary family planning projects. Projects must offer a broad range of acceptable and effective medically approved family planning methods and services. The statute requires that, to the extent practicable, Title X service providers should encourage family participation. Title X family planning funds may not be used in programs where abortion is a method of family planning.

Requirements regarding the provision of family planning services under title X can be found in the Title X statute, the implementing regulations which govern project grants for family planning services (42 CFR part 59, Subpart A), and the ''Program Guidelines for Project Grants for Family Planning Service,'' published in January 2001. A copy of the Program Guidelines may be obtained by contacting the Office of Grants Management for Family Planning Services (at the address above), or downloaded from the Office of Population Affairs web site at *www.hhs.gov/opa/grants.html.* All Title X requirements—including those derived from the statute, the regulations, and the Program Guidelines—apply to all activities funded under this announcement. (For example, projects must meet the regulatory requirements set out at 42 CFR 59.5 regarding charges to clients, and the funding criteria set out at 42 CFR 59.7 apply to all applicants under this announcement. As stipulated in § 59.7(b) ''* * * No grant may be made for less than 90 percent of the project's costs, as so estimated, unless the grant is to be made for a project that was supported, under section 1001, for less than 90 percent of its costs in fiscal year 1975. In that case, the grant shall be not be for less than the percentage of costs covered by the grant in fiscal year 1975.'' Furthermore, § 59.7(c) stipulates that ''No grant may be made for an amount equal to 100 percent for the project's estimated costs.'')

The anticipated FY 2002 appropriation for the Title X Family Planning program is approximately $253.9 million. Of this amount, approximately $11.4 million will be

made available for competing grant awards. A minimum of ten grants will be awarded. (See Table I for approximate amount of awards.) The remaining funds will be used for continued support of grants and activities which are not competitive in FY 2002. This program announcement is subject to the appropriation of funds and is a contingency action taken to ensure that, should funds become available for this purpose, applications can be processed in an orderly fashion, and funds can be awarded in a timely fashion.

This notice announces the anticipated availability of funds for competitive family planning service grants in 10 states. Competing grant applications are invited for the following areas (please note, in order to maximize access to family planning services, one or more grants may be awarded for each area listed):

TABLE I

Populations/areas to be served	Approximate funding available	Application due date	Approx. grant funding date
Region I			
New Hampshire	$1,100,000	09–01–01	01–01–02
Rhode Island	710,000	09–01–01	01–01–02
Massachusetts	4,300,000	09–01–01	01–01–02
Region II			
No competitive grants available in FY 2002.			
Region III			
Washington, D.C.	930,000	09–01–01	01–01–02
Region IV			
No competitive grants available in FY 2002.			
Region V			
No competitive grants available in FY 2002.			
Region VI			
No competitive grants available in FY 2002.			
Region VII			
No competitive grants available in FY 2002.			
Region VIII			
Wyoming	594,000	09–01–01	01–01–02
South Dakota	650,000	03–01–02	07–01–02
Migrant workers in the Greely, CO area	150,000	06–01–02	09–30–02
Region IX			
Gila River Indian	239,000	03–01–02	07–01–02
Region X			
Oregon	2,300,000	03–01–02	07–01–02
Alaska—Anchorage and surrounding suburbs; Homer; Sitka; Soldotna; Mat-Su Burrow	425,000	03–01–02	07–01–02

Incorporation Program Priorities and Key Issues for Family Planning

The following priorities represent overarching goals for the Title X program. The application should describe how the proposed project will address each priority:

(1) Assurance of continued high quality clinical family planning and reproductive health services that will improve the overall health of individuals;

(2) Increasing access to family planning and reproductive health services by partnering with public health providers and other community-based organizations that have related interests and that work with similar populations;

(3) Emphasis on clinical services for hard-to-reach populations, e.g., uninsured or under-insured women, males in need of clinical services, adolescents, substance abusers, migrant workers, and the homeless; and

(4) Assuring access to comprehensive family planning and reproductive health clinical services, including provision of highly effective contraceptive methods; breast and cervical cancer screening and prevention; and STD and HIV prevention education, counseling, and testing.

In addition, the following key issues impact the current and future delivery of family planning services, and should be considered when developing the proposal:

(1) The U.S. Department of Health and Human Services' priorities and Healthy People 2010 objectives (*http://www.health.gov/healthypeople*);

(2) Medicaid waivers, managed care, State Children's Health Insurance Program (SCHIP), Temporary Assistance to Needy Families (TANF), Title XX of the Social Services Block Grant, state support, and private insurance coverage related to family planning and reproductive health services;

(3) Increased need for current and reliable data to use in program planning and monitoring program performance;

(4) Use of electronic technologies in program activities and management;

(5) Use of science-based information to support program activities; and

(6) Legislative mandates such as counseling teens on involving families and avoiding coercive sexual relationships, and program compliance with state reporting laws regarding sexual abuse.

Application Requirements

Application kits (including the application form, PHS 5161–1, Revised 7/00, OMB Approval No. 0937–0189) may be obtained by contacting the Office of Grants Management for Family Planning Services (at the address listed above), or downloaded from the Office of Population Affairs web site at www.hhs.gov/opa/grants.html. Completed applications must be submitted to the Office of Grants Management for Family Planning Services.

Applications will be considered as meeting the deadline if they are

postmarked on or before the application due date (listed for all areas in Table I). A legibly dated receipt from a commercial carrier or U.S. Postal Service will be accepted in lieu of a postmark. Private metered postmarks will not be accepted as proof of timely mailing. All hand delivered applications must be received between the hours of 8:30 a.m. and 5 p.m. on or before the application due date. Applications which do not meet the deadline will be considered late and will not be accepted for review. Also, applications which do not meet the requirements of this program announcement and/or the applicable regulatory requirements at 42 CFR part 59, Subpart A, will not be accepted for review. Any application which is not accepted will be returned to the applicant. Applications will not be accepted by fax or e-mail. The submission deadlines will not be extended.

Applications must address all applicable regulatory requirements [59.7(a)]. The information collections (reporting requirements) contained in this notice have been approved by the Office of Management and Budget and assigned control number 0937–0189.

The Office of Public Health and Science (OPHS) requires all grant recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. This is consistent with the OPHS mission to protect and advance the physical and mental health of the American people.

Application Review and Evaluation

Each regional office is responsible for evaluating applications and setting funding levels according to criteria in 42 CFR 59.7.

Applications will be evaluated based on the following criteria (42 CFR 59.7(a)):

(1) The degree to which the project plan adequately provides for the requirements set forth in the Title X regulations (20 points);

(2) The extent to which family planning services are needed locally (20 points);

(3) The number of patients, and, in particular, the number of low-income patients to be served (15 points);

(4) The adequacy of the applicant's facilities and staff (15 points);

(5) The capacity of the applicant to make rapid and effective use of the Federal assistance (10 points);

(6) The relative availability of non-Federal resources within the community to be served and the degree to which those resources are committed to the project (10 points); and

(7) The relative need of the applicant (10 points).

Review Under Executive Order 12372

Applicants under this announcement are subject to the review requirements of Executive Order 12372, Intergovernmental Review of Department of Health and Human Services Programs and Activities, as implemented by 45 CFR part 100. As soon as possible, the applicant should discuss the project with the State Single Point of Contact (SPOC) for each State to be served. The application kit contains the currently available listing of the SPOCs which have elected to be informed of the submission of applications. For those States not listed, further inquiries regarding the review process designed by their state should be made to the Governor's office of the pertinent State. In order to be considered, the Grants Management Office must receive State Single Point of Contact comments not later than 30 days prior to the grant funding date.

Grant Awards

When final funding decisions have been made, each applicant will be notified by letter of the outcome of its application. Applicant projects selected for funding will receive a Notice of Grant Award, the official document notifying an applicant that a project application has been approved for funding. This document specifies to the grantee the amount of money awarded, the purposes of the grant, the length of the project period, and terms and conditions of the grant award.

Grant projects are generally approved for 3 to 5 years. An annual non-competitive continuation application is required to obtain continued support. Application kits for non-competing grants will automatically be sent to the project director indicated on the Notice of Grant Award. Continuation awards are subject to factors such as the availability of funds and satisfactory progress of the project. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the Federal Government.

Mireille B. Kanda,

Acting Director, Office of Population Affairs.

[FR Doc. 01–14457 Filed 6–7–01; 8:45 am]

BILLING CODE 4150–34–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 01117]

Controlling Asthma in American Cities Project (CAACP); Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2001 funds for a cooperative agreement program for Controlling Asthma in American Cities Project (CAACP). This program addresses the ''Healthy People 2010'' focus areas of Respiratory Diseases, Environmental Health, and Access to Quality Health Services.

The purpose of the CAACP is to utilize past successes and other innovative approaches to improve overall asthma management in order to decrease asthma-related morbidity among children (0–18 years) in a defined urban population with a large and unmet asthma control need.

No research may be conducted as part of this cooperative agreement.

B. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations, or local chapters of national advocacy associations that deal primarily or largely with asthma. This includes universities, hospitals, and city or county public health departments. In addition, applicants must have direct access to the target population(s) and be located in the community that will be served by the proposed interventions.

To be an eligible applicant, the total population of the communities to be served must be between 300,000 and 700,000 people. Note: For a metropolitan area of greater than 700,000 people, the population requirement may be met by proposing to work in selected communities within the area. This information must be submitted in the abstract of the application. The documentation accepted to verify eligibility may be based on the most current census data available. If this information is not included, the application will be determined as non-responsive and will be returned to the applicant without review.

Note: Title 2 of the United States Code, Chapter 26, Section 1611 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 $3,000,000 is available in FY 2001 to fund approximately four to six planning projects (Phase I). It is expected that the average award will be approximately $450,000, ranging from $300,000 to $500,000.

Applications that request more than the maximum level of funding ($500,000) will be determined non-responsive to this announcement and returned to the applicant.

It is expected that the awards will begin on or about September 30, 2001, and will be made for a 12-month budget period within a project period of two years. Funding estimates may change.

Depending on the availability of funds, a new competitive announcement, limited to Phase I awardees, may be announced in the future that will implement the intervention activities. It is expected that the number of Phase II (Intervention) recipients awarded will be approximately three.

Use of Funds

Budgeted funds may not be used to fund asthma surveillance, except those directly related to the evaluation of the CAACP project.

Funding Preferences

Funding preference may include: (1) geographic balance; (2) minority populations with a disproportionate asthma burden, and (3) a balance of proposed intervention strategies.

D. Programmatic Interests

Intervention Ideas/Concepts

Decreasing asthma-related morbidity in a defined population will require a comprehensive and innovative approach, based on current scientific knowledge and an in-depth understanding of the communities to be focused upon, to improving asthma medical care and self-care within families with a child with asthma. Intervention ideas should be based on asthma care concepts which have been analyzed through the peer-review process and shown to be effective in improving asthma control.

Collaboration

Success of the planning phase and intervention phase of the proposed project will depend heavily on the ability of the grantee to form or work through an effective consortium. The applicant must have the experience, ability, and vision to lead such an effort through the active coordination and participation of the most important and influential health and health care leaders in their communities.

E. 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. Develop a plan that includes time-phased intervention objectives, protocols, relevant policy initiatives, and evaluation plans that address the asthma objective(s) in Healthy People 2010.

b. Collect baseline asthma data in the communities to be served by the project. The data should include measures of asthma morbidity and actual asthma care representative of the entire study population before the intervention phase begins.

c. Develop or enhance an asthma consortium that includes, among others, public, private, and academic partners and community based organizations (CBO's) that can be sustained for subsequent research and program development.

d. Serve as a resource for other asthma projects.

e. Disseminate relevant findings.

2. CDC Activities

a. Provide technical assistance, as requested, in the development of intervention protocols, evaluation plans, communication issues, policy issues, and the interpretation of the scientific literature related to asthma management and control.

b. Provide liaison among grantees and potential sources of information and assistance.

c. Coordinate activities among sites, when appropriate.

d. Convene meetings among collaborators to discuss findings and improve outcomes.

F. Content

Letter of Intent

A one-page non-binding letter of intent (LOI) is requested to enable CDC to determine the level of interest in this announcement. The LOI should provide a brief description of the proposed project and identify the principle investigator, organizations actively involved in the proposed project, and the address and telephone number for key contacts.

Applications

Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The narrative should be no more than 25 double-spaces, printed on one side, with one inch margins and unreduced font. The applicant should provide a detailed description of activities. In addition to the application forms, the application must contain the following in this order:

1. Table of Contents

A table of contents that provides page numbers for each of the following sections should be included.

2. Abstract

A one-page, single-spaced abstract must be submitted with the application. The heading should include the title of the cooperative agreement, project title, organization's name and address, and the principle investigator's name and telephone number. The abstract should briefly summarize the program for which funds are requested, the activities to be undertaken, and the applicant's organizational structure. The abstract must also contain a verification that the total population of the communities to be served will be between 300,000 and 700,000 people.

3. Project Narrative

The narrative must contain the following sections:

a. Time-framed Objectives. Specific, measurable, and time-framed objectives should be developed based on the project narrative. Creation of a two year time-line for meeting these objectives is expected.

b. Understanding of the medical and psychological literature regarding asthma control techniques and past intervention attempts. Emphasis should be placed on population-based methods of asthma control.

c. A brief description of the community or segment of city (or city as a whole) identified as the population to be served by this project. This should include basic demographic, socio-economic, and health information (*i.e.,* number of primary care physicians, asthma specialists, hospitals, public clinics in these areas or accessible to the people living in these areas).

d. Understanding of the asthma care and control issues facing the community selected to be served by this project. Specific documentation of unmet needs, such as the proportion of children uninsured, measures of asthma morbidity, and information on the quality of asthma care, if available, should be described here. Why these

communities or areas of the city were chosen for project inclusion should also be briefly explained.

e. Collaboration within the consortium. A description of the important health care leaders and institutions in your city and how and in what way you plan to involve them in the project activities must be included. Using the list of potential collaborators (See addendum 2, V) as a template, you may wish to explain what role each of these organizations play in the asthma control plans of your city and why they will or will not be included/emphasized in the project. The expected financial arrangements between applicant and collaborators should be described here. A letter from representatives of each of the major collaborators in the consortium describing how they plan to actively participate and add to the project should be included in the application.

f. Initial intervention ideas. A description of your initial intervention ideas should be elaborated upon, including their potential feasibility and benefit in controlling asthma symptoms or unscheduled visits.

g. Process of creating comprehensive intervention strategies (including protocols) from the initial intervention ideas. The process conceived to take place over the two year planning period in order to be ready for the intervention period should be described in this section.

h. Plans for an evaluation of the two year planning period (phase I). The project evaluation should address the experiences and lessons of such city-wide collaboration efforts, community assessment and information sharing, protocol development, and other planning phase activities. Evaluation measures, whether quantitative or qualitative, should be described.

i. A detailed plan to obtain a comprehensive baseline assessment of asthma-related morbidity and care practices in the communities involved in this project. A critical description of how this baseline assessment will be used to ultimately evaluate the intervention activities of the project (i.e., changes in population-based measures of asthma morbidity, asthma care, asthma education, access to primary care, or other issues important to asthma control addressed in the intervention strategies) must be included. Evaluation measures, whether quantitative or qualitative, should be described.

j. A description of those activities conducted by the applicant and/or the applicant's organization related to, but not supported by the cooperative agreement.

4. Identification of Project Personnel

Include a biographical sketch (*i.e.,* one page summary or abbreviated curriculum vitae) for the principal investigator and/or project coordinator and other key personnel. Describe the overall personnel capabilities of the applicant's organization in relation to the potential project needs. To the extent possible, list of all the proposed project staff regardless of their funding source. The list should include title, qualifications, relevant experience, percentage of time each will devote to the project, as well as that portion of the salary to be paid by the cooperative agreement.

5. Facilities and Equipment

Describe the access and availability of any facilities and equipment necessary to carry out the planning phase project.

6. Budget and Budget Justification

Provide a detailed budget which indicates the anticipated costs for personnel, fringe benefits, travel, supplies, contractual, consultants, equipment, indirect and other items. The required detailed budget is not considered to be part of the program narrative.

G. Application Submission and Deadline

Submit the original and two copies of PHS 5161–1 (OMB Number 0920–0428) on or before August 10, 2001, 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:

1. Received on or before the deadline date; or

2. 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 1. or 2. above will be returned to the applicant.

H. Evaluation Criteria

Each application will be evaluated individually against the following criteria by an independent panel of experts appointed by CDC:

1. Goals and Objectives: (10 percent)

The extent to which the applicant has described a plan to make use of this two year planning period. This should include: Details in explaining how this time period will be used to create or strengthen a city-wide asthma consortium, design and fine tune effective intervention strategies, begin efforts to improve quality of asthma care locally, and initiate the processes of community empowerment/change that will be focused on.

2. Background: (10 percent)

The extent to which the proposal addresses the critical evaluation of existing asthma control literature, and the identification of the asthma care gaps and issues in the specific communities designated to be the focus of this intervention project will be evaluated. Such an evaluation of the asthma care gaps in the proposed community could include the proportion of children uninsured, measures of asthma morbidity, and information on the quality of asthma care.

3. Asthma Control Intervention Ideas: (20 percent)

a. The extent to which the application describes a plan to improve asthma care in the specific communities selected by the applicant will be evaluated. This includes how well conceived the intervention concepts are in terms of practicality, effectiveness (likelihood to change asthma morbidity), inclusiveness (whether all children with asthma in the study area will have access to the interventions), comprehensiveness (providing multiple ways to address asthma control problems), originality, and level of detail included in proposal (*i.e.,* appropriate use of examples to strengthen ideas in the proposal).

b. The extent to which the proposed processes to improve and expand these intervention ideas during the planning phase are described.

4. Collaborative Effort: (25 percent)

The extent to which the applicant and the consortium have the experience, ability, and vision to succeed in an effort to reduce the asthma burden in the proposed community through the participation of the most important and influential health care and civic leaders in the community. This includes the specific ways in which the consortium will operate, a history of successful operation of the consortium in that city or community, or other evidence that a proposed collaboration would be effective, and detailed plans to ensure

active collaboration of all project participants during the entire period of this project.

5. Principal Investigator and Staff: (20 percent)

a. The extent to which the qualifications and the proposed project time allocation of the principal investigator are described. A principal investigator who has conducted, evaluated, and published asthma research in peer-reviewed journals, and has specific authority and responsibility to carry out the proposed project is expected.

b. The extent to which a description of additional staff to be assigned to this project, their qualifications, the proposed project time allocation, and the role of the proposed staff is linked to program objectives.

c. The extent to which the facilities and other resources that would define the applicant's capacity to accomplish the project are described.

6. Evaluation Plans: (15 percent)

The extent to which the applicant has described a realistic and comprehensive plan to accurately measure changes in population-based asthma morbidity, specific asthma care, asthma education or other significant intervention strategies over time using qualitative and quantitative methods will be scored. The ability of the applicant to begin the baseline data collection during the planning phase and to conduct a process evaluation of the planning period will be part of this evaluation score.

7. Budget: (not scored)

The extent to which the budget is clearly detailed, justified, and appropriate for activities proposed.

I. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Semi-annual progress reports.
2. Financial status report, no more than 90 days after the end of the budget period.
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–7 Executive Order 12372 Review

AR–8 Public Health System Reporting 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–15 Proof of Non-Profit Status

J. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 301 of the Public Health Service Act, [42 U.S.C. section 241 and 247b], as amended. The Catalog of Federal Domestic Assistance number is 93.283.

K. 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 Program Announcement number of interest.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Sonia Rowell, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, MS E–13, Atlanta, GA 30341–4146. Telephone number: 770–488–2724, Email address: svp1@cdc.gov.

For program technical assistance, contact: Michael Friedman, M.D., Air Pollution and Respiratory Health Branch, National Center for Environmental Health, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., MS E–17, Atlanta, Georgia 30333, Telephone number: 404–639–2520, Email address: mff7@cdc.gov.

Signed: June 4, 2001.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–14447 Filed 6–7–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee to the Director, Centers for Disease Control and Prevention: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following Advisory Committee meeting.

Name: Advisory Committee to the Director, CDC.

Time and Date: 8:30 a.m.–4 p.m., July 13, 2001.

Place: The Sheraton Colony Square Hotel, 188 14th Street, NE., Atlanta, Georgia 30361.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Purpose: The committee will anticipate, identify, and propose solutions to strategic and broad issues facing CDC.

Matters to be Discussed: Agenda items will include updates from Dr. Jeffrey P. Koplan, M.D., M.P.H., Director, CDC regarding the current CDC Director's priorities with discussions of program activities including updates on CDC scientific and programmatic activities.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Kathy Cahill, Executive Secretary, Advisory Committee to the Director, CDC, 1600 Clifton Road, NE, M/S D–24, Atlanta, Georgia 30333. Telephone 404/639–7060.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: June 4, 2001.

John Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 01–14449 Filed 6–7–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Meeting; Office of the Director, Centers for Disease Control and Prevention (CDC), Announces the Following Meeting

NAME: Guide to Community Preventive Services (GCPS) Task Force Meeting.

TIMES AND DATES: 9 a.m.–6 p.m., June 13, 2001. 9 a.m.–4 p.m., June 14, 2001.

PLACE: The Old Courthouse on the Square, 101 East Court Square, Decatur, Georgia 30030, telephone (404) 373–1088.

STATUS: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

PURPOSE: The mission of the Task Force is to develop and publish a Guide to Community Preventive Services, which is based on the best available scientific evidence and current expertise regarding essential public health services and what works in the delivery of those services.

MATTERS TO BE DISCUSSED: Agenda items include: presentation of recommendations for approval for the following chapters: Cancer, Physical Activity, Tobacco, Vaccine Preventive Diseases and Violence Prevention; presentation of the dissemination plan; and general updates on Methods and the Clinical Guide.

Agenda items are subject to change as priorities dictate.

CONTACT PERSON FOR ADDITIONAL INFORMATION: Stephanie Zaza, M.D., M.P.H., Chief, Community Guide Branch, Division of Prevention Research and Analytic Methods, Epidemiology Program Office, CDC, 4770 Buford Highway, M/S K–73, Atlanta, Georgia 30341, telephone 770/488–8189. Persons interested in reserving a space for this meeting should call 770/488–8189 by close of business on June 11, 2001.

The Director, Management Analysis and Services office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: June 4, 2001.

John Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 01–14448 Filed 6–7–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB review; Comment request

Title: Voluntary Surveys of Program Partners to Implement Executive Order.

OMB No.: 0980–0266.

Description: Description: Under the provisions of the Federal Paperwork Reduction Act of 1995 (Pub. L. 104–13), the Administration for Children and Families (ACF) is requesting clearance for instruments to implement Executive Order 12862 within the ACF. The purpose of the data collection is to obtain customer satisfaction information from those entities who are funded to be our partners in the delivery of services to the American public. ACF partners are those entities that receive funding to deliver services or assistance from ACF programs. Examples of partners are States and local governments, territories, service providers, Indian Tribal organizations, grantees, researchers, or other intermediaries serving target populations identified by and funded directly or indirectly by ACF. The surveys will obtain information about how well ACF is meeting the needs or our partners in operating the ACF programs.

Respondents: State, Local, Tribal Governments or Not-for Profit institutions.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
In-depth Interview	476	3.16	.33	496
Estimated Total Annual Burden Hours				496

Additional Informqation: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACE.

Dated: June 1, 2001.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 01–14456 Filed 6–7–01; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Endocrinologic and Metabolic Drugs Advisory Committe; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Endocrinologic and Metabolic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 26 and 27, 2001, 8 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballrooms, 8120 Wisconsin Ave., Bethesda, MD.

Contact: Kathleen Reedy or LaNise Giles, Center for Drug Evaluation and Research (HFD–21), Food and Drug

Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX 301–827–6776, or e-mail: reedyk@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12536. Please call the Information Line for up-to-date information on this meeting.

Agenda: On July 26, 2001, the committee will discuss new drug application (NDA) 21–332, Symlin™ (pramlintide acetate, Amylin Pharmaceuticals, Inc.) as an adjunctive therapy to insulin to improve glycemic and metabolic control in patients with type 1 or type 2 diabetes mellitus alone or in combination with oral hypoglycemic agents. On July 27, 2001, the committee will discuss NDA 21–318, Fortéo™ (teriparatide injection, rDNA origin, Eli Lilly and Co.) for the treatment of osteoporosis in men and in postmenopausal women.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 20, 2001. Oral presentations from the public will be scheduled between approximately 11 a.m. and 11:30 a.m. each day. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 20, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 31, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–14410 Filed 6–7–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1194–N]

Medicare Program; Meeting of the Practicing Physicians Advisory Council on June 25, 2001

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the Practicing Physicians Advisory Council. This meeting is open to the public.

DATES: The meeting is scheduled for June 25, 2001, from 8:30 a.m. until 5 p.m., e.d.t.

ADDRESSES: The meeting will be held in Room 505A, 5th Floor, Hubert H. Humphrey, 200 Independence Avenue, SW., Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Paul Rudolf, M.D., J.D., Executive Director, Practicing Physicians Advisory Council, Room 435–H, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, (202) 690–7874. News media representatives should contact the HCFA Press Office, (202) 690–6145. Please refer to the HCFA Advisory Committees Information Line (1–877–449–5659 toll free)/(410 786–9379 local) or the internet (*http://www.hcfa.gov/fac*) for additional information and updates on committee activities.

SUPPLEMENTARY INFORMATION: The Secretary of the Department of Health and Human Services (the Secretary) is mandated by section 1868 of the Social Security Act to appoint a Practicing Physicians Advisory Council (the Council) based on nominations submitted by medical organizations representing physicians. The Council meets quarterly to discuss certain proposed changes in regulations and carrier manual instructions related to physicians' services, as identified by the Secretary. To the extent feasible and consistent with statutory deadlines, the consultation must occur before publication of the proposed changes. The Council submits an annual report on its recommendations to the Secretary and the Administrator of the Health Care Financing Administration not later than December 31 of each year.

The Council consists of 15 physicians, each of whom has submitted at least 250 claims for physicians' services under Medicare or Medicaid in the previous year. Members of the Council include both participating and nonparticipating physicians, and physicians practicing in rural and underserved urban areas. At least 11 members must be doctors of medicine or osteopathy authorized to practice medicine and surgery by the States in which they practice. Members have been invited to serve for overlapping 4-year terms. In accordance with section 14 of the Federal Advisory Committee Act, this Council automatically terminates two years after its date of establishment, unless the Council is renewed before the termination date by appropriate agency action. Therefore, terms of more than two years for members are contingent upon the renewal.

The Council held its first meeting on May 11, 1992.

The current members are: Jerold M. Aronson, M.D.; Richard Bronfman, D.P.M.; Joseph Heyman, M.D.; Sandral Hullett, M.D.; Stephen A. Imbeau, M.D.; Angelyn L. Moultrie, D.O.; Derrick K. Latos, M.D. (pending re-appointment); Dale Lervick, O.D.; Sandra B. Reed, M.D.; Amilu Rothhammer, M.D.; Victor Vela, M.D.; and Kenneth M. Viste, Jr., M.D.; and Douglas L. Wood, M.D. The Council chairperson is pending selection.

The agenda will provide for discussion and comment on the following topics:

- Inputs and insights on the draft instructions to implement Advance Beneficiary Notices.
- Physician Regulatory Issues Team (PRIT) update.
- Evaluation and Management Documentation Guidelines (update and discussion on medical review form).
- Physician Participation in Evaluation and Management Guidelines Pilot Studies (How to address issues of miscoding and medical review in the studies).
- Contractor Oversight Issues (provider education, customer service, medical review, and contractor performance evaluation).

For additional information and clarification on the topics listed, call the contact person in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Individual physicians or medical organizations that represent physicians and who wish to be scheduled to make 5-minute oral presentations on agenda issues should contact the Executive Director by 12 noon, June 15, 2001. Testimony is limited to the listed agenda issues only. The number of oral presentations may be limited by the time available. A written copy of the presenter's oral remarks should be submitted to the Executive Director no later than 12 noon, June 18, 2001, for distribution to Council members for review prior to the meeting. Physicians and organizations not scheduled to speak may also submit written comments to the Executive Director and Council members. The meeting is open to the public, but attendance is limited to the space available. Individuals requiring sign language interpretation for the hearing impaired or other special accommodation should contact John

Lanigan (202) 690–7418 at least 10 days before the meeting.

(Section 1868 of the Social Security Act (42 U.S.C. 1395ee) and section 10(a) of Public Law 92–463 (5 U.S.C. App. 2, section 10(a))

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 6, 2001.

Thomas A. Scully,

Administrator, Health Care Financing Administration.

[FR Doc. 01–14595 Filed 6–7–01; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

State Grants for Traumatic Brain Injury

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that about $1.2 million in fiscal year (FY) 2001 funds is available for up to 14 State Grants for Traumatic Brain Injury (TBI) awards. Grant programs for TBI provide health and other services for people who have sustained a traumatic brain injury. Awards will be made in two categories—Planning Grants, to assist States in developing the infrastructure needed to implement a State TBI program; and a new category of Post Demonstration Grants for States which have successfully completed a TBI Implementation Grant. All grants will be made under the program authority of the Public Health Service Act, Title XII, Section 1252 (42 U.S.C. 300d–52), as amended, and will be administered by the Maternal and Child Health Bureau (MCHB), HRSA. Awards for TBI Planning Grants (CFDA #93.234B) may be approved for up to two years, and range from $50,000 to $75,000. Awards for TBI Post Demonstration Grants (CFDA #93.234C) are available for only one year, in amounts up to $100,000. Funding for these grant categories beyond FY 2001 is contingent upon the availability of funds.

DATES: Entities which intend to submit an application for this grant program are expected to notify MCHB's Division of their intent by June 18, 2001. The deadline for receipt of applications is July 16, 2001. Applications will be considered ''on time'' if they are either received on or before the deadline date or postmarked on or before the deadline date. The projected award date is September 29, 2001.

ADDRESSES: To receive a complete application kit, applicants may telephone the HRSA Grants Application Center at 1–877–477–2123 (1–877–HRSA–123) beginning June 4, 2001, or register on-line at: *http://www.hrsa.gov/_order3.htm* directly. The Traumatic Brain Injury State Grant Program uses the standard Form PHS 5161–1 (rev. 7/00) for applications (approved under OMB No. 0920–0428). Applicants must use Catalog of Federal Domestic Assistance (CFDA) #93.234B when requesting an application kit. The CFDA is a Government-wide compendium of enumerated Federal programs, project services, and activities which provide assistance. All applications must be mailed or delivered to Grants Management Officer, MCHB: HRSA Grants Application Center, 1815 N. Fort Meyer Drive, Suite 300, Arlington , Virginia 22209: telephone 1–877–477–2123: E-mail: *hrsagac@hrsa.gov.*

Necessary application forms and an expanded version of this **Federal Register** notice may be downloaded in either Microsoft Office 2000 or Adobe Acrobat format (.pdf) from the MCHB Home Page at *http://www.mchb.hrsa.gov.* Please contact Joni Johns, at 301/443–2088, or *jjohns@hrsa.gov/,* if you need technical assistance in accessing the MCHB Home Page via the Internet.

This notice will appear in the **Federal Register** and or HRSA Home Page at *http://www.hrsa.dhhs.gov/.* **Federal Register** notices are found on the World Wide Web by following instructions at: *http://www.access.gpo.gov/su_docs/aces/aces140.html.*

Letter of Intent: Notification of intent to apply should be directed to Betty Hastings, M.S.W., by email, *bhastings@hrsa.gov/;* or mail, MCHB, HRSA; Division of Child, Adolescent and Family Health, Parklawn Building, Room 18A–38; 5600 Fishers Lane; Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Betty Hastings, M.S.W., 301/443–5599, or email: *bhastings@hrsa.gov/* (for questions specific to project objectives and activities of the program; or the required Letter of Intent); Marilyn Stewart, 301/443–1440, email *mstewart@hrsa.gov/* (for grants policy, budgetary, and business questions).

SUPPLEMENTARY INFORMATION: Traumatic brain injury (i.e., cranio-cerebral head trauma) is an occurrence of injury to the head arising from blunt or penetrating trauma or from acceleration-deceleration forces that is associated with any of these symptoms or signs attributed to the injury: Decreased level of consciousness, amnesia, other neurologic or neuropsychologic abnormalities, skull fracture, diagnosed intracranial lesions, or death.

Motor vehicle crashes, falls, violence, and sports injuries are the major causes of TBI; the number one killer and cause of disability for young people in the United States. The Centers of Disease Control and Prevention has found that approximately 5.3 million Americans live with the effects of TBI. About half the estimated 1.9 million Americans who experience TBI each year incur at least short-term disability; 52,000 people die as a result of their injuries and more than 90,000 people sustain severe brain injuries leading to debilitating loss of function. The direct medical costs for treatment of TBI have been estimated at more than $4 billion annually.

In 1996, Public Law 104–166 established a program of grants to States to carry out TBI demonstration projects to increase access to rehabilitation, employment, education, and other long-term community support services, in addition to health and medical services.

State Grants for TBI support projects by States to implement statewide systems, ensuring access to comprehensive and coordinated TBI Services. These projects are successfully bringing together representatives of relevant State agencies, disciplines, organizations, and consumers.

Until FY 2001, two categories of TBI demonstration grant programs were available—State TBI Planning Grants and State TBI Implementation Grants. To date, 31 States and the District of Columbia have received basic planning support to establish the necessary infrastructure core capacity components needed to develop an Action Plan to improve the State's TBI service system. State TBI planning grantees develop four ''core capacity'' components, identified as the essential elements in any plan for State implementation of a TBI service system. These include: (1) A statewide TBI Advisory Board; (2) Designated State agency and staff position(s) responsible for State TBI activities; (3) a statewide needs/resource assessment to address the full spectrum of services from initial acute treatment through rehabilitation and long-term community services for individuals with TBI; and (4) a statewide Action Plan to develop a comprehensive, community-based system of care that encompasses physical, psychological, educational, vocational, and social aspects of TBI services. This Action

Plan must also address the needs of individuals with TBI and their families.

State TBI Implementation Grants have been used to help States move toward a statewide system that will assure access to comprehensive and coordinated services for people with TBI. Through implementation grants, States focus on the key priorities identified in their statewide action plans. Since FY 1997, 26 States have received Implementation Grants, which have addressed the following initiatives within the program: (1) Leadership in integrating individuals with TBI and their families into the broader service delivery system; (2) Human resources, personnel, training, and education on TBI issues; (3) Data collection, evaluation, and information management to improve delivery of TBI services; (4) Public information and education regarding TBI issues; (5) and Coordination with other public health and disability community services.

As part of the reauthorization of the TBI program, in the Children's Health Act of 2000, a third grant category has been established—Post Demonstration Grants for States which have successfully completed a TBI Implementation Grant. The purpose of these grants is to continue the systems development efforts begun by an Implementation Grant. These new grants will address issues that will encompass specific State capacity building initiatives to contribute to sustainable change in the system of community services and supports that reflect the best practices in the field of traumatic brain injury.

This Notices announces availability of funds only for TBI Planning Grants and TBI Post Demonstration Grants. No awards will be made through the Notice for TBI Implementation Grants in FY 2001.

Authorization: Public Health Service Act, Title XII, Section 1252, 42 U.S.C. 300d–52, as amended by Public Law 106–310, Section 1304.

Purpose: The purpose of the TBI grant program is to improve access, availability, appropriateness and the acceptability of health and other services for people who have sustained a traumatic brain injury (TBI) and their families, through funding systems change initiatives. State TBI Planning Grants provide funds to assist States in developing infrastructure in the four identified ''core capacity'' components identified above. State TBI Post Demonstration Grants provide funds for capacity-building initiatives to contribute to sustainable change in their systems of community services and supports that reflect best practices.

Eligibility: For all TBI grants, State governments are the only eligible applicants for funding. It is understood that applications for a TBI Post-Demonstration Grant will come from the State agency designated as the lead for TBI services; the State must have completed a three-year State TBI Implementation Demonstration Grant.

Funding Level/Project Period: Approximately $525,000 is available in FY 2001 to support seven State TBI State Planning awards, at $75,000 per award, for project periods of up to two years. Approximately $700,000 is available in FY 2001 to support seven TBI State Post Demonstration awards, at $100,000 per award, for a one-year project period. For each award, the State must contribute, in cash or in kind (including plant, equipment and services), not less than $1 for each $2 of Federal funds provided under the TBI State Grants. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in the amount of such contributions.

The initial budget period for TBI Planning Grants is expected to be 12 months, with any subsequent budget period being 12 months. Continuation of any TBI project from one budget period to the next is subject to satisfactory performance, availability of funds, and program priorities.

Review Criteria: Applications will be reviewed using criteria covering the following areas:

(1) State Planning Grants:

(a) The strength of the plan to develop a statewide Advisory Board.

(b) The adequacy of the State's methodology to develop the four ''core capacity'' components.

(c) The comprehensiveness of the approach to collaboration and partnership.

(d) The adequacy of the organizational and management plan.

(2) Post Demonstration Grants:

(a) The capabilities of the designated State lead agency.

(b) The adequacy of the involvement of the statewide Advisory Board.

(c) The strength of the statewide TBI Action Plan in addressing community services and supports that reflect the best practice in the field of traumatic brain injury.

(d) The State's capacity building efforts.

Final criteria used to review and rank applications for this competition are included in the application kit. Applicants should pay strict attention to addressing these criteria, as they are the basis upon which their applications will be judged.

Executive Order 12372: This program has been determined to be a program which is subject to the provisions of Executive Order 12372 concerning intergovernmental review of Federal programs by appropriate health planning agencies, as implemented by 45 CFR Part 100. Executive Order 12372 allows States the option of setting up a system for reviewing applications from within their States for assistance under certain Federal programs. The application packages to be made available under this notice will contain a listing of States which have chosen to set up such a review system and will provide a single point of contact (SPOC) in the States for review. Applicants (other than federally-recognized Indian tribal governments) should contact their State SPOCs as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC of each affected State. The due date for State process recommendations is 60 days after the application deadline for new and competing awards. The granting agency does not guarantee to ''accommodate or explain'' for State process recommendations it receives after that date. (See Part 148, Intergovernmental Review of PHS Programs under Executive Order 12372 and 45 CFR Part 100 for a description of the review process and requirements).

Dated: May 31, 2001.

Elizabeth M. Duke,

Acting Administrator.

[FR Doc. 01–14455 Filed 6–7–01; 8:45 am]

BILLING CODE 4160–15–U

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4644–N–23]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Clifford Taffet, room 7266, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington,

DC 20410; telephone (202) 708–1234; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration*, No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to Brian Rooney, Division of Property Management, Program Support Center, HHS, room 5B–41, 5600 Fishers Lane, Rockville, MD 20857; (301) 443–2265. (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Clifford Taffet at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*i.e.,* acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: *Army:* Mr. Jeff Holste, Military Programs, U.S. Army Corps of Engineers, Installation Support Center, Planning Branch, Attn: CEMP–IP, 441 G Street, NW, Washington, DC 20314–1000; (202) 761–5737; *DOT:* Mr. Rugene Spruill, Principal, Space Management, SVC–140, Transportation Administrative Service Center, Department of Transportation, 400 7th Street, SW, Room 2310, Washington, DC 20590; (202) 366–4246; *Energy:* Mr. Tom Knox, Department of Energy, Office of Contract & Resource Management, MA–53, Washington, DC 20585; (202) 586–8715; *GSA:* Mr. Brian K. Polly, Assistant Commissioner, General Services Administration, Office of Property Disposal, 18th and F Streets, NW, Washington, DC 20405; (202) 501–0052; *Navy:* Mr. Charles C. Cocks, Director, Department of the Navy, Real Estate Policy Division, Naval Facilities Engineering Command, Washington Navy Yard, 1322 Patterson Ave., SE, Suite 1000, Washington, DC 20374–5065; (202) 685–9200; (These are not toll-free numbers).

Dated: May 31, 2001.

John D. Garrity,

Director, Office of Special Needs Assistance Programs.

Title V, Federal Surplus Property Program, Federal Register Report for 6/8/01

Suitable/Available Properties

Buildings (by State)

Alaska

Bldg. 00229
Fort Richardson
Ft. Richardson Co: AK 99505–6500
Landholding Agency: Army
Property Number: 21200120085
Status: Excess
Comment: 13,056 sq. ft., off-site use only

Arizona

Bldg. 22523
Fort Huachuca
Sierra Vista Co: Cochise AZ 85613—
Landholding Agency: Army
Property Number: 21200120086
Status: Excess
Comment: 63 sq ft., most recent use—storage, off-site use only

California

Bldg. 02453
Naval Air Weapons Station
China Lake Co: CA 93555–6001
Landholding Agency: Navy
Property Number: 77200120110
Status: Excess
Comment: 48 sq. ft., most recent use—storage locker, off-site use only

Bldg. 32027
Naval Air Weapons Station
China Lake Co: CA 93555–6001
Landholding Agency: Navy
Property Number: 77200120111
Status: Excess
Comment: 331 sq. ft., off-site use only

Bldg. 32534
Naval Air Weapons Station
China Lake Co: CA 93555–6001
Landholding Agency: Navy
Property Number: 77200120112
Status: Excess
Comment: 2252 sq. ft., most recent use—repair shop, off-site use only

Bldg. 32537
Naval Air Weapons Station
China Lake Co: CA 93444–6001
Landholding Agency: Navy
Property Number: 77200120113
Status: Excess
Comment: most recent use—instrument bldg., off-site use only

Maryland

Bldg. 618A
Fort George G. Meade
Ft. Meade Co: Anne Arundel MD 20755–5115
Landholding Agency: Army
Property Number: 21200120087
Status: Unutilized
Comment: 400 sq. ft., presence of asbestos/lead paint, most recent use—heat plant bldg., off-site use only

Bldg. 901
Fort George G. Meade

Ft. Meade Co: Anne Arundel MD 20755–5115
Landholding Agency: Army
Property Number: 21200120088
Status: Unutilized
Comment: 2740 sq. ft., presence of asbestos/lead paint, most recent use—storage, off-site use only

Bldgs. 902, 932, 937
Fort George G. Meade
Ft. Meade Co: Anne Arundel MD 20755–5115
Landholding Agency: Army
Property Number: 21200120089
Status: Unutilized
Comment: 2208 sq. ft., presence of asbestos/lead paint, most recent use—admin/dining, off-site use only

4 Bldgs.
Fort George G. Meade
#903, 906, 933, 936
Ft. Meade Co: Anne Arundel MD 20755–5115
Landholding Agency: Army
Property Number: 21200120090
Status: Unutilized
Comment: 1144 sq. ft., presence of asbestos/lead paint, most recent use—admin/storage/dayroom, off-site use only

10 Bldgs.
Fort George G. Meade
#904, 905, 913, 916, 923–926, 934, 935
Ft. Meade Co: Anne Arundel MD 20755–5115
Landholding Agency: Army
Property Number: 21200120091
Status: Unutilized
Comment: 4720 sq. ft., presence of asbestos/lead paint, most recent use—admin., off-site use only

Bldg. 907
Fort George G. Meade
Ft. Meade Co: Anne Arundel MD 20755–5115
Landholding Agency: Army
Property Number: 21200120092
Status: Unutilized
Comment: 2306 sq. ft., presence of asbestos/lead paint, most recent use—storage, off-site use only

Bldg. 908
Fort George G. Meade
Ft. Meade Co: Anne Arundel MD 20755–5115
Landholding Agency: Army
Property Number: 21200120093
Status: Unutilized
Comment: 3663 sq. ft., presence of asbestos/lead paint, most recent use—admin., off-site use only

Bldgs. 912, 917, 922, 927
Fort George G. Meade
Ft. Meade Co: Anne Arundel MD 20755–5115
Landholding Agency: Army
Property Number: 21200120094
Status: Unutilized
Comment: 1297 sq. ft., presence of asbestos/lead paint, most recent use—admin/storage, off-site use only

Bldg. 918
Fort George G. Meade
Ft. Meade Co: Anne Arundel MD 20755–5115
:Landholding Agency: Army
Property Number: 21200120095
Status: Unutilized
Comment: 2331 sq. ft., presence of asbestos/lead paint, most recent use—admin/classroom, off-site use only

4 Bldgs.
Fort George G. Meade
#928, 929, 2832, 2834
Ft. Meade Co: Anne Arundel MD 20755–5115
Landholding Agency: Army
Property Number: 21200120096
Status: Unutilized
Comment: 2284 sq. ft., presence of asbestos/lead paint, most recent use—admin., off-site use only

Bldg. 930
Fort George G. Meade
Ft. Meade Co: Anne Arundel MD 20755–5115
Landholding Agency: Army
Property Number: 21200120097
Status: Unutilized
Comment: 3108 sq. ft., presence of asbestos/lead paint, most recent use—storage, off-site use only

Bldgs. 938
Fort George G. Meade
Ft. Meade Co: Anne Arundel MD 20755–5115
Landholding Agency: Army
Property Number: 21200120098
Status: Unutilized
Comment: 1676 sq. ft., presence of asbestos/lead paint, most recent use—admin., off-site use only

Bldg. 2810
Fort George G. Meade
Ft. Meade Co: Anne Arundel MD 20755–5115
Landholding Agency: Army
Property Number: 21200120099
Status: Unutilized
Comment: 2441 sq. ft., poor condition, presence of asbestos/lead paint, most recent use—admin., off-site use only

Bldg. 2811
Fort George G. Meade
Ft. Meade Co: Anne Arundel MD 20755–5115
Landholding Agency: Army
Property Number: 21200120100
Status: Unutilized
Comment: 4720 sq. ft., poor condition, presence of asbestos/lead paint, most recent use—admin., off-site use only

Bldg. 2837
Fort George G. Meade
Ft. Meade Co: Anne Arundel MD 20755–5115
Landholding Agency: Army
Property Number: 21200120101
Status: Unutilized
Comment: 7670 sq. ft., presence of asbestos/lead paint, most recent use—admin., off-site use only

Bldg. 00262
Aberdeen Proving Ground
Aberdeen Co: Harford MD 21005–5001
Landholding Agency: Army
Property Number: 21200120102
Status: Unutilized
Comment: 24 sq. ft., presence of asbestos/lead paint, most recent use—access control facility, off-site use only

Bldg. 0310A
Aberdeen Proving Ground
Aberdeen Co: Harford MD 21005–5001
Landholding Agency: Army
Property Number: 21200120103
Status: Unutilized
Comment: 120 sq. ft., poor condition, presence of asbestos/lead paint, most recent use—storage, off-site use only

Bldg. 00313
Aberdeen Proving Ground
Aberdeen Co: Harford MD 21005–5001
Landholding Agency: Army
Property Number: 21200120104
Status: Unutilized
Comment: 983 sq. ft., most recent use—storage, off-site use only

Bldg. 00340
Aberdeen Proving Ground
Aberdeen Co: Harford MD 21005–5001
Landholding Agency: Army
Property Number: 21200120105
Status: Unutilized
Comment: 384 sq. ft., most recent use—storage, off-site use only

Bldg. 0459B
Aberdeen Proving Ground
Aberdeen Co: Harford MD 21005–5001
Landholding Agency: Army
Property Number: 21200120106
Status: Unutilized
Comment: 225 sq. ft., poor condition, most recent use—equipment bldg., off-site use only

Bldg. 00785
Aberdeen Proving Ground
Aberdeen Co: Harford MD 21005–5001
Landholding Agency: Army
Property Number: 21200120107
Status: Unutilized
Comment: 160 sq. ft., poor condition, most recent use—shelter, off-site use only

Bldg. E3325
Aberdeen Proving Ground
Aberdeen Co: Harford MD 21005–5001
Landholding Agency: Army
Property Number: 21200120108
Status: Unutilized
Comment: 452 sq. ft., poor condition, possible contamination, most recent use—lab, off-site use only

Bldg. E3728
Aberdeen Proving Ground
Aberdeen Co: Harford MD 21005–5001
Landholding Agency: Army
Property Number: 21200120109
Status: Unutilized
Comment: 2596 sq. ft., presence of asbestos/lead paint, most recent use—testing facility, off-site use only

Bldg. E3870
Aberdeen Proving Ground
Aberdeen Co: Harford MD 21005–5001
Landholding Agency: Army
Property Number: 21200120110
Status: Unutilized
Comment: 1208 sq. ft., presence of asbestos/lead paint, most recent use—lab/test facility, off-site use only

Bldg. E3948
Aberdeen Proving Ground
Aberdeen Co: Harford MD 21005–5001
Landholding Agency: Army
Property Number: 21200120111
Status: Unutilized
Comment: 1416 sq. ft., presence of asbestos/lead paint, most recent use—utility bldg., off-site use only

Bldg. 05213
Aberdeen Proving Ground
Aberdeen Co: Harford MD 21005–5001
Landholding Agency: Army
Property Number: 21200120112
Status: Unutilized
Comment: 200 sq. ft., poor condition, most recent use—storage, off-site use only

Bldg. E5239
Aberdeen Proving Ground
Aberdeen Co: Harford MD 21005–5001
Landholding Agency: Army
Property Number: 21200120113
Status: Unutilized
Comment: 230 sq. ft., most recent use—storage, off-site use only

Bldg. E5317
Aberdeen Proving Ground
Aberdeen Co: Harford MD 21005–5001
Landholding Agency: Army
Property Number: 21200120114
Status: Unutilized
Comment: 3158 sq. ft., presence of asbestos/lead paint, most recent use—lab, off-site use only

Bldg. E5637
Aberdeen Proving Ground
Aberdeen Co: Harford MD 21005–5001
Landholding Agency: Army
Property Number: 21200120115
Status: Unutilized
Comment: 312 sq. ft., presence of asbestos/lead paint, most recent use—lab, off-site use only

Bldg. 493
Naval Air Station
Patuxent River Co: MD 20670–
Landholding Agency: Navy
Property Number: 77200120155
Status: Excess
Comment: 5476 sq. ft., presence of asbestos, most recent use—maint/storage, off-site use only

New York

Bldg. 267
Fort Drum
Ft. Drum Co: Jefferson NY 13602–
Landholding Agency: Army
Property Number: 21200120116
Status: Unutilized
Comment: 1144 sq. ft., most recent use—hq. bldg., off-site use only

Bldg. 268
Fort Drum
Ft. Drum Co: Jefferson NY 13602–
Landholding Agency: Army
Property Number: 21200120117
Status: Unutilized
Comment: 1144 sq. ft., most recent use—hq. bldg., off-site use only

Bldg. 269
Fort Drum
Ft. Drum Co: Jefferson NY 13602–
Landholding Agency: Army
Property Number: 21200120118
Status: Unutilized
Comment: 2731 sq. ft., most recent use—hq. bldg., off-site use only

Lockport Comm. Facility Annex
6625 Shawnee Road
Wheatfield Co: NY 14120–
Landholding Agency: GSA
Property Number: 54200120009
Status: Excess
Comment: 3334 sq. ft., presence of asbestos, most recent use—admin/storage
GSA Number: 1–D–NY–885

Ohio

Bldg. 304
Defense Supply Center
Columbus Co: Franklin OH 43216–5000
Landholding Agency: Army
Property Number: 21200120131
Status: Unutilized
Comment: 219 sq. ft., most recent use—storage, off-site use only

Oklahoma

Bldg. P–706
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21200120119
Status: Unutilized
Comment: 103 sq. ft., possible asbestos/lead paint, most recent use—storage, off-site use only

Bldg. P–747
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21200120120
Status: Unutilized
Comment: 9232 sq. ft., possible asbestos/lead paint, most recent use—lab, off-site use only

Bldg. S–830
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21200120121
Status: Unutilized
Comment: 7356 sq. ft., possible asbestos/lead paint, most recent use—vehicle maint., off-site use only

Bldg. S–831
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21200120122
Status: Unutilized
Comment: 7344 sq. ft., possible asbestos/lead paint, most recent use—classroom, off-site use only

Bldg. P–842
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21200120123
Status: Unutilized
Comment: 192 sq. ft., possible asbestos/lead paint, most recent use—storage, off-site use only

Bldg. T–911
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21200120124
Status: Unutilized
Comment: 3080 sq. ft., possible asbestos/lead paint, most recent use—office, off-site use only

Bldg. P–1390
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21200120125
Status: Unutilized
Comment: 106 sq. ft., possible asbestos/lead paint, most recent use—utility plant, off-site use only

Bldg. P–1672
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21200120126
Status: Unutilized
Comment: 1056 sq. ft., possible asbestos/lead paint, most recent use—storage, off-site use only

Bldg. S–2362
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21200120127
Status: Unutilized
Comment: 64 sq. ft., possible asbestos/lead paint, most recent use—gatehouse, off-site use only

Bldg. P–2421
Fort Sill
Lawton Co: Comanche OK 73505–5100
Landholding Agency: Army
Property Number: 21200120128
Status: Unutilized
Comment: 100 sq. ft., most recent use—storage, off-site use only

Bldg. P–2589
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21200120129
Status: Unutilized
Comment: 3672 sq. ft., possible asbestos/lead paint, most recent use—storage, off-site use only

Bldg. T–3043
Fort Sill
Lawton Co: Comanche OK 73503–5100
Landholding Agency: Army
Property Number: 21200120130
Status: Unutilized
Comment: 80 sq. ft., possible asbestos/lead paint, most recent use—guard shack, off-site use only

Virginia

Bldgs. SS0305, SS0306
Fort A.P. Hill
Bowling Green Co: Caroline VA 22428–
Landholding Agency: Army
Property Number: 21200120132
Status: Unutilized
Comment: 1250 sq. ft., concrete block, off-site use only

Bldg. 16
Defense Supply Center
Richmond Co: Chesterfield VA 23297–
Landholding Agency: Army
Property Number: 21200120133
Status: Unutilized
Comment: 165 sq. ft., most recent use—sewage lift station bldg., off-site use only

Bldg. 46
Defense Supply Center
Richmond Co: Chesterfield VA 23297–
Landholding Agency: Army
Property Number: 21200120134
Status: Unutilized
Comment: 124 sq. ft., most recent use—storage, off-site use only

Bldg. 52
Defense Supply Center
Richmond Co: Chesterfield VA 23297–
Landholding Agency: Army
Property Number: 21200120135
Status: Unutilized
Comment: 240 sq. ft., presence of lead paint, most recent use—storage, off-site use only

Bldg. 68
Defense Supply Center
Richmond Co: Chesterfield VA 23297–

Landholding Agency: Army
Property Number: 21200120136
Status: Unutilized
Comment: 400 sq. ft., most recent use—storage, off-site use only

Bldg. 75
Defense Supply Center
Richmond Co: Chesterfield VA 23297–
Landholding Agency: Army
Property Number: 21200120137
Status: Unutilized
Comment: 1010 sq. ft., site contamination, most recent use—storage, off-site use only

Bldg. 112
Defense Supply Center
Richmond Co: Chesterfield VA 23297–
Landholding Agency: Army
Property Number: 21200120138
Status: Unutilized
Comment: 1744 sq. ft., presence of pesticides/asbestos, most recent use—storage, off-site use only

Wisconsin

Bldg. 2160
Fort McCoy
Ft. McCoy Co: Monroe WI 54656–5136
Landholding Agency: Army
Property Number: 21200120139
Status: Unutilized
Comment: 7036 sq. ft., needs rehab, most recent use—office, off-site use only

Suitable/Unavailable Properties

Land (by State)

Virginia

2.6 acres
Naval Station
Norfolk Co: VA 23508–1273
Landholding Agency: Navy
Property Number: 77200120131
Status: Underutilized
Comment: most recent use—brush/debris storage

1.15 acres
Naval Amphibious Base Little Creek
Norfolk Co: VA 23508–
Landholding Agency: Navy
Property Number: 77200120132
Status: Underutilized
Comment: most recent use—brush/debris storage

Unsuitable Properties

Buildings (by State)

California

Bldg. 70140
Naval Air Weapons Station
China Lake Co: CA 93555–6100
Landholding Agency: Navy
Property Number: 77200120107
Status: Excess
Reason: Extensive deterioration

Bldg. 70141
Naval Air Weapons Station
China Lake Co: CA 93555–6100
Landholding Agency: Navy
Property Number: 77200120108
Status: Excess
Reason: Extensive deterioration

Bldg. 70143
Naval Air Weapons Station
China Lake Co: CA 93555–6100
Landholding Agency: Navy
Property Number: 77200120109
Status: Excess
Reason: Extensive deterioration

Bldg. 25062
Naval Air Weapons Station
China Lake Co: CA 93555–6001
Landholding Agency: Navy
Property Number: 77200120114
Status: Excess
Reason: Extensive deterioration

Bldg. 33023
Naval Air Weapons Station
China Lake Co: CA 93555–6001
Landholding Agency: Navy
Property Number: 77200120115
Status: Excess
Reason: Extensive deterioration

Bldg. 33054
Naval Air Weapons Station
China Lake Co: CA 93555–6001
Landholding Agency: Navy
Property Number: 77200120116
Status: Excess
Reason: Extensive deterioration

Bldg. 106
Naval Amphibious Base
Naval Base Coronado
San Diego Co: CA 92135–7040
Landholding Agency: Navy
Property Number: 77200120134
Status: Excess
Reason: Extensive deterioration

Bldg. 108
Naval Amphibious Base
Naval Base Coronado
San Diego Co: CA 92135–7040
Landholding Agency: Navy
Property Number: 77200120135
Status: Excess
Reason: Extensive deterioration

Bldg. 109
Naval Amphibious Base
Naval Base Coronado
San Diego Co: CA 92135–7040
Landholding Agency: Navy
Property Number: 77200120136
Status: Excess
Reason: Extensive deterioration

Bldg. 110
Naval Amphibious Base
Naval Base Coronado
San Diego Co: CA 92135–7040
Landholding Agency: Navy
Property Number: 77200120137
Status: Excess
Reason: Extensive deterioration

Bldg. 147
Naval Amphibious Base
Naval Base Coronado
San Diego Co: CA 92135–7040
Landholding Agency: Navy
Property Number: 77200120138
Status: Excess
Reason: Extensive deterioration

Bldg. 163
Naval Amphibious Base
Naval Base Coronado
San Diego Co: CA 92135–7040
Landholding Agency: Navy
Property Number: 77200120139
Status: Excess
Reason: Extensive deterioration

Bldg. 244
Naval Amphibious Base
Naval Base Coronado
San Diego Co: CA 92133–5704
Landholding Agency: Navy
Property Number: 77200120140
Status: Excess
Reason: Extensive deterioration

Bldg. 250
Naval Amphibious Base
Naval Base Coronado
San Diego Co: CA 92135–7040
Landholding Agency: Navy
Property Number: 77200120141
Status: Excess
Reason: Extensive deterioration

Bldg. 251
Naval Amphibious Base
Naval Base Coronado
San Diego Co: CA 92135–7040
Landholding Agency: Navy
Property Number: 77200120142
Status: Excess
Reason: Extensive deterioration

Bldg. 252
Naval Amphibious Base
Naval Base Coronado
San Diego Co: CA 92135–7040
Landholding Agency: Navy
Property Number: 77200120143
Status: Excess
Reason: Extensive deterioration

Bldg. 311
Naval Amphibious Base
Naval Base Coronado
San Diego Co: CA 92135–7040
Landholding Agency: Navy
Property Number: 77200120144
Status: Excess
Reason: Extensive deterioration

Bldg. 313
Naval Amphibious Base
Naval Base Coronado
San Diego Co: CA 92135–7040
Landholding Agency: Navy
Property Number: 77200120145
Status: Excess
Reason: Extensive deterioration

Bldg. 318
Naval Amphibious Base
Naval Base Coronado
San Diego Co: CA 92135–7040
Landholding Agency: Navy
Property Number: 77200120146
Status: Excess
Reason: Extensive deterioration

Bldg. 339
Naval Amphibious Base
Naval Base Coronado
San Diego Co: CA 92135–7040
Landholding Agency: Navy
Property Number: 77200120147
Status: Excess
Reason: Extensive deterioration

Bldg. C–54
North Island
Naval Base Coronado
San Diego Co: CA 92135–7040
Landholding Agency: Navy
Property Number: 77200120148
Status: Excess
Reason: Extensive deterioration

Bldg. C–114
North Island
Naval Base Coronado
San Diego Co: CA 92135–7040

Landholding Agency: Navy
Property Number: 77200120149
Status: Excess
Reason: Extensive deterioration

Bldg. C–124
North Island
Naval Base Coronado
San Diego Co: CA 92135–7040
Landholding Agency: Navy
Property Number: 77200120150
Status: Excess
Reason: Extensive deterioration

Bldg. C–311
North Island
Naval Base Coronado
San Diego Co: CA 92135–7040
Landholding Agency: Navy
Property Number: 77200120151
Status: Excess
Reason: Extensive deterioration

Bldg. 312
North Island
Naval Base Coronado
San Diego Co: CA 92135–7040
Landholding Agency: Navy
Property Number: 77200120152
Status: Excess
Reason: Extensive deterioration

Bldg. 605
North Island
Naval Base Coronado
San Diego Co: CA 92135–7040
Landholding Agency: Navy
Property Number: 77200120153
Status: Excess
Reason: Extensive deterioration

Bldg. 610
North Island
Naval Base Coronado
San Diego Co: CA 92135–7040
Landholding Agency: Navy
Property Number: 77200120154
Status: Excess
Reason: Extensive deterioration

Florida

Bldg. C–25
Naval Air Station
Key West Co: Monroe FL 33040–
Landholding Agency: Navy
Property Number: 77200120117
Status: Unutilized
Reason: Extensive deterioration

Bldg. A–222
Naval Air Station
Key West Co: Monroe FL 33040–
Landholding Agency: Navy
Property Number: 77200120118
Status: Unutilized
Reason: Extensive deterioration

Bldg. 226
Naval Air Station
Key West Co: Monroe FL 33040–
Landholding Agency: Navy
Property Number: 77200120119
Status: Unutilized
Reason: Extensive deterioration

Bldg. A–255
Naval Air Station
Key West Co: Monroe FL 33040–
Landholding Agency: Navy
Property Number: 77200120120
Status: Unutilized
Reason: Extensive deterioration

Bldg. 299
Naval Air Station
Key West Co: Monroe FL 33040–
Landholding Agency: Navy
Property Number: 77200120121
Status: Unutilized
Reason: Extensive deterioration

Bldg. A–325
Naval Air Station
Key West Co: Monroe FL 33040–
Landholding Agency: Navy
Property Number: 77200120122
Status: Unutilized
Reason: Extensive deterioration

Bldg. A–628
Naval Air Station
Key West Co: Monroe FL 33040–
Landholding Agency: Navy
Property Number: 77200120123
Status: Unutilized
Reason: Extensive deterioration

Bldg. A–634
Naval Air Station
Key West Co: Monroe FL 33040–
Landholding Agency: Navy
Property Number: 77200120124
Status: Unutilized
Reason: Extensive deterioration

Bldg. A–728
Naval Air Station
Key West Co: Monroe FL 33040–
Landholding Agency: Navy
Property Number: 77200120125
Status: Unutilized
Reason: Extensive deterioration

New Jersey

30 Bldgs.
Camp Charles Wood
Ft. Monmouth Co: Eatontown NJ
Landholding Agency: GSA
Property Number: 5420012008
Status: Excess
Reason: Within 2000 ft. of flammable or explosive material
GSA Number: 1–D–NJ–470f

Quarters C
USCG Training Center
Cape May Co: NJ 08204–5002
Landholding Agency: GSA
Property Number: 87200120012
Status: Excess
Reason: Secured Area

Central Heating Plant
USCG Training Center
Cape May Co: NJ 08204–5002
Landholding Agency: DOT
Property Number: 87200120013
Status: Excess
Reason: Secured Area

Hangar/Shop
USCG Training Center
Cape May Co: NJ 08204–5002
Landholding Agency: DOT
Property Number: 87200120014
Status: Excess
Reason: Secured Area

North Carolina

Bldg. M–319
Marine Corps Base
Camp Lejeune Co: Onslow NC 28542–
Landholding Agency: Navy
Property Number: 77200120127
Status: Unutilized
Reason: Secured Area

Tennessee

Bldg. 9723–16
National Security Complex
Oak Ridge Co: Anderson Tn 37831–
Landholding Agency: Energy
Property Number: 41200120010
Status: Unutilized
Reasons: Secured Area Extensive deterioration

Virginia

Bldg. CEP–207
Naval Station
Norfolk Co: VA 23511–
Landholding Agency: Navy
Property Number: 77200120129
Status: Excess
Reason: Extensive deterioration

Bldg. 232
St. Julian's Creek Annex
Portsmouth Co: VA
Landholding Agency: Navy
Property Number: 77200120130
Status: Excess
Reason: Extensive deterioration

Washington

Bldg. 133
Naval Undersea Warfare Station
Keyport Co: Kitsap WA 98345–7610
Landholding Agency: Navy
Property Number: 77200120133
Status: Unutilized
Reasons: Within 2000 ft. of flammable or explosive material; Secured Area; Extensive deterioration

Unsuitable Properties

Land (by State)

North Carolina

Parcel of land
144 sq. ft.
Marine Corps Base
Camp Lejeune Co: Onslow NC 28542–
Landholding Agency: Navy
Property Number: 77200120126
Status: Underutilized
Reason: Secured Area

[FR Doc. 01–14122 Filed 6–7–01; 8:45 am]

BILLING CODE 4210–29–M

DEPARTMENT OF THE INTERIOR

Office of the Secretary

John H. Chafee Blackstone River Valley National Heritage Corridor Commission; Notice of Meeting

Notice is hereby given in accordance with Section 552b of Title 5, United States Code, that a meeting of the John H. Chafee Blackstone River Valley National Heritage Corridor Commission will be held on Thursday, June 21, 2001.

The Commission was established pursuant to Public Law 99–647. The purpose of the Commission is to assist federal, state and local authorities in the development and implementation of an integrated resource management plan

for those lands and waters within the Corridor.

The meeting will convene at 7 PM at the Corridor Commission Office located at One Depot Square, Woonsocket, RI for the following reasons:

1. Approval of Minutes
2. Chairman's Report
3. Executive Director's Report
4. Public Input

It is anticipated that about twenty people will be able to attend the session in addition to the Commission members.

Interested persons may make oral or written presentations to the Commission or file written statements. Such requests should be made prior to the meeting to: Michael Creasey, Executive Director, John H. Chafee, Blackstone River Valley National Heritage Corridor Commission, One Depot Square, Woonsocket, RI 02895, Tel.: (401) 762–0250.

Further information concerning this meeting may be obtained from Michael Creasey, Executive Director of the Commission at the aforementioned address.

Michael Creasey,

Executive Director BRVNHCC.

[FR Doc. 01–14504 Filed 6–7–01; 8:45 am]

BILLING CODE 4310–RK–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Initial Approved Information Collection; Training Applications

AGENCY: Fish and Wildlife Service, Interior

ACTION: 60-Day notice; request for comments.

SUMMARY: The U.S. Fish and Wildlife Service is announcing its intention to automate the collection of training applications and provide an optional alternative application specifically for the training conducted by the USFWS National Conservation Training Center. Applicants who wish to participate in training sponsored by the National Conservation Training Center (NCTC) fill out a training request nomination application offered in both hard copy and web registration format. Fish and Wildlife Service employees requesting non NCTC training or conference attendance complete the electronic SF–182 application via the Training Server Applications.

The USFWS currently utilizes the Office of Personnel Management, Standard Form 182 (Rev 12/79) which was designed with five or ten parts with carbon attachments and to be completed via type writer and is not kept electronically.

We will submit the collection of information listed below to the Office of Management and Budget (OMB) for approval under the provisions of the Paperwork Reduction Act of 1995. If you wish to obtain copies of the proposed information collection requirement, related forms, and explanatory material, contact the Collection Clearance Officer at the address listed below.

DATES: OMB has up to 60 days to approve or disapprove information collection, but may respond after 30 days. Therefore, to ensure maximum consideration you must submit comments on or before August 1, 2001.

ADDRESSES: Send your comments and suggestions on specific requirements to the Office of Management and Budget, Attention: Rebecca Mullin, Collection Clearance Officer, U.S. Fish and Wildlife Service, MS 222–ARLSQ; 4401 N. Fairfax Drive, Arlington, VA 22203.

FOR FURTHER INFORMATION CONTACT: To request a copy of the information collection request, explanatory information and related forms, contact Rebecca A. Mullin, Collection Clearance Officer at 703–358–2287, or electronically to: *Rebecca_Mullin@fws.gov*

SUPPLEMENTARY INFORMATION: OMB regulations at 5 CFR part 1320, which implement the provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and record keeping activities (see 5 CFR 1320.8(d)). The U.S. Fish and Wildlife Service (WE) has submitted a request to OMB to approve collection of information for the Service's training application form. We are requesting a 3-year approval for the information collection activity.

We invite comments concerning this information collection on: (1) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden, (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond. The information collection in this program are part of a system of record covered by the Privacy Act (5 U.S.C. 552a).

Federal agencies may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The information collection requirements in this submission implement the regulatory requirements of the Statute Title 5 U.S.C. Chapter 41, Section 5 CFR part 410, and 231 FW1 Training Management Policy and Responsibilities.

OMB Control Number: 1018–

Service Form Number: FWS Form 3–2193

Frequency of Collection: As training enrollment dictates

Description of Respondents: All affiliations of persons who wish to participate in training given at or sponsored by the USFWS National Conservation Training Center. These are generally natural conservation related affiliates such as Service employees, Department of Interior employees, other Federal employees such as EPA, DOD biologists, OPM, state agency personnel, private, not-for-profit agencies such as The Conservation Fund, and university personnel.

Total Annual Burden Hours: 73,500.

Total Annual Responses: 14,212.

Total Annual Non-Hour Cost Burden: $0.

Dated: May 30, 2001.

Rebecca A. Mullin,

Information Collection Officer, U.S. Fish and Wildlife Service.

[FR Doc. 01–14181 Filed 6–1–01; 8:45 am]

BILLING CODE 4310–55–M

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–455]

Certain Network Interface Cards and Access Points for Use in Direct Sequence Spread Spectrum Wireless Local Area Networks and Products Containing Same; Notice of Decision To Extend the Deadlines for Determining Whether To Review Two Determinations

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to extend until June 25, 2001, the deadlines for determining whether to review two initial determinations (''IDs'') issued by the presiding administrative law judge (ALJ) in the above-captioned investigation (Orders Nos. 12 and 13), granting the motions of Intersil Corporation (''Intersil'') and Agere

Systems, Inc. (''Agere''), respectively, to intervene but denying them respondent status.

FOR FURTHER INFORMATION CONTACT: Michael Liberman, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–3115. Copies of the ALJ's ID and all other nonconfidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS-ON-LINE) at *http://dockets.usitc.gov/eol/public.*

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on April 9, 2001, based on a complaint filed by Proxim, Inc. (''Proxim'') against 14 entities which do not include Intersil or Agere. The notice of investigation was published in the **Federal Register** on April 9, 2001. 66 FR 18507 (2001). The complaint alleges violations of section 337 of the Tariff Act of 1930 in the importation into the United States, sale for importation, and/or sale within the United States after importation of certain wireless network interface cards and access points by reason of infringement of certain U.S. patents owned by Proxim. On April 16, 2001, Intersil and Agere, both, filed the motions to intervene as the respondents in the investigation.

On May 8, 2001, and on May 15, 2001, the presiding administrative law judge (ALJ) (Judge Morriss) issued two IDs (Orders Nos. 12 and 13) granting Intersil's and Agere's motions, respectively. The IDs allow Intersil and Agere to become intervenors in the present investigation, but deny Intersil and Agere respondent status.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in section 210.42 of the Commission's Rules of Practice and Procedure (19 CFR 210.42).

Issued: June 4, 2001.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 01–14429 Filed 6–7–01; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: United States International Trade Commission

TIME AND DATE: June 11, 2001 at 11 a.m.

PLACE: Room 101, 500 E Street SW., Washington, DC 20436, Telephone: (202) 205–2000

STATUS: Open to the public

MATTERS TO BE CONSIDERED:

1. Agenda for future meeting: None

2. Minutes

3. Ratification List

4. Inv. No. 731–TA–932 (Preliminary) (Folding Metal Tables and Chairs from China)—briefing and vote. (The Commission is currently scheduled to transmit its determination to the Secretary of Commerce on June 11, 2001; Commissioners' opinions are currently scheduled to be transmitted to the Secretary of Commerce on June 18, 2001.)

5. Inv. Nos. 731–TA–926–927 (Preliminary) (Spring Table Grapes from Chile and Mexico)—briefing and vote. (The Commission is currently scheduled to transmit its determination to the Secretary of Commerce on June 11, 2001; Commissioners' opinions are currently scheduled to be transmitted to the Secretary of Commerce on June 18, 2001.)

6. Outstanding action jackets:

(1) Document No. INV–01–076: Concerning Inv. No. TA–204–6 (Certain Steel Wire Rod).

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

Issued: June 4, 2001.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 01–14576 Filed 6–6–01; 10:58 am]

BILLING CODE 7020–02–U

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review; Comment Request

May 30, 2001.

The Department of Labor (DOL) has submitted the following public information collection requests (ICRs) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). A copy of each individual ICR, with applicable supporting documentation, may be obtained by contacting the Department of Labor. To obtain documentation contact Darris King at (202) 693–4129 or E-Mail *King-Darrin@dol.gov*.

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for ETA, Office of Management and Budget, Room 10235, Washington, DC 20503 ((202) 395–7316), within 30 days from the date of this publication in the **Federal Register**.

The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Type of Review: Extension of a currently approved collection.

Agency: Employment and Training Administration (ETA).

Title: NAFTA Customer Survey Data Request.

OMB Number: 1205–0337.

Affected Public: Business or other for-profit.

Frequency: On occasion.

Number of Respondents: 1,050.

Number of Annual Responses: 1,050.

Estimated Time Per Response: 2 hours.

Total Burden Hours: 2,100.

Total Annualized Capital/Startup Costs: $0.

Total Annual Costs (operating/maintaining systems or purchasing services): $0.

Description: The information collected on the form ETA–9044 is required for the Secretary of Labor to make determinations of eligibility for petitioning workers to apply for transition adjustment assistance in accordance with Subchapter D of the North American Free Trade Agreement Implementation Act amending the Trade Act of 1974.

Type of Review: Extension of a currently approved collection.

Agency: Employment and Training Administration (ETA).

Title: NAFTA Confidential Data Request.

OMB Number: 1205–0339.

Affected Public: Business or other for-profit.

Frequency: On occasion.

Number of Respondents: 1,000.

Number of Annual Responses: 1,000.

Estimated Time Per Response: 3 hours to complete the form ETA 9043 and 4.5 hours for Governors to conduct a State review.

Total Burden Hours: 7,500.

Total Annualized Capital/Startup Costs: $0.

Total Annual Costs (operating/maintaining systems or purchasing services): $0.

Description: Subchapter D of the North American Free Trade Agreement Implementation Act amends the Trade Act of 1974 by requiring business confidential data in order to make timely determination as to whether imports have contributed to worker separations. The form ETA 9043 is used by workers to apply for NAFTA Adjustment Assistance.

Darrin A. King,

Acting Departmental Clearance Officer.

[FR Doc. 01–14426 Filed 6–7–01; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review; Comment Request

May 30, 2001.

The Department of Labor (DOL) has submitted the following public information collection requests (ICRs) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). A copy of this ICR, with applicable supporting documentation, may be obtained by calling the Department of Labor. To obtain documentation contact Darrin King at (202) 693–4129 or E-Mail King-Darrin@dol.gov.

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for ETA, Office of Management and Budget, Room 10235, Washington, DC 20503 ((202) 395–7316), within 30 days from the date of this publication in the **Federal Register**.

The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: Employment and Training Administration (ETA).

Type of Review: New collection.

OMB Number: 1205–0NEW.

Title: Placement Verification and Follow-up of Job Corps Participants.

Affected Public: Individuals or households; Business or other for-profit.

Number of Respondents: 36,088.

Respondent category	Annual responses	Frequency	Average time per response (minutes)	Burden hours
Placed Former Enrollees at 90 Days	6,020	One time	15	1,505
Placed Graduated at 90–120 Days	26,400	One time	15	6,600
Non-Placed Former Enrollees at 90 Days	1,330	One time	10	226
Non-Placed Graduates at 12 Months	1,365	One time	10	228
Placed Graduates at 6 Months	24,640	One time	12	4,928
Placed Graduates at 12 Months	23,000	One time	10	3,833
Employer/Institution Re-verification	973	On occasion	10	165
Totals	83,728			17,485

Total Annualized Capital/Startup Costs: $0.

Total Annual Costs (operating/maintaining systems or purchasing services): $0.

Description: The Department of Labor is requesting approval of three data collection instruments that will be used to collect follow-up data on individuals who are no longer actively participating in Job Corps. The instruments are comprised of modules that include questions designed to obtain the following information: re-verification of initial job and/or school placements; employment and educational experiences; job search activities of those who are neither working nor in school; and information about former participants' satisfaction with the services provided by Job Corps.

Darrin A. King,

Acting Departmental Clearance Officer.

[FR Doc. 01–14427 Filed 6–7–01; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance and NAFTA Transitional Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, as amended, the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment

assistance for workers (TSA–W) issued during the period of May, 2001.

In order for an affirmative determination to be made and a certification of eligibility to apply for worker adjustment assistance to be issued, each of the group eligibility requirements of Section 222 of the Act must bet met.

(1) that a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated,

(2) that sales or production, or both, of the firm or subdivision have decreased absolutely, and

(3) that increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Negative Determinations for Worker Adjustment Assistance

In each of the following cases the investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA–W–38,854; Troy Laminating and Coating, Inc., Invex Chargeurs, Troy, OH

In the following cases, the investigation revealed that the criteria for eligibility have not been met for the reasons specified.

Increased imports did not contribute importantly to worker separations at the firm.

TA–W–38,953; Steag Hamatech, Inc., Saco, ME

TA–W–39.142; Teamstaff, El Paso, TX

TA–W–39,160; Fraser Papers, Inc., West Carrollton Mill, West Carrollton, OH

The workers firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA–W–38,860; Coil Center Corp., Howell MI

TA–W–38,988; Delta Dental Plan of Minnesota, Eagan, MN

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued; the date following the company name and location of each determination references the impact date for all workers of such determination.

TA–W–38,961; Hamburg Unifirms, Hamburg, AR: March 15, 2000.

TA–W–38,991; VF Imagewear (West), Inc., Formerly Red Kap Industries, Columbus, MS: March 9, 2000.

TA–W–38,767; The Ohio Art Co., Bryan, OH: May 23, 2001.

TA–W–39,212; E.I. DuPont, Nylon Division, Camden, SC: April 23, 2000.

TA–W–38,779; Maxxim Medical, Inc., Columbus, MS: February 5, 2000.

TA–W–38,696; Purolator Products, Elmira, NY: February 2, 2000.

TA–W–38,959; Carlisle Tire and Wheel, Clinton, TN: March 19, 2000.

Also, pursuant to Title V of the North American Free Trade Agreement Implementation Act (Pub. L. 103–182) concerning transitional adjustment assistance hereinafter called (NAFTA–TAA) and in accordance with Section 250(a), Subchapter D, Chapter 2, Title II, of the Trade Act as amended, the Department of Labor presents summaries of determinations regarding eligibility to apply for NAFTA–TAA issued during the month of May, 2001.

In order for an affirmative determination to be made and a certification of eligibility to apply for NAFTA–TAA the following group eligibility requirements of section 250 of the Trade Act must be met:

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, (including workers in any agricultural firm or appropriate subdivision thereof) have become totally or partially separated from employment and either—

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely,

(3) That imports from Mexico or Canada of articles like or directly competitive with articles produced by such firm or subdivision have increased, and that the increases in ports contributed importantly to such workers' separations or threat of separation and to the decline in sales or production of such firm or subdivision; or

(4) That there has been a shift in production by such workers' firm or subdivision to Mexico or Canada of articles like or directly competitive with articles which are produced by the firm or subdivision.

Negative Determinations NAFTA–TAA

In each of the following cases the investigation revealed that criteria (3) and (4) were not met. Imports from Canada or Mexico did not contribute importantly to workers' separations. There was no shift in production from the subject firm to Canada or Mexico during the relevant period.

None

The investigation revealed that the criteria for eligibility have not been met for the reasons specified.

None

Affirmative Determinations NAFTA–TAA

NAFTA–TAA–04858; Blue Cast Denim Co., Inc., El Paso, TX: May 8, 2000.

NAFTA–TAA–04782; Tyco Electronics, Harrisonburg, VA: April 20, 2000.

NAFTA–TAA–04731; Meridian Automotive Systems, Lapeer Operations, Lapeer, MI: March 26, 2000.

NAFTA–TAA–04702; Renfro Hoisery, Inc., Riverside Plant, Wepamat Department, Mount Airy, NC: March 28, 2000.

NAFTA–TAA–04669; VF Imagewear (West), Inc., Formerly Red Kap Industries, Columbus, MS: March 9, 2000.

I hereby certify that the aforementioned determinations were issued during the month of May, 2001. Copies of these determinations are available for inspection in Room C–5311, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 during normal business hours or will be mailed to persons who write to the above address.

Dated: May 25, 2001.

Edward A. Tomchick,

Director, Division of Trade Adjustment Assistance.

[FR Doc. 01–14413 Filed 6–7–01; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–38,713, et al.]

AgriFrozen Foods, Woodburn, OR, et al.; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on April 17, 2001, applicable to workers of AgriFrozen Foods, Woodburn, Oregon. The notice was published in the **Federal Register** on May 3, 2001 (66 FR 22262).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. The workers are engaged in the production of frozen vegetables. New findings show that worker separations occurred at the Administrative Office of AgriFrozen Foods located in Salem, Oregon. The Salem, Oregon location is the headquarters office and provides

administrative support functions to AgriFrozen's production facilities including Woodburn, Oregon.

The intent of the Department's certification is to include all workers of AgriFrozen Foods adversely affected by increased imports of frozen vegetables.

Accordingly, the Department is amending the certification to properly reflect this matter.

The amended notice applicable to TA–W–38,713 is hereby issued as follows:

All workers of AgriFrozen Foods, Woodburn, Oregon (TA–W–38,713) and Administrative Office, Salem, Oregon (TA–W–38,713A) who became totally or partially separated from employment on or after February 9, 2000 through April 17, 2003 are eligible to apply for adjustment assistance under section 223 of the Trade Act of 1974.

Signed at Washington, DC this 22nd day of May, 2001.

Edward A. Tomchick,

Director, Division of Trade Adjustment Assistance.

[FR Doc. 01–14421 Filed 6–7–01; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–38,293]

Dresser Rand, Painted Post, New York; Dismissal of Application for Reconsideration

Pursuant to 29 CFR 90.18(C) an application for administrative reconsideration was filed with the Director of the Division of Trade Adjustment Assistance for workers at Dresser Rand, Painted Post, New York. The application contained no new substantial information which would bear importantly on the Department's determination. Therefore, dismissal of the application was issued.

TA–W–38,293; Dresser Rand, Painted Post, New York (May 24, 2001)

Signed at Washington, DC this 25th day of May, 2001.

Edward A. Tomchick,

Director, Division of Trade Adjustment Assistance.

[FR Doc. 01–14414 Filed 6–7–01; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–38,496]

Dynamic Metal Forming, Inc., Koppel, Pennsylvania; Dismissal of Application for Reconsideration

Pursuant to 29 CFR 90.18(C) an application for administrative reconsideration was filed with the Director of the Division of Trade Adjustment Assistance for workers at Dynamic Metal Forming, Inc., Koppel, Pennsylvania. The application contained no new substantial information which would bear importantly on the Department's determination. Therefore, dismissal of the application was issued.

TA–W–38,496; Dynamic Metal Forming, Inc., Koppel, Pennsylvania (May 24, 2001)

Signed at Washington, DC this 25th day of May, 2001.

Edward A. Tomchick,

Director, Division of Trade Adjustment Assistance.

[FR Doc. 01–14414 Filed 6–7–01; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–38,334]

General Magnetic, A Wholly Owned Subsidiary of International Jensen, Inc., Dallas, Texas; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 USC 2273) the U.S. Department Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on February 20, 2001, applicable to workers of General Magnetic, Dallas, Texas. The notice was published in the **Federal Register** on April 5, 2001 (FR 66 18118).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. The workers were engaged in the production of ceramic ring magnets for loudspeakers. New information provided by the State shows that General Magnetic is a wholly owned subsidiary of International Jensen, Inc. located in Lake Forest, Illinois. New information also shows that workers separated from employment at the subject firm had their wages reported under a separate unemployment insurance (UI) tax account at International Jensen, Inc., Lake Forest, Illinois.

Accordingly, the Department is amending the certification to properly reflect this matter.

The intent of the Department's certification is to include all workers of General Magnetic who were adversely affected by increased imports of ceramic ring magnets.

The amended notice applicable to TA–W–38,334 is hereby issued as follows:

All workers of the General Magnetic, a wholly owned subsidiary of International Jensen, Inc., Dallas, Texas who became totally or partially separated from employment on or after November 6, 1999 through February 20, 2003 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed at Washington DC this 23rd day of May, 2001.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 01–14417 Filed 6–7–01; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

TA–W–38,986, Gilda Activewear, Miami, Florida; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, an investigation was initiated on April 9, 2001, in response to a worker petition which was filed on behalf of workers at Gilda Activewear, Miami, Florida.

The company official closed the facility and no one is available to provide information regarding the laid off workers. In a telephone conversation with a petitioner he stated that the company official moved to another State and closed the distribution facility also that the workers provided warehouse and distribution services and did not produce an article. Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed at Washington, DC this 23rd day of May 2001.

Edward A. Tomchick,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 01–14423 Filed 6–7–01; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–38,321]

International Paper, Lock Haven, Pennsylvania; Notice of Affirmative Determination Regarding Application for Reconsideration

By letter of March 14, 2001, the petitioner (a company official), requests administrative reconsideration of the Department of Labor's Negative Determination Regarding Eligibility to Apply for Worker Adjustment Assistance applicable to workers of the subject firm. The notice of negative determination was published in the **Federal Register** on March 2, 2001 (66 FR 13086).

The company presents new evidence regarding sales, production and employment at the subject firm.

Conclusion

After careful review of the application, I conclude that the claim is of sufficient weight to justify reconsideration of the Department of Labor's prior decision. The application is, therefore, granted.

Signed at Washington, DC this 24th day of May 2001.

Edward A. Tomchick,

Director, Division of Trade Adjustment Assistance.

[FR Doc. 01–14416 Filed 6–7–01; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

TA–W–39,049 Saunders Manufacturing Co., Inc., Winthrop, Maine; TA–W–39,049A Saunders Manufacturing Co., Inc., Meridian, Mississippi; Notice of Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, an investigation was initiated on April 16, 2001, in response to a petition filed on behalf of workers at Saunders Manufacturing Company, Inc., Winthrop, Maine and Meridian, Mississippi.

The company official submitting the petition has requested that the petition be withdrawn. Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed in Washington, DC this 22nd day of May, 2001.

Edward A. Tomchick,

Certifying Officer, Divison of Trade Adjustment Assistance.

[FR Doc. 01–14424 Filed 6–7–01; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

Workforce Investment Act; Native American Employment and Training Council

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice of meeting.

SUMMARY: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (FACA) (Pub. L. 92–463), as amended, and section 166(h)(4) of the Workforce Investment Act (WIA) [29 U.S.C. 2911(h)(4)], notice is hereby given of the next meeting of the Native American Employment and Training Council as constituted under WIA.

Time and Date: The meeting will begin at 9:00 a.m. EDT on Tuesday, June 19, 2001, and continue until 5:00 p.m. EDT that day. The meeting will reconvene at 9:00 a.m. EDT on Wednesday, June 20, 2001, and adjourn at approximately 3:00 p.m. EDT on that day. The period from 3:00 p.m. to 5:00 p.m. EDT on June 19 will be reserved for participation and presentation by members of the public.

Place: Both days' sessions will be held in Room N–3437 A, B, and C, Frances Perkins Building, the U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

Status: The meeting will be open to the public.

Matters to be Considered: The formal agenda will focus on the following topics: (1) Comments from the Department on overall employment and training issues, including WIA implementation; (2) Council work group reports; (3) election of Council Chairperson and Vice-Chairperson; (4) status of the Council report to the Department and Congress; (5) status of the Technical Assistance and Training Initiative; and (6) status of the PY 2001 Partnership Effort.

FOR FURTHER INFORMATION CONTACT: Mr. James C. DeLuca, Chief, Division of Indian and Native American Programs, Office of National Programs, Employment and Training Administration, U.S. Department of Labor, Room N–4641, 200 Constitution Avenue, N.W., Washington, DC 20210. *Telephone:* (202) 693–3754 (VOICE) or (202) 326–2577 (TDD) (these are not toll-free numbers).

Signed at Washington, DC, this 31st day of May, 2001.

Shirley M. Smith,

Administrator, Office of Adult Services.

[FR Doc. 01–14505 Filed 6–7–01; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

[NAFTA–4287]

ABB/Westinghouse, Hematite Plant, Festus, Missouri; Notice of Negative Determination on Reconsideration

By application dated March 3, 2001, a petitioner requests administrative reconsideration of the Department's negative determination regarding eligibility to apply for North American Free Trade Agreement-Transitional Adjustment Assistance (NAFTA–TAA), applicable to workers and former workers of the subject firm. The denial notice applicable to workers of the subject firm was issued on February 7, 2001, and was published in the **Federal Register** on March 2, 2001 (66 FR 13087).

The petitioner presented new evidence regarding company imports of pellets from Canada.

The Department denied NAFTA–TAA to workers of ABB/Westinghouse, Hematite Plant, Festus, Missouri, producing nuclear fuel rods and pellets because criteria (3) and (4) of the group eligibility requirements of paragraph (a)(1) of section 250 of the Trade Act of 1974, as amended, were not met. There were no company imports of articles like or directly competitive with those produced by the workers. The production at the Festus, Missouri plant was shifted to a country other than Mexico or Canada.

On February 7, all workers of the subject firm were certified eligible to apply for Trade Adjustment Assistance (TA–W–38, 300). That investigation revealed that production at the Festus, Missouri, plant was being transferred to a foreign source outside of the United States, Mexico and Canada. The investigative findings also revealed that company imports, from countries other than Mexico and Canada, of articles like or directly competitive with those produced by the workers in Festus, Missouri, increased significantly.

On reconsideration, the Department has carefully reviewed the materials

submitted by the petitioner with respect to the pellet imports shipped from Canada. This review finds that the company imports from countries other than Mexico or Canada contributed more importantly to declines in sales or production and to worker separations at ABB/Westinghouse, Hematite Plant, Festus, Missouri, than the Canadian imports identified by the petitioner.

Conclusion

After reconsideration, I affirm the original notice of negative determination of eligibility to apply for NAFTA–TAA for workers and former workers of ABB/Westinghouse, Hematite Plant, Festus, Missouri.

Signed at Washington, DC this 24th day of May 2001.

Edward A. Tomchick,

Director, Division of Trade Adjustment Assistance.

[FR Doc. 01–14419 Filed 6–7–01; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[NAFTA–04543, et al.]

AgriFrozen Foods, Woodburn, Oregon, et al.; Amended Certification Regarding Eligibility To Apply for NAFTA Transitional Adjustment Assistance

In accordance with section 250(a), Subchapter 2, Title II, of the Trade Act of 1974, as amended (19 U.S.C. 2273), the Department of Labor issued a Certification of Eligibility to Apply for NAFTA Transitional Adjustment Assistance on April 17, 2001, applicable to workers of AgriFrozen Foods, Woodburn, Oregon. The notice was published in the **Federal Register** on May 3, 2001 (66 FR 22263).

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. The workers are engaged in the production of frozen vegetables. New findings show that worker separations occurred at AgriFrozen Foods' headquarters office in Salem, Oregon and at two production facilities in Grandview and Walla Walla, Washington. Findings also show that all remaining workers of the subject firm will be separated when it closes at the end of June, 2001.

The intent of the Department's certification is to include all workers of AgriFrozen Foods who were adversely affected by an increase in company imports of frozen vegetables from Mexico.

Accordingly, the Department is amending the certification to properly reflect this matter.

The amended notice applicable to NAFTA–04543 is hereby issued as follows:

All workers of AgriFrozen Foods, Woodburn, Oregon (NAFTA–TAA–04543), Salem, Oregon (NAFTA–04543A), Grandview, Washington (NAFTA–04543B) and Walla Walla, Washington (NAFTA–TAA–04543C) who became totally or partially separated from employment on or after February 9, 2000 through April 17, 2003 are eligible to apply for NAFTA–TAA under Section 250 of the Trade Act of 1974.

Signed at Washington, DC this 22nd day of May, 2001.

Edward A. Tomchick,

Director, Division of Trade Adjustment Assistance.

[FR Doc. 01–14422 Filed 6–7–01; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[NAFTA–TAA–04482]

Master Pattern, Inc., Norton Shores, Michigan; Dismissal of Application for Reconsideration

Pursuant to 29 CFR 90.18(C) an application for administrative reconsideration was filed with the Director of the Division of Trade Adjustment Assistance for workers at Master Pattern, Inc., Norton Shores, Michigan. The application contained no new substantial information which would bear importantly on the Department's determination. Therefore, dismissal of the application was issued.

NAFTA–TAA–04482; Master Pattern, Inc. Norton Shores, Michigan (May 23, 2001)

Signed at Washington, DC, this 24th day of May, 2001.

Edward A. Tomchick,

Director, Division of Trade Adjustment Assistance.

[FR Doc. 01–14420 Filed 6–7–01; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[NAFTA–4426]

Southern Oregon Log Scaling and Grading Bureau, Roseburg, Oregon; Notice of Negative Determination Regarding Application for Reconsideration

By application dated March 2, 2001, a petitioner and the Oregon AFL–CIO (petitioners) request administrative reconsideration of the Department's negative determination regarding eligibility to apply for North American Free Trade Agreement-Transitional Adjustment Assistance (NAFTA–TAA), applicable to workers and former workers of the subject firm. The denial notice applicable to workers of Southern Oregon Log Scaling and Grading Bureau, Roseburg, Oregon, was signed on February 9, 2001, and was published in the **Federal Register** on March 2, 2001 (66 FR 13087).

Pursuant to 29 CFR 90.18(c) reconsideration may be granted under the following circumstances:

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) if it appears that the determination complained of was based on a mistake in the determination of facts not previously considered; or

(3) if in the opinion of the Certifying Officer, a misinterpretation of facts or of the law justified reconsideration of the decision.

The petitioners explain that the firm was created about 50 years ago by the timber industry, in cooperation with Federal and State authorities. The Board of Directors of the subject firm has historically been made up of persons representing the timber industry, some of which are the mill owners. The petitioners view is that the subject firm is related by control (to NAFTA–TAA certified worker groups) by its creation, daily operation, and by the make-up of the Board of Directors and their connection to the timber industry in specific and in general.

The NAFTA–TAA petition for workers of the subject firm was denied because the workers provided a service and did not produce an article within the meaning of in paragraph (a)(1) of Section 250 of the Trade Act, as amended. The workers at Southern Oregon Log Scaling and Grading Bureau, in Roseburg, Oregon, measure and grade (appraise) logs for their customers.

A Board of Directors cannot be considered a parent firm, a firm related to the subject firm by ownership, or a firm related by control.

Conclusion

After review of the application and investigative findings, I conclude that there has been no error or misinterpretation of the law or of the facts which would justify reconsideration of the Department of Labor's prior decision. Accordingly, the application is denied.

Signed at Washington, DC this 23rd day of May 2001.

Edward A. Tomchick,

Director, Division of Trade Adjustment Assistance.

[FR Doc. 01–14418 Filed 6–7–01; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment Standards Administration

Wage and Hour Division; Minimum Wage for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study of local wage conditions and data made available from other sources. They specify the basic hourly wage rates and fringe benefits which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of a similar character and in the localities specified therein.

The determinations in these decisions of prevailing rates and fringe benefits have been made in accordance with 29 CFR part 1, by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) (and of other Federal statutes referred to in 29 CFR part 1, Appendix, as well as such additional statutes as may from time to time be enacted containing provisions for the payment of wages determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act. The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public comment procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in the effective date as prescribed in that section, because the necessity to issue current construction industry wage determinations frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions, and modifications and supersedeas decisions thereto, contained no expiration dates and are effective from their date of notice in the **Federal Register**, or on the date written notice is received by the agency, whichever is earlier. These decisions are to be used in accordance with the provisions of 29 CFR parts 1 and 5. Accordingly, the applicable decision, together with any modifications issued, must be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR part 5. The wage rates and fringe benefits, notice of which is published herein, and which are contained in the Government Printing Office (GPO) document entitled ''General Wage Determinations Issued Under The Davis-Bacon And Related Acts,'' shall be the minimum paid by contractors and subcontractors to laborers and mechanics.

Any person, organization, or governmental agency having an interest in the rates determined as prevailing is encouraged to submit wage rate and fringe benefit information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Division of Wage Determinations, 200 Constitution Avenue, NW., Room S–3014, Washington, DC 20210.

Modification to General Wage Determination Decisions

The number of decisions listed to the Government Printing Office document entitled ''General Wage Determination Issued Under the Davis-Bacon and related Acts'' being modified are listed by Volume and State. Dates of publication in the **Federal Register** are in parentheses following the decisions being modified.

Volume I

None

Volume II

Pennsylvania
PA010001 (Mar. 02, 2001)
PA010020 (Mar. 02, 2001)

Volume III

Kentucky
KY010001 (Mar. 02, 2001)
KY010002 (Mar. 02, 2001)
KY010003 (Mar. 02, 2001)
KY010004 (Mar. 02, 2001)
KY010006 (Mar. 02, 2001)
KY010007 (Mar. 02, 2001)
KY010025 (Mar. 02, 2001)
KY010028 (Mar. 02, 2001)
KY010029 (Mar. 02, 2001)
KY010032 (Mar. 02, 2001)
KY010033 (Mar. 02, 2001)
KY010035 (Mar. 02, 2001)
KY010049 (Mar. 02, 2001)

Volume IV

Michigan
MI010017 (Mar. 02, 2001)
MI010081 (Mar. 02, 2001)
MI010082 (Mar. 02, 2001)
MI010084 (Mar. 02, 2001)
Ohio
OH010001 (Mar. 02, 2001)
OH010002 (Mar. 02, 2001)
OH010003 (Mar. 02, 2001)
OH010006 (Mar. 02, 2001)
OH010008 (Mar. 02, 2001)
OH010009 (Mar. 02, 2001)
OH010012 (Mar. 02, 2001)
OH010013 (Mar. 02, 2001)
OH010018 (Mar. 02, 2001)
OH010020 (Mar. 02, 2001)
OH010022 (Mar. 02, 2001)
OH010023 (Mar. 02, 2001)
OH010024 (Mar. 02, 2001)
OH010026 (Mar. 02, 2001)
OH010027 (Mar. 02, 2001)
OH010028 (Mar. 02, 2001)
OH010029 (Mar. 02, 2001)

Volume V

Louisiana
LA010001 (Mar. 02, 2001)
LA010004 (Mar. 02, 2001)
LA010005 (Mar. 02, 2001)
LA010009 (Mar. 02, 2001)
LA010012 (Mar. 02, 2001)
LA010014 (Mar. 02, 2001)
LA010016 (Mar. 02, 2001)
LA010018 (Mar. 02, 2001)
LA010048 (Mar. 02, 2001)
LA010052 (Mar. 02, 2001)
LA010054 (Mar. 02, 2001)

Volume VI

Washington
WA010001 (Mar. 02, 2001)
WA010003 (Mar. 02, 2001)

Volume VII

None

General Wage Determination Publication

General wage determinations issued under the Davis-Bacon and related Acts, including those noted above, may be found in the Government Printing Office (GPO) document entitled ''General Wage Determinations Issued Under The Davis-Bacon And Related Acts''. This publication is available at each of the 50 Regional Government Depository Libraries and many of the 1,400 Government Depository Libraries across the country.

General wage determinations issued under the Davis-Bacon and related Acts are available electronically at no cost on the Government Printing Office site at *www.access.gpo.gov/davisbacon.* They are also available electronically by subscription to the FedWorld Bulletin Board System of the National Technical Information Service (NTIS) of the U.S. Department of Commerce at 1–800–363–2068.

Hard-copy subscriptions may be purchased from: Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, (202) 512–1800.

When ordering hard-copy subscription(s), be sure to specify the State(s) of interest, since subscriptions may be ordered for any or all of the six separate volumes, arranged by State. Subscriptions include an annual edition (issued in January or February) which includes all current general wage determinations for the States covered by each volume. Throughout the remainder of the year, regular weekly updates will be distributed to subscribers.

Signed at Washington, DC this 31st day of May 2001.

Carl J. Poleskey,

Chief, Branch of Construction Wage Determinations.

[FR Doc. 01–14190 Filed 6–7–01; 8:45 am]

BILLING CODE 4510–27–M

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Proposed Information Collection Request Submitted for Public Comment and Recommendations; Safety Defects, Examination, Correction, and Records

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

DATES: Submit comments on or before August 7, 2001.

ADDRESSES: Send comments to Brenda C. Teaster, Acting Chief, Records Management Division, 4015 Wilson Boulevard, Room 709A, Arlington, VA 22203–1984. Commenters are encouraged to send their comments on a computer disk, or via Internet E-mail to bteaster@msha.gov, along with an original printed copy. Ms. Teaster can be reached at (703) 235–1470 (voice), or (703) 235–1563 (facsimile).

FOR FURTHER INFORMATION CONTACT: Brenda C. Teaster, Acting Chief, Records Management Division, U.S. Department of Labor, Mine Safety and Health Administration, Room 709A, 4015 Wilson Boulevard, Arlington, VA 22203–1984. Ms. Teaster can be reached at bteaster@msha.gov (Internet E-mail), (703) 235–1470 (voice), or (703) 235–1563 (facsimile).

SUPPLEMENTARY INFORMATION:

I. Background

Title 30 CFR 56.13015 and 57.13015 require compressed-air receivers and other unfired pressure vessels be inspected by inspectors holding a valid National Board Commission and in accordance with the applicable chapters of the National Board Inspection Code, a manual for Boiler and Pressure Vessels Inspectors, 1979.

Title 30 CFR 56.13030 and 57.13030 require that fired pressure vessels (boilers) be equipped with safety devices approved by the American Society of Mechanical Engineers (ASME) to protect against hazards from overpressure, flameouts, fuel interruptions and low water level. 56/57.13030 require that records of inspections and repairs be retained by the mine operator in accordance with the requirements of the ASME Boiler and Pressure Vessel Code and the National Board Inspection Code (progressive records—no limit on retention time) and made available to the Secretary or his/her authorized representative.

Title 30 CFR 56.14100 and 57.14100 require equipment operators to inspect equipment, machinery, and tools that are to be used during a shift for safety defects before the equipment is placed in operation. Defects affecting safety are required to be corrected in a timely manner. In instances where the defect makes continued operation of the equipment unsafe, the standards require removal from service, tagging to identify that it is out of use, and repair before use is resumed.

Title 30 CFR 56.18002 and 57.180002 require that a competent person designated by the operator shall examine each working place at least once each shift for conditions which may adversely affect safety or health. A record that such examinations were conducted shall be kept by the operator for a period of one year, and shall be made available for review by the Secretary or his/her authorized representative.

II. Desired Focus of Comments

Currently, the Mine Safety and Health Administration (MSHA) is soliciting comments concerning the proposed extension of the information collection related to the Safety Defects, Examination, Correction, and Records. MSHA is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technolgy, e.g., permitting electronic submissions of responses. A copy of the proposed information collection request may be viewed on the Internet by accessing the MSHA Home Page (*http://www.msha.go*) and selecting ''Statutory and Regulatory Information'' then ''Paperwork Reduction Act submission (*http://www.msha.gov/regspwork.htm*)'', or by contacting the employee listed above in the **FOR FURTHER INFORMATION CONTACT** section of this notice for a hard copy.

III. Current Actions

Additionally, the inspection records denote any hazards that were discovered and how the hazards or unsafe conditions were abated. Federal inspectors use the records to ensure that unsafe conditions are identified early and corrected.

Type of Review: Extension.

Agency: Mine Safety and Health Administration.

Title: Safety Defects, Examination, Correction, and Records of Pressure Vessels, Equipment, Machinery and Working Places technology, e.g., permitting electronic submissions of responses.

Cite/reference	Total respondents	Frequency	Total responses	Average time per response (minutes)	Burden hours*
56/56.13015	13,074	Annually	4,148	5 min.	345
56/57.13030	13,074	Annually	7,464	5 min.	621
56/57.14100	13,074	Daily	11,685,509	5 min.	822,089
56/57.18002	13,074	Daily	1,638,940	23 min.	650,390
Totals	13,074		13,336,061		1,473,445

*Discrepancies due to rounding.

Total Burden Cost (capital/startup): $0.

Total Burden Cost (operating/maintaining): $0.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: May 30, 2001.

Brenda C. Teaster,

Acting Chief, Records Management Division.

[FR Doc. 01–14425 Filed 6–7–01; 8:45 am]

BILLING CODE 4510–43–M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. ICR–1218–0003(2001)]

Gear-Certification Forms (29 CFR Part 1919); Extension of the Office of Management and Budget's (OMB) Approval of Information-Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice of an opportunity for public comment.

SUMMARY: OSHA solicits comments concerning its request to decrease the existing burden-hour estimates for, and to extend OMB approval of, the information-collection requirements specified in the gear-certification forms required by 29 CFR part 1919 (''Gear Certification''). The reference numbers and titles of these forms are 70 (''Application for Accreditation to Perform Gear Certification Functions''; Rev. July 1993), 71 (''Certificate of Unit Test and/or Examination of Crane, Derrick, or Other Material''; Rev. July 1993), and 72 (''Notice to Owner of Deficiencies Found on Certification Survey''; Rev. July 1993). The Agency believes these forms provide an effective and efficient means to apply for accreditation to certify material-handling devices used in marine terminals and longshoring, and for OSHA, employers, and employees to determine if these devices are safe to operate.

DATES: Submit written comments on or before August 7, 2001.

ADDRESSES: Submit written comments to the Docket Office, Docket No. ICR–1218–0003(2001), OSHA, U.S. Department of Labor, Room N–2625, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693–2350. Commenters may transmit written comments of 10 pages or less in length by facsimile to (202) 693–1648.

FOR FURTHER INFORMATION CONTACT: Theda Kenney, Directorate of Safety Standards Programs, OSHA, U.S. Department of Labor, Room N–3609, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693–2222. A copy of the Agency's Information-Collection Request (ICR) supporting the need for the information collections specified in OSHA gear-certification forms 70, 71, and 72 is available for inspection and copying in the Docket Office or by requesting a copy from Theda Kenney at (202) 693–2222 or Todd Owen at (202) 693–2444. For electronic copies of the ICR contact OSHA on the Internet at http://www.osha.gov/comp-links.html, and select ''Information Collection Requests.''

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of its continuing effort to reduce paperwork and respondent (i.e., employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information-collection requirements in accordance with the Paperwork Reduction Act of 1995 (PRA–95) (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collection instruments are understandable, and OSHA's estimate of the information-collection burden is correct. The Occupational Safety and Health Act of 1970 authorizes information collection by employers as necessary or appropriate for enforcement of the Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents. (29 U.S.C. 657.)

The provisions of 29 CFR part 1919 (''Gear Certification'') require the use of three gear-certification forms. The reference numbers and titles of these forms are 70 (''Application for Accreditation to Perform Gear Certification Functions''; Rev. July 1993), 71 (''Certificate of Unit Test and/or Examination of Crane, Derrick, or Other Material''; Rev. July 1993), and 72 (''Notice to Owner of Deficiencies Found on Certification Survey''; Rev. July 1993).

Paragraph (a) of § 1919.3 (''Application for Accreditation'') specifies that a person (i.e., an individual, partnership, corporation, agency, association, or organization) seeking accreditation from OSHA to test and examine material-handling devices as required by parts 1917 (''Marine Terminals'') and 1918 (''Longshoring'') must file an application form provided by the Agency; OSHA currently uses form 70 for this purpose. The form collects principally information regarding the applicant's past experience in testing and examining material-handling devices. This Information is necessary for the Agency to evaluate the applicant's competence to test and examine these devices, and

serves as the basis for accrediting the applicant to certify the devices for safe operation. Once accredited, OSHA designates the applicant as an ''accredited person.''

Under paragraph (a) and (b) of § 1919.90 (''Documentation''), if an accredited person tests and examines a material-handling device and finds that it is in compliance with applicable Agency requirements, they must certify the device using a form approved by OSHA; currently, the Agency authorizes accredited persons to use of form 71 to certify these devices. Form 71 collects the following information: Name of the device's owner; a description of the device (i.e., type, manufacturer, model, serial number, owner's identification (if any), and boom length and type); the location of the device; service status (i.e., lifting, clamshell, magnet, or other); test loads applied (i.e., radius, proof loads, rated loads, means used to apply the proof load, and the basis for assigning load ratings), remarks and limitations; presence of fitted and non-fitted devices indicating load or limit, including the accuracy of these devices; the name and address of the accredited or otherwise authorized organization conducting the test and/or examination; the name, address, and signature of the authorized person conducting the test and/or examination; the position of the signatory in the organization conducting the test and/or examination; and the certification date. This information is necessary to accurately identify the certified device, ensure that it underwent proper testing and examination, specify any operating limitations, and ensure that an authorized person conducted the tests and examinations and provided certification. Accordingly, form 71 assures employers and employees that an accredited person properly administered the applicable testing and examination requirements and found the device safe to operate under the conditions specified in the certificate.

The Agency adopted form 72 in response to paragraph (a) of § 1919.12 (''Recordkeeping and Related Procedures Concerning Records in Custody of the Vessel''), which requires completion and maintenance of a register that describes detailed findings of inspections and examinations conducted under specified provisions of 29 CFR part 1919. While form 71 provides findings that support certification of material-lifting devices, OSHA approved form 72 to document deficiencies found during a certification survey. The information requested by form 72 includes: Name of the device's owner; identification, location, and specific description of the device; a detailed description of each deficiency found during the survey; and the same information regarding the accredited or otherwise authorized organization, authorized person, and signatory conducting the test and/or examination contained on form 71. Similar to form 71, the information on this form permits employers and employees to readily identify deficient material-lifting devices and to avoid operating them. In addition, form 72 informs mechanics regarding the servicing and repair problems of deficient devices. Prior to returning a device to service, employers can review the form to ensure that the mechanics performed the necessary repairs and maintenance.

Taken together, forms 71 and 72 ensure that employers use only devices that are in safe working order, thereby preventing serious injury and death to operators and other employees who use or work near the devices. These forms also provide the most efficient means for an OSHA compliance officer to determine the operating status of a device and that employers are using only properly certified devices.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information-collection requirements are necessary for the proper performance of the Agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and cost) of the information-collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information-collection and -transmission techniques.

III. Proposed Actions

OSHA is requesting a decrease in the existing burden-hour estimate for, as well as an extension of OMB approval of, the collection-of-information requirements specified in its gear-certification forms 70, 71, and 72. Accordingly, the Agency is requesting to decrease the current burden-hour estimate from 93 hours to 76 hours, a total reduction of 17 hours. This reduction occurred because of a decrease in the time estimated for employers to provide forms 71 and 72 to an OSHA compliance officer during an inspection. The Agency will summarize the comments submitted in response to this notice, and will include this summary in its request to OMB to extend its approval of these information-collection requirements.

Type of Review: Extension of currently approved information-collection requirements.

Title: Gear-Certification Forms.

OMB Number: 1218–0003.

Affected Public: Business or other for-profit; not-for-profit institutions; Federal government; State, local or tribal governments.

Number of Respondents: 80.

Frequency of Response: Quadrennially; annually.

Average Time per Response: Varies from 2 minutes (.03 hour) for an employer to retrieve a copy of form 71 or 72 during an OSHA inspection to 45 minutes (.75 hour) for an applicant to complete form 70.

Estimated Total Burden Hours: 76.

Estimated Cost (Operation and Maintenance): $713,181.

IV. Authority and Signature

R. Davis Layne, Acting Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506) and Secretary of Labor's Order No. 3–2000 (65 FR 50017).

Signed at Washington, DC on June 4, 2001.

R. Davis Layne,

Acting Assistant Secretary of Labor.

[FR Doc. 01–14499 Filed 6–7–01; 8:45 am]

BILLING CODE 4510–26–M

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice.

SUMMARY: NARA is giving public notice that the agency proposes to request extension of a currently approved information collection prepared by organizations that want to make paper-to-paper copies of archival holdings with their personal copiers. The public is invited to comment on the proposed information collection pursuant to the Paperwork Reduction Act of 1995.

DATES: Written comments must be received on or before August 7, 2001 to be assured of consideration.

ADDRESSES: Comments should be sent to: Paperwork Reduction Act Comments

(NHP), Room 4400, National Archives and Records Administration, 8601 Adelphi Rd, College Park, MD 20740–6001; or faxed to 301–713–6913; or electronically mailed to tamee.fechhelm@nara.gov.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the proposed information collections and supporting statements should be directed to Tamee Fechhelm at telephone number 301–713–6730, or fax number 301–713–6913.

SUPPLEMENTARY INFORMATION: Pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13), NARA invites the general public and other Federal agencies to comment on proposed information collections. The comments and suggestions should address one or more of the following points: (a) Whether the proposed collection information is necessary for the proper performance of the functions of NARA; (b) the accuracy of NARA's estimate of the burden of the proposed information collections; (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 the use of information technology. The comments that are submitted will be summarized and included in the NARA request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this notice, NARA is soliciting comments concerning the following information collection:

Title: Request to use personal paper-to-paper copiers at the National Archives at the College Park facility.

OMB number: 3095–0035.

Agency form number: None.

Type of review: Regular.

Affected public: Business or other for-profit.

Estimated number of respondents: 5.

Estimated time per response: 3 hours.

Frequency of response: On occasion.

Estimated total annual burden hours: 15 hours.

Abstract: The information collection is prescribed by 36 CFR 1254.71(e). Respondents are organizations that want to make paper-to-paper copies of archival holdings with their personal copiers. NARA uses the information to determine whether the request meets the criteria in 36 CFR 1254.71(e) and to schedule the limited space available.

Dated: June 4, 2001.

L. Reynolds Cahoon,

Assistant Archivist for Human Resources and Information Services.

[FR Doc. 01–14509 Filed 6–7–01; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL SCIENCE FOUNDATION

Committee Management; Notice of Establishment

The Deputy Director of the National Science Foundation has determined that the ten committees listed below are necessary and in the public interest in connection with the performance of duties imposed upon the National Science Foundation (NSF), by 42 U.S.C. 1861 *et seq.* This determination follows consultation with the Committee Management Secretariat, General Services Administration.

Name of Committee: Proposal Review Panel for Biological Infrastructure (10743).

Purpose: Advise NSF on the merit of proposals requesting financial support of research and research-related activities under the purview of the Division of Biological Infrastructure.

Name of Committee: Proposal Review Panel for Environmental Biology (10744).

Purpose: Advise NSF on the merits of proposals requesting financial support of research and research-related activities under the purview of the Division of Environmental Biology.

Name of Committee: Proposal Review Panel for Integrative Biology and Neuroscience (10745).

Purpose: Advise NSF on the merit of proposals requesting financial support of research and research-related activities under the purview of the Division of Integrative Biology and Neuroscience.

Name of Committee: Proposal Review Panel Molecular and Cellular Biosciences (10746).

Purpose: Advise NSF on the merit of proposals requesting financial support of research and research-related activities under the purview of the Division of Molecular and Cellular Biosciences.

Name of Committee: Proposal Review Panel for Atmospheric Sciences (10751).

Purpose: Advise NSF on the merit of proposals requesting financial support of research and research-related activities under the purview of the Division of Atmospheric Sciences.

Name of Committee: Proposal Review Panel for Ocean Sciences (10752).

Purpose: Advise NSF on the merit of proposals requesting financial support of research and research-related activities under the purview of the Division of Ocean Sciences.

Name of Committee: Proposal Review Panel for Behavioral and Cognitive Sciences (10747).

Purpose: Advise NSF on the merit of proposals requesting financial support of research and research-related activities under the purview of the Division of Behavioral and Cognitive Sciences.

Name of Committee: Proposal Review Panel for Social and Economic Sciences (10748).

Purpose: Advise NSF on the merit of proposals requesting financial support of research and research-related activities under the purview of the Division of Social and Economic Sciences.

Name of Committee: Proposal Review Panel for International Programs (10749).

Purpose: Advise NSF on the merit of proposals requesting financial support of research and research-related activities under the purview of the Division of International Programs.

Name of Committee: Advisory Panel for Science Resource Studies (10750).

Purpose: Advise NSF on the survey preparation, fielding, and analysis plans and interpretation of survey findings under the purview of the Division of Science Resource Studies.

NSF Contact: Ms. Susanne Bolton, Committee Management Officer, National Science Foundation, 4201 Wilson Boulevard, Suite 315, Arlington, VA 22230, telephone, (703) 292–7488.

Susanne Bolton,

Committee Management Officer.

[FR Doc. 01–14500 Filed 6–7–01; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL SCIENCE FOUNDATION

Committee Management; Renewals

The NSF management officials having responsibility for the four advisory committees listed below have determined that renewing these groups for another two years is necessary and in the public interest in connection with the performance of duties imposed upon the Director, National Science Foundation (NSF), by 42 U.S.C. 1861 *et seq.* The committees will be renamed (the current name is in parenthesis). The committee number is to stay the same. This determination follows consultation with the Committee Management Secretariat, General Services Administration.

1. #1756—Proposal Review Panel for Earth Sciences (Earth Sciences Proposal Review Panel)
2. #1569—Proposal Review for Geosciences (Special Emphasis Panel in Geosciences)
3. #1766—Proposal Review Panel for Social, Behavioral, and Economic Sciences (Special Emphasis Panel in Social, Behavioral and Economic Sciences)
4. #1373—Advisory Panel for Integrative Activities (Special Emphasis Panel in Integrative Activities)

Authority for these Committees will expire on June 30, 2003, unless they are

renewed. For more information, please contact Susanne Bolton, NSF, at (703) 292–7488.

Dated: June 5, 2001.

Susanne Bolton,

Committee Management Officer.

[FR Doc. 01–14502 Filed 6–7–01; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL SCIENCE FOUNDATION

Committee Management; Renewals

The NSF management officials having responsibility for the seven advisory committees listed below have determined that renewing these groups for another two years is necessary and in the public interest in connection with the performance of duties imposed upon the Director, National Science Foundation (NSF), by 42 U.S.C. 1861 *et seq.* This determination follows consultation with the Committee Management Secretariat, General Services Administration.

1. Advisory Committee for Small Business Industrial Innovation (#61)
2. Advisory Committee for Biological Sciences (#1110)
3. Advisory Committee for Education & Human Resources (#1119)
4. Advisory Committee for Polar Programs (#1130)
5. Advisory Committee for Engineering (#1170)
6. Alan T. Waterman Award Committee (#1172)
7. Advisory Committee for Geosciences (#1755)

Authority for these Committees will expire on June 30, 2003, unless they are renewed. For more information, please contact Susanne Bolton, NSF, at (703) 292–7488.

Dated: June 5, 2001.

Susanne Bolton,

Committee Management Officer.

[FR Doc. 01–14501 Filed 6–7–01; 8:45 am]

BILLING CODE 7555–01–M

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–482]

Kansas City Power & Light Company (Wolf Creek Generating Station); Order Approving Application Regarding Proposed Corporate Restructuring

I

Kansas City Power & Light Company (KCPL) holds a 47 percent ownership interest in Wolf Creek Generating Station (WCGS) and in connection therewith is a holder of Facility Operating License No. NPF–42. The facility is located in Coffey County, Kansas. The other co-owner licensees for WCGS are Kansas Gas & Electric Company (KGE) (with a 47 percent share of WCGS), and Kansas Electric Power Cooperative, Inc. (KEPCo) (with a 6 percent share). Wolf Creek Nuclear Operating Corporation (WCNOC) is the licensed operator of WCGS, and KCPL also owns a 47 percent interest in WCNOC, with KGE and KEPCo owning 47 percent and 6 percent interests in WCNOC, respectively. KCPL, as well as KGE and KEPCo, hold possession-only licenses.

II

Pursuant to section 184 of the Atomic Energy Act of 1954, as amended, and 10 CFR 50.80, KCPL filed an application dated February 20, 2001, which was supplemented by submittals dated February 27, March 5, March 8, March 28, and May 4, 2001, from counsel for KCPL, requesting approval of the indirect transfer of the WCGS license, to the extent such would result from the proposed restructuring of KCPL. As stated in the application, the proposed restructuring encompasses the formation by KCPL of a new holding company as yet unnamed (''*HoldingCo*''). Upon the proposed restructuring, KCPL will cease to be publicly-traded and become a wholly-owned subsidiary of *HoldingCo,* but will retain ownership of its regulated electric power generation, transmission, and distribution assets, including its interests in WCGS and WCNOC. No direct transfer of the license to *HoldingCo* or otherwise is being proposed. WCNOC would remain as the managing agent for the joint owner licensees (KCPL, KGE, and KEPCo) of the facility and would continue to have exclusive responsibility for the management, operation, and maintenance of WCGS as the non-owner operator licensee. The application does not propose a change in the rights, obligations, or interests of the licensees of WCGS. In addition, no physical changes to WCGS or operational changes are being proposed.

KCPL stated that it and *HoldingCo* will be able to respond more effectively to increased competition in the energy industry and pursue pending unregulated electric generation ventures as a result of the new corporate structure.

Notice of the application and an opportunity for hearing was published in the **Federal Register** on May 2, 2001 (66 FR 22019). No written comments or hearing requests were received.

Under 10 CFR 50.80, no license shall be transferred, directly or indirectly, through transfer of control of the license, unless the Commission gives its consent in writing. Upon review of the information provided by KCPL in its application, the supplements thereto, and other information before the Commission, the NRC staff has determined that the proposed restructuring will not affect the qualifications of KCPL or WCNOC as holders of the license referenced above and that the indirect transfer of the license, to the extent effected by the proposed restructuring of KCPL, is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission, subject to the conditions set forth herein. These findings are supported by a safety evaluation dated June 1, 2001.

III

Accordingly, pursuant to sections 161b, 161i, 161o, and 184 of the Atomic Energy Act of 1954, as amended, 42 USC §§ 2201(b), 2201(i), 2201(o), and 2234; and 10 CFR 50.80, *it is hereby ordered* that the application regarding the proposed restructuring of KCPL and indirect license transfer is approved, subject to the following conditions:

(1) KCPL shall provide the Director of the Office of Nuclear Reactor Regulation a copy of any application, at the time it is filed, to transfer (excluding grants of security interests or liens) from KCPL to its proposed parent, or to any other affiliated company, facilities for the production, transmission, or distribution of electric energy having a depreciated book value exceeding 10 percent (10%) of KCPL's consolidated net utility plant as recorded on KCPL's books of account.

(2) Should the proposed restructuring of KCPL not be completed by June 1, 2002, this Order shall become null and void, provided, however, upon application and for good cause shown, such date may be extended.

This Order is effective upon issuance.

For further details with respect to this action, see the license transfer application filed by KCPL dated February 20, 2001, and the supplemental submittals dated February 27, March 5, March 8, March 28, and May 4, 2001, from counsel for KCPL, and the safety evaluation dated June 1, 2001, which are available for public inspection at the Commission's Public Document Room located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland, and accessible electronically through the ADAMS Public Electronic Reading

Room link at the NRC Web site (http://www.nrc.gov).

Dated at Rockville, Maryland, this first day of June 2001.

For the Nuclear Regulatory Commission.

Jon R. Johnson,

Acting Director, Office of Nuclear Reactor Regulation.

[FR Doc. 01–14495 Filed 6–7–01; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY ADMINISTRATION

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Nuclear Regulatory Commission.

DATE: Weeks of June 11,18, 25, July 2, 9, 16, 2001.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Maryland.

STATUS: Public and Closed.

MATTERS TO BE CONSIDERED:

Week of June 11, 2001

Thursday, June 14, 2001

9:55 a.m; Affirmation Session (Public Meeting) (If needed)

10:00 a.m; Meeting with Nuclear Waste Technical Review Board (Public Meeting)

1:30 p.m; Briefing on License Renewal Program (Public Meeting) (Contact: David Solorio, 301–415–1973)

Week of June 18, 2001—Tentative

There are no meetings scheduled for the Week of June 18, 2001.

Week of June 25, 2001—Tentative

Wednesday, June 27, 2001

9:25 a.m; Affirmation Session (Public Meeting) (If needed)

Week of July 2, 2001—Tentative

There are no meetings scheduled for the Week of July 2, 2001.

Week of July 9, 2001—Tentative

Monday, July 9, 2001

1:25 p.m; Affirmation Session (Public Meeting) (If needed)

Week of July 16, 2001—Tentative

Thursday, July 19, 2001

9:25 a.m; Affirmation Session (Public Meeting) (If needed)

9:30 a.m; Briefing on Results of Agency Action Review Meeting—Reactors (Public Meeting) (Contact: Ron Frahm, 301–415–2986)

1:30 p.m; Briefing on Readiness for New Plant Applications and Construction (Public Meeting) (Contact: Nanette Gilles, 301–415–1180)

Friday, July 20, 2001

9:30 a.m; Briefing on Results of Reactor Oversight Process Initial Implementation (Public Meeting) (Contact: Tim Frye, 301–415–1287)

1:00 p.m; Briefing on Risk-Informing Special Treatment Requirements (Public Meeting) (Contact: John Nakoski, 302–415–1278)

* * * * *

The NRC Commission Meeting Schedule can be found on the Internet at: http://www.nrc.gov/SECY/smj/schedule.htm

* * * * *

This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it, or would like to be added to 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 you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to dkw@nrc.gov.

Dated: June 5, 2001.

David Louis Gamberoni,

Technical Coordinator, Office of the Secretary.

[FR Doc. 01–14594 Filed 6–6–01; 12:20 pm]

BILLING CODE 7590–01–M

OVERSEAS PRIVATE INVESTMENT CORPORATION

Sunshine Act Meeting

TIME AND DATE: Tuesday, June 19, 2001, 1 PM (OPEN Portion) 1:30 PM (CLOSED Portion)

PLACE: Offices of the Corporation, Twelfth Floor Board Room, 1100 New York Avenue, NW., Washington, DC

STATUS: Meeting OPEN to the Public from 1 PM to 1:30 PM Closed portion will commence at 1:30 PM (approx.)

MATTERS TO BE CONSIDERED:

1. President's Report
2. Approval of December 12, 2000 Minutes (Open Portion)

FURTHER MATTERS TO BE CONSIDERED: (Closed to the Public 1:30 PM)

1. Finance Project in Peru
2. Finance Project in Brazil
3. Finance Project in Argentina
4. Insurance Project in Nigeria
5. Approval of December 12, 2001 Minutes (Closed Portion)
6. Pending Major Projects
7. Reports

CONTACT PERSON FOR INFORMATION: Information on the meeting may be obtained from Connie M. Downs at (202) 336–8438.

Connie M. Downs,

OPIC Corporate Secretary.

[FR Doc. 01–14567 Filed 6–6–01; 10:21 am]

BILLING CODE 3210–01–M

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of filings and Information Services, Washington, DC 20549

Extension

Rule 17a–5(c); SEC File No. 270–199; OMB Control No. 3235–0199.

Rule 17a–7; SEC File No. 270–147; OMB Control No. 3235–0131.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collections of information summarized below. The Commission plans to submit these existing collections of information to the Office of Management and Budget for extension and approval.

Rule 17a–5(c) under the Securities Exchange Act of 1934 requires certain broker-dealers who carry customer accounts to provide statements of financial condition to their customers. It is estimated that approximately 659 broker and dealer respondents with approximately 97,600,000 customer accounts incur an average burden of 542,222 hours per year to comply with this rule.

Rule 17a–5(c) does not contain record retention requirements. Compliance with the rule is mandatory. Responses are not confidential.

Rule 17a–7 under the Securities Exchange Act of 1034 requires non-resident brokers or dealers registered or applying for registration pursuant to Section 15 of the Exchange Act to maintain—in the United States—complete and current copies of books and records required to be maintained under any rule adopted under the Securities Exchange Act of 1934. Alternatively, Rule 17a–7 provides that the non-resident broker or dealer may sign a written undertaking to furnish the requisite books and records to the Commission upon demand.

There are approximately 72 non-resident brokers and dealers. Based on

the Commission's experience in this area, it is estimated that the average amount of time necessary to preserve the books and records required by Rule 17a–7 is one hour per year. Accordingly, the total burden is 72 hours per year.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

Written 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. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Direct your written comments to Michael E. Bartell, Associate Executive Director, Office of Information Technology, Securities and Exchange Commission, 450 5th Street, NW., Washington, DC 20549.

Dated: June 4, 2001.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–14458 Filed 6–7–01; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

Extension

Rule 8c–1; SEC File No. 270–455; OMB Control No. 3235–0514.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for approval.

Rule 8c–1 generally prohibits a broker-dealer from using its customers' securities as collateral to finance its own trading, speculating, or underwriting transactions. More specifically, the rule states three main principles: First, that a broker-dealer is prohibited from commingling the securities of different customers as collateral for a loan without the consent of each customer; second, that a broker-dealer cannot commingle customers' securities with its own securities under the same pledge; and third, that a broker-dealer can only pledge its customers' securities to the extent that customers are in debt to the broker-dealer. *See* Securities Exchange Act Release No. 2690 (November 15, 1940); Securities Exchange Act Release No. 9428 (December 29, 1971). Pursuant to Rule 8c–1, respondents must collect information necessary to prevent the hypothecation of customer accounts in contravention of the rule, issue and retain copies of notices to the pledgee of hypothecation of customer accounts in accordance with the rule, and collect written consents from customers in accordance with the rule. The information is necessary to ensure compliance with the rule, and to advise customers of the rule's protections.

There are approximately 231 respondents per year (*i.e.,* broker-dealers that conducted business with the public, filed Part II of the FOCUS Report, did not claim an exemption from the Reserve Formula computation, and reported that they had a bank loan during at least one quarter of the current year) that require an aggregate total of 5,198 hours to comply with the rule. Each of these approximately 231 registered broker-dealers makes an estimated 45 annual responses, for an aggregate total of 10,395 responses per year. Each response takes approximately 0.5 hours to complete. Thus, the total compliance burden per year is 5,198 burden hours. The approximate cost per hour is $20, resulting in a total cost of compliance for the respondents of $103,960 (5,198 hours @ $20 per hour).

Written comments are invited one: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the 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. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Direct your written comments to Michael E. Bartell, Associate Executive Director, Office of Information Technology, Securities and Exchange Commission, 450 5th Street, NW., Washington, DC 20549.

Dated: May 31, 2001.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–14459 Filed 6–7–01; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94–409, that the Securities and Exchange Commission will hold the following meeting during the week of June 11, 2001.

A closed meeting will be held on Tuesday, June 12, 2001, at 10 a.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(5), (7), (9)(A), 9(B), and (10) and 17 CFR 200.402(a)(5), (7), (9)(i), (9)(ii) and (10), permit consideration of the scheduled matters at the closed meeting.

The subject matters of the closed meeting scheduled for Tuesday, June 12, 2001 will be: institution and settlement of injunctive actions; and institution and settlement of administrative proceedings of an enforcement nature.

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: June 5, 2001.

Jonathan G. Katz,

Secretary.

[FR Doc. 01–14574 Filed 6–6–01; 11:06 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–44383; File Nos. SR–Amex–2001–18; SR–CBOE–2001–15; SR–ISE–2001–07; SR–PCX–2001–18; and SR–Phlx–2001–37]

Self-Regulatory Organizations: Order Aproving Proposed Rule Changes, as Amended, and Notice of Filing and Order Granting Accelerated Approval of Amendment No. 3 to Proposed Rule Changes by the American Stock Exchange LLC, Amendment Nos. 2 and 3 by the Chicago Board Options Exchange, Inc., Amendment No. 2 by the International Securities Exchange LLC, Amendment No. 2 by the Pacific Exchange, Inc., and Amendments Nos. 3, 4, and 5 by the Philadelphia Stock Exchange, Inc. Relating to the Application of the Quote Rule to Options Trading

June 1, 2001.

On March 15, 2001, the American Stock Exchange LLC (''Amex''); on March 30, 2001, the Chicago Board Options Exchange, Inc. (''CBOE''); on February 28, 2001, the International Securities Exchange LLC (''ISE''); on March 29, 2001, the Pacific Exchange, Inc. (''PCX''); and on March 12, 2001, the Philadelphia Stock Exchange, Inc. (''Phlx'') (referred to collectively as ''Exchanges'') filed with the Securities and Exchange Commission (''Commission'' or ''SEC''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'') [1] and Rule 19b–4 thereunder,[2] proposed rule changes relating to the implementation of sixty-day pilot programs to conform the Exchanges' rules to Rule 11Ac1–1 under the Exchange Act (''Quote Rule'') [3] by the compliance date of April 1, 2001.[4]

Amex submitted to the Commission Amex Amendment No. 1 to its proposed rule change on March 21, 2001 [5] and Amex Amendment No. 2 on March 28, 2001.[6] CBOE filed CBOE Amendment No. 1 to its proposed rule change on March 30, 2001.[7] ISE submitted ISE Amendment No. 1 to its proposal on March 30, 2001.[8] The PCX submitted PCX Amendment No. 1 on March 29, 2001.[9] The Phlx submitted Phlx Amendment No. 1 to its proposal on March 16, 2001 [10] and Phlx Amendment No. 2 on March 29, 2001.[11] Notice of the Exchanges' proposed rule changes, as amended, and an order granting partial accelerated approval of the proposed rule changes on a sixty-day basis (''Pilot Programs'') was published in the **Federal Register** on April 10, 2001.[12] The Commission received two comment letters regarding the Exchanges' proposed rule changes, as amended.[13]

On May 30, 2001, the Amex submitted Amex Amendment No. 3 to its pilot program; [14] on June 1, 2001, the CBOE submitted CBOE Amendment No. 2 to its pilot program; [15] on June 1, 2001, the CBOE submitted CBOE Amendment No. 3 to its pilot program; [16] on May 30, 2001, the ISE submitted ISE Amendment No. 2 to its pilot program; [17] on May 23, 2001, the PCX submitted PCX Amendment No. 2 to its pilot program, [18] on May 11, 2001, the Phlx submitted Phlx Amendment No. 3 to its pilot program; [19] on May 21, 2001, Phlx submitted Phlx Amendment No. 4; [20] and on May 29, 2001, the Phlx submitted Phlx Amendment No. 5 to its pilot program.[21] The Commission is approving the Pilot Program on a permanent basis, as amended, and publishing this notice to solicit comments on Amex Amendment No. 3, CBOE Amendment Nos. 2 and 3, ISE Amendment No. 2, PCX, Amendment No. 2, and Phlx Amendment Nos. 3, 4, and 5 from interested persons.[22] As discussed below, the Commission also

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.11Ac1–1.

[4] Securities Exchange Act Release No. 43591 (November 17, 2000), 65 FR 75439 (December 1, 2000) (''Adopting Release'').

[5] *See* letter from Claire P. McGrath, Vice President and Special Counsel, Derivative Securities, Amex, to Nancy Sanow, Assistant Director, Division of Market Regulation (''Division''), Commission, dated March 20, 2001 (''Amex Amendment No. 1'').

[6] *See* letter from Claire P. McGrath, Vice President and Special Counsel, Derivative Securities, Amex, to Nancy Sanow, Assistant Director, Division, Commission, dated March 27, 2001 (''Amex Amendment No. 2'').

[7] *See* letter from Madge M. Hamilton, Legal Division, CBOE, to Nancy Sanow, Assistant Director, Division, Commission, dated March 30, 2001 (''CBOE Amendment No. 1'').

[8] *See* letter from Michael Simon, Senior Vice President and General Counsel, ISE, to Nancy Sanow, Assistant Director, Division, Commission, dated March 29, 2001 (replacing Form 19b–4 in its entirety) (''ISE Amendment No. 1'').

[9] *See* letter from Michael D. Pierson, Senior Vice President Regulatory Policy, PCX, to John Roeser, Division, Commission, dated March 29, 2001 (''PCX Amendment No. 1'').

[10] *See* letter from Richard S. Rudolph, Counsel, Phlx, to Nancy J. Sanow, Assistant Director, Division, Commission, dated March 15, 2001 (''Phlx Amendment No. 1'').

[11] *See* letter from Richard S. Rudolph, Counsel, Phlx, to Nancy J. Sanow, Assistant Director, Division, Commission, dated March 28, 2001 (''Phlx Amendment No. 2'').

[12] Securities Exchange Act Release No. 44145 (April 2, 2001), 66 FR 18662 (April 10, 2001) (''Pilot Approval Order'').

[13] *See* letter from Meyer S. Frucher, Chairman and Chief Executive Officer, Phlx, to Jonathan G. Katz, Secretary, Commission, dated May 2, 2001 (''Phlx Letter'') and electronic mail message from Mike Ianni, sent May 17, 2001 (''Ianni Letter'').

[14] *See* letter from Claire P. McGrath, Vice President and Special Counsel, Derivative Securities, Amex, to Nancy J. Sanow, Assistant Director, Division, Commission, dated May 30, 2001 (''Amex Amendment No. 3''). In Amex Amendment No. 3, Amex requested permanent approval of its pilot rules, codified an exemption granted by the Commission regarding the treatment of foreign broker-dealers, made conforming changes to better reference the Quote Rule, and clarified that when there is an error in size, the responsible broker or dealer is obligated for ten contracts.

[15] *See* letter from Madge M. Hamilton, Legal Division, CBOE, to Nancy Sanow, Assistant Director, Division, Commission, dated May 31, 2001 (''CBOE Amendment No. 2''). In CBOE Amendment No. 2, CBOE requested permanent approval of its pilot rules, implemented non-substantive reorganization to the rule text, and deleted a provision proposed in its initial filing that had not been approved as part of the Pilot Approval Order relating to multiple orders from the same beneficial owner.

[16] *See* letter from Madge M. Hamilton, Legal Division, CBOE, to Nancy Sanow, Assistant Director, Division, Commission, dated June 1, 2001 (''CBOE Amendment No. 3''). In CBOE Amendment No. 3, CBOE clarified that it is requesting accelerated approval of CBOE Amendment No. 2, pursuant Section 19(b)(2) of the Exchange Act.

[17] *See* letter from Michael Simon, Senior Vice President and General Counsel, ISE, to John Roeser, Attorney, Division, Commission, dated May 29, 2001 (''ISE Amendment No. 2''). In ISE Amendment No. 2, ISE requested permanent approval of its pilot rules and deleted its provision relating to obvious errors.

[18] *See* letter from Michael D. Pierson, Senior Vice President Regulatory Policy, PCX, to John Roeser, Attorney, Division, Commission, dated May 23, 2001 (''PCX Amendment No. 2''). In PCX Amendment No. 2, PCX requested permanent approval of its pilot rules and made a technical change to its rule text regarding unusual market conditions.

[19] *See* letter from Richard S. Rudolph, Counsel, Phlx, to Nancy J. Sanow, Assistant Director, Division, Commission, dated May 11, 2001 (''Phlx Amendment No. 3''). In Phlx Amendment No. 3, Phlx requested permanent approval of its pilot rules, provided more detailed procedures for determining and monitoring when quotes are not firm, clarified in its rule text that Phlx will notify specified persons when quotes are not firm through the Options Price Reporting Authority (''OPRA'') using an agreed upon indicator, clarified that it will publish size for customer orders through OPRA and on its website, and specified that the designee of the Director of Surveillance may be any person employed by the Phlx in the Options Surveillance Department.

[20] *See* letter from Richard S. Rudolph, Counsel, Phlx, to Nancy J. Sanow, Assistant Director, Division, Commission, dated May 21, 2001 (''Phlx Amendment No. 4''). Phlx Amendment No. 5 supersedes and replaces Phlx Amendment No. 4.

[21] *See* letter from Richard S. Rudolph, Counsel, Phlx, to Nancy J. Sanow, Assistant Director, Division, Commission, dated May 29, 2001 (''Phlx Amendment No. 5''). In Phlx Amendment No. 5, Phlx made conforming changes to its floor procedure advices to reflect Phlx Amendment No. 3 and deleted a provision proposed in its initial filing that had not been approved as part of the Pilot Approval Order regarding the unbundling of orders for the primary purpose of availing upon the execution guarantee requirement.

[22] For ease of comparison and review, the Commission has consolidated the Exchanges' proposed amendments into one notice, which combines and summarizes the main provisions of such amendments.

is granting accelerated approval to the amended proposals.

I. Text of the Proposed Amendments to the Pilot Program

The Exchange propose to amend their Pilot Programs to conform to the requirements of the Quote Rule. The text of the proposed rule changes follows. Text added by amendments since the publication of the Exchanges' proposals is italicized and deleted text is bracketed.

A. Amex Proposed Rule Text

Rule 958A. Application of the Firm Quote Rule

(a) Definitions—(i) For purposes of this rule the temrs ''aggregated quotation size'', ''best bid and best offer'', ''bid and offer'', ''quotation size'', ''quotation vendor'', ''reported security'', ''listed option'', ''option class'', ''option series'', and ''trading rotation'' shall have the meanings set forth in SEC Rule 11Ac1–1.

(ii) For purposes of this rule and SEC Rule 11Ac1–1 as applied to the Exchange and its members, the term ''responsible broker or dealer'' shall mean, with respect to any bid or offer for any listed option made available by the Exchange to quotation vendors, the specialist and any registered options traders constituting the trading crowd in such option series shall collectively be the responsible broker or dealer to the extent of the aggregate quotation size specified.

(b) Dissemination Requirements of the Exchange—(*i*) WIth respect to paragraph (b) of SEC Rule 11Ac1–1 [and except as set forth in Commentary .01 of this rule], the Exchange shall, at all times it is open for trading:

(A) Collect, process and make available to quotation vendors the best bid, the best offer, quotation sizes and aggregate quotation sizes associated therewith for each option series that is a reported security and for which a responsible broker or dealer is obligated to execute any customer order as set forth in paragraph (c)(1)(*A*) below; and

(B) Shall for each listed option class, establish [by rule] and periodically published the quotation size for which the responsible broker or dealer is obligated to execute an order for the account of a *U.S. registered or foreign registered* broker or dealer to buy or sell an option series that is a reported security at its publish bid or offer as set forth in paragraph (c)[(ii)] *(i)(B)* below. The exchange may collect, process and make available to quotation vendors a best bid or best offer determined by an automated quotation system.

(ii) The Exchange's obligations to collect, process and make available data as set forth above shall not include:

(A) collecting, processing or making available any such bid or offer which is executed immediately after being made in the crowd and any such bid or offer which is cancelled or withdrawn if not executed immediately after being made; or

(B) data communicated during any period when trading in such reported security has been suspended or halted; prior to the commencement of trading in such reported security on any trading day; or during a trading rotation.

[The minimum quotation size made available to quotation vendors established by rule and published by the Exchange shall be ten contracts for each option series.]

(c) Obligations of a Responsible Broker or Dealer—*(i)* Pursuant to SEC Rule 11Ac1–1 each responsible broker or dealer for each series of each listed option class shall promptly communicate to the Exchange its best bid, best offer, quotation size and aggregate quotation size. No responsible broker or dealer shall communicate a quotation size or aggregate quotation size for less than ten contracts. This obligation may be fulfilled by the use of an automated quotation system.

[i]*(A)* Subject to the provisions of paragraph (d) of this rule, each responsible broker or dealer shall be obligated to execute any customer order in an option series in an amount up to its published quotation size.

[ii]*(B)* Subject to the provisions of paragraph (d) of this rule, each responsible broker or dealer shall be obligated to execute any order for the account of a *U.S. registered or foreign* broker or dealer in a listed option in an amount up to the quotation size established [by rule] and periodically published by the Exchange *which quotation size shall be for at least one contract.*

[iii]*(C)* Subject to the provisions of paragraph (d) of this Rule, each responsible broker or dealer shall comply with the Thirty Second Response provisions set forth in paragraph (d)(3) of SEC Rule 11Ac1–1.

(ii) Non responsible broker or dealer shall be obligated to execute a transaction for any listed option as provided in paragraph (c)(i) when:

(A)(1) Prior to the presentation of an order to sell (buy), a responsible broker or dealer has communicated to the exchange, a revised quotation size;

(2) At the time an order to sell (buy) is presented, a responsible broker or dealer is in the process of effecting a transaction in such class and/or series of option, and immediately after the completion of such transaction it communicates to the Exchange a revised quotation size, such responsible broker or dealer shall not be obligated by paragraph (c)(i) of this Rule to sell (buy) that option in an amount greater than such revised quotation size.

(3) Before the order sought to be executed is presented, a responsible broker or dealer has communicated to the Exchange a revised bid or offer; or

(4) At the time the order sought to be executed is presented, a broker or dealer is in the process of effecting a transaction in such class and/or series of option, and, immediately after the completion of such transaction, a responsible broker or dealer communicates to the exchange a revised bid or offer; provided, however, that the responsible broker or dealer shall nonetheless be obligated to execute any such order as provided in paragraph (c)(i) at its revised bid or offer in any amount up to its published quotation size or revised quotation size; or

(B) The order for the purchase or sale of a listed option is presented during a trading rotation in that listed option.

(d) Use of Unusual Market Exception—Nothwithstanding paragraphs (b) and (c) above and pursuant to paragraph (b)(3) of SEC Rule 11Ac1–1, if the Exchange determines, in accordance with the procedures set forth below, that the level of trading activity or the existence of unusual market conditions is such that the Exchange [cannot] *is incapable of* collect*ing*, process*ing* and mak*ing* available to quotation vendors quotation data in a manner which accurately reflects the current state of the market at the Exchange, the Exchange shall immediately notify the persons specified in paragraph (b)(3) of SEC Rule 11Ac1–1 [below] and, upon such notification, the obligation imposed upon Exchange members under paragraph (c)(2) of SEC Rule 11Ac1–1 and the Exchange under paragraphs (b)(1) and (2) of SEC Rule 11Ac1–1 shall be suspended, until a determination by the Exchange that the unusual market activity or condition has terminated and the specified persons have been notified that the usual market activity or condition has terminated:

(i) If a responsible broker or dealer is unable to update his quotations on a timely basis due to the high level of trading activity or the existence of an unusual market conditions, he shall promptly notify a Floor Official.

(ii) Upon notification by a responsible broker or dealer, the Floor Official shall promptly verify the existence of the unusual market activity or condition

and if, in his judgment, the responsible broker or dealer is unable to update his quotations on a timely basis, the Floor Official shall promptly notify the Market Operations Division of the Exchange. If a Floor Official, independent of notification by a responsible broker or dealer, becomes aware of any unusual market activity or condition which adversely affects a responsible broker or dealer's ability to promptly communicate quotation data, he shall likewise promptly advice the Market Operations Division.

(iii) If the Exchange is unable to accurately collect, process, and/or disseminate quotation data owing to the high level of trading activity or the existence of unusual market conditions, the Market Operations Division of the Exchange, after consultation with a Floor Official, shall make a determination that this is the case.

(iv) The Market Operations Division, after receiving notification from a Floor Official pursuant to either subparagraphs (i) and (iii) above, shall notify the persons specified in paragraph (b)(3) of SEC Rule 11Ac1–1 regarding the Exchange's inability to accurately collect, process, and make available the quotation data required by SEC Rule 11Ac1–1. The Exchange shall append to each quotation made available to a quotation vendor an identifier which will indicate that the obligation imposed upon Exchange members and the Exchange by SEC Rule 11Ac1ndash;1 has been suspended.

(v) The Floor Official or the Market Operations Division (as the case may be) shall monitor the unusual market activity or condition until it has terminated. Thereupon, the Market Operations Division shall immediately notify the persons specified in paragraph (b)(3) of SEC Rule 11Ac1–1 that the Exchange is once again capable of disseminations the quotation data required by Rule SEC 11Ac1–1 and responsible brokers or dealers shall be once again obligated under SEC Rule Rule 11Ac1–1 as made applicable to Exchange members pursuant to this Rule 958A.

* * * * *

* * * Commentary

[.01 As of April 1, 2001, the compliance date for application of SEC Rule 11Ac1–1 to the trading of options, the Exchange is able to disseminate to quotation vendors the quotation size or aggregate quotation size of the best bid or best offer in most, but not all, option classes. This is not expected to be a permanent condition and it is anticipated that quotation sizes will be available for all option classes shortly after the compliance date. However, until such time as the Exchange is able to disseminate quotation size for all option classes, for those option classes for which it is unable to do so, it will collect, process and disseminate the best bid and best offer, and establish by rule and periodically publish the quotation size for which the responsible broker or dealer is obligated to execute a customer order to buy or sell an option series in that class.]

[.02] *.01* No specialist shall be deemed to be a responsible broker or dealer with respect to a published bid or offer that is erroneous as a result of an error or omission made by the Exchange or any quotation vendor. If a published bid or published offer is accurate but the published quotation size (or published aggregate quotation size, as the case may be) associated with it is erroneous as a result of an error or omission made by the Exchange or any quotation vendor, then the specialist who is responsible for the published bid or published offer shall be obligated to the extent set forth in paragraph (c) of Rule 11Ac1–1 but only to the extent of [one unit of trading in the reported security in question] *ten contracts.*

[.03].*02* Absent unusual market conditions, the responsible broker or dealer shall honor any bid or offer then being displayed by quotation vendors which is erroneous, up to the quotation size then being so displayed, which has been displayed for six minutes or more. Provided, however, that the specialist shall not be required to honor such a bid or offer which is erroneous as to either price or size or both if:

(i) As a matter or record, an execution, cancellation or update of such bid or offer was in effect or in process;

(ii) In honoring such a bid or offer, the resulting transaction would violate applicable Exchange rules or federal regulations;

(iii) Equipment failure prevents the specialist from monitoring such bid or offer; or

(iv) The price sought upon such quotation is above the current bid or below the current offer, on the Floor, by (a) $.25 or more in the case of a reported security trading at $3 or less or

(b) $.50 or more in the case of a reported security trading at more than $3.

* * * * *

Rule 590—Minor Rule Violation Fine System

Part 1 General Rule Violations

(a) through (g) No change.

(h) The following is a list of the rule violations and applicable fines that may be imposed by the Exchange's Minor Floor Violation Disciplinary Committee pursuant to Part 1 of this Rule.

1. Failure to comply with the SEC firm quote rule land honoring 10-up market for customer option orders]. (SEC Rule 11 Ac1–1 and Rule 958A.)

B. CBOE Propose Rule Text

Rule 8.51.—Firm Disseminated Market Quotes

(a) Definitions.

(1) For the purposes of this rule, and SEC Rule 11Ac1–1 as applied to the Exchange and members on the floor, the term ''responsible broker or dealer'' shall mean, with respect to any bid or offer for any reported security made available by the Exchange to quotation vendors, the trading crowd in a series or class of option, which shall be the responsible broker or dealer to the extent of the quotation size specified in [(b) or] (c) of this rule.

(2) For purposes of this rule, the term ''reported security'' means any security or class of securities for which transactions reports are collected, processed and made available pursuant to an effective national market system plan for reporting transactions in listed options.

(b) Firm Quote Requirement [for Non-broker-dealer Orders]. [All classes and series shall be subject to the requirements of this rule.

(1) The appropriate Floor Procedure Committee may establish the firm quote requirement for each series of option, which shall be for at least one contract, for non-broker-dealer orders. The Exchange will periodically publish the firm quote requirement for each series of option. In the event the Exchange disseminates quotation size, the firm quote requirement would be for up to the disseminated size.]

(*1*[2]) The firm quote requirement obligates the responsible broker or dealer to sell (buy) at least the established number of contracts at the offer (bid) which is displayed when the responsible broker or dealer receives a buy (sell) order at the trading station where the *reported security* [particular option class] is located for trading.

[(3) When orders for the same class (whether for the same series or different series) from the same beneficial owner are represented at the trading station at approximately the same time, then only the first of such orders that cumulatively equal or add up to less than the firm quote requirement shall be entitled to an execution pursuant to paragraphs (b) and (c) above.]

(c) Firm Quote *Size* [Requirement for Broker-Dealer Orders].

(1) The appropriate Floor Procedure Committee may establish *separate* [the] firm quote requirements for each series of option, which shall be for at least one contract, for *(i) non-broker-dealer orders and (ii)* broker-dealer orders. [The Exchange will periodically publish the firm quote requirement for each series of option. In the event the Exchange disseminates quotation size, if the disseminated quotation size is for a lesser amount than the firm quote requirement, then the broker-dealer firm quote requirement would be for the disseminated size.] For purposes, of this Rule, the term broker-dealer includes foreign broker-dealers as defined in Rule 1.1(xx). *The Exchange will periodically publish the firm quote size requirement for each series of option for both order types.*

(*2*) *The firm quote requirement size for non-broker-dealer orders shall be the size that the Exchange periodically publishes along with the quotes disseminated to vendors. In the event the Exchange has not published a size along with its quotes for a particular series, then the firm quote requirement size for non-broker-dealer orders shall be that size published by the Exchange in a different manner (e.g., on its website). The Exchange also publish separately the firm quote requirement size for broker-dealers orders. In the case of broker-dealer orders, it the size for a particular series disseminated along with the quotes is less than the size published for broker-dealer orders, then the firm quote requirement for broker-dealer orders shall be the size published along with the quotes.*

(d) Thirty Seconds Rule. Each responsible broker or dealer within thirty seconds from receiving an order that is greater than the quotation size established by paragraph [(b) or] (c) of the rule must:

(1) Execute the entire order; or

(2) (*i*[A]) Executive that portion of the order equal to at least the quotation size established by paragraph[s (b) or] (c) of this rule; and

(*ii*[B]) Revise its bid or offer.

(e) Exemptions to Firm Quote Requirement. Non-Firm Mode.

(1) *The responsible broker or dealer shall be relieved of its obligations under this Rule 8.51* [with respect to such reported security] *and with*[With] respect to paragraph (b)(3) of SEC Rule 11Ac1–1:

(i) *When*[Any] two Floor Officials, on a case by case basis, for either a class or series within a class, [may] make a determination[,] that the level of trading activity or the existence of unusual market conditions are such that the Exchange is incapable of collecting, processing and making available to quotation vendors bids, offers and quotation sizes with respect to one or more class or series within a class of option in a manner which accurately reflects the current state of the market on the floor[.]*;* [During any period that the market in a reported security is in a non-firm mode, the responsible broker or dealer shall be relieved of their obligations under SEC Rule 11Ac1–1 as applicable to such members under this Rule 8.51 with respect to such reported security, but the responsible broker or dealer shall report bids and offers or revised bids and offers in such reported security, for publication, on a ''best efforts'' basis; or]

(ii) *When the* [The] senior person, then in charge of the Exchange's Control Room, suspends the firm quote requirements of paragraph[s] (b) [or (c)] with respect to a class of options if he or she determines that the level of trading activity or the existence of unusual market conditions are such that the Exchange is incapable of collecting, processing and making available to quotation vendors bids, offers and quotation sizes with respect to one or more class or series of option in a manner which accurately reflects the current state of the market on the floor. After exercising such authority, that senior person shall immediately seek approval by two Floor Officials, who may confirm or overrule the decision; *or* [. During any period that the market in a reported security is in a non-firm mode, the responsible broker dealer shall be relieved on their obligations under SEC Rule 11Ac1–1 as applicable to such members under this Rule 8.51 with respect to such reported security, but the responsible broker or dealer shall report bids and offers or revised bids and offers in such reported security, for publication, on a ''best efforts'' basis.]

(iii) When the order for the purchase or sale of a reported security is presented during a trading rotation in that reported security.

(2) When it has been relieved of its firm quote obligation, the responsible broker or dealer shall report bids and offers or revised bids and offers in a reported security, for publication, on a ''best effort'' basis.

(3)[(iii)] Whenever two Floor Officials or the senior person then in charge of the Exchange's Control Room make a determination under subparagraphs (i) or (ii) above with respect to any reported security, the Exchange's Control Room will disseminate a message notifying the specified persons that the displayed quotes are not firm.

(4)[(iv)] During any period that the market in a reported security is in a non-firm mode, the Floor Officials shall monitor the activity or condition, which formed the basis for [his or]their determination. No more than 30 minutes after such market has been designated to be in a non-firm mode, the DPM shall review the condition of such market with the Floor Officials. Continuation of the non-firm mode for longer than 30 minutes shall require the reaffirmation of the reviewing Floor Officials. Such review and reaffirmation shall occur not less frequently than every 30 minutes thereafter while the non-firm mode is effect.

(5)[(v)] When the Exchange is once again capable of collecting, processing and making available to quotation vendors bids and offers with respect to a reported security that is in non-firm mode in a manner which accurately reflects the current state of the market on the floor then the senior person then in charge of the Exchange's Control Room, or two Floor Officials shall lift the non-firm mode designation. Once the non-firm mode designation has been lifted, the responsible broker or dealer[s] shall be obligated for the firm quote requirements as stated in paragraph[s] (b) [or (c)].

(6)[(2)] No responsible broker or dealer shall be obligated to execute a transaction for any listed option as provided in paragraph[s] (b) [and (c)] of this rule [23] when:

(i) Revised Quotation Size

(A) Prior to the presentation of an order to sell(buy), a responsible broker or dealer has communicated to the exchange, a revised quotation size; or

(B) At the time an order to sell(buy) is presented, responsible broker or dealer is in the process of effecting a transaction in such class and/or series of option, and immediately after the completion of such transaction, it communicates to the exchange a revised quotation size, such responsible broker or dealer shall not be obligated by paragraph (b), [(c)] or (d) of this Rule to sell(buy) that option in an amount greater than such revised quotation size.

(ii) Revised Bid or Offer

(*A*[C]) Before the order sought to be executed is presented, a responsible broker or dealer has communicated to the exchange, a revise bid or offer; or

(*B*[D]) At the time order sought to be executed is presented, a responsible broker or dealer is in the process of

[23] This section is pursuant to SEC Rule 11Ac1–1(d)(4). The responsible broker or dealer shall also be relieved of *its* [their] obligations under SEC Rule 11 Ac1–1(c)(2).

effecting a transaction in such class or series of option, and, immediately after the completion of such transaction, a responsible broker or dealer communicates to the exchange, a revised bid or offer; provided, however, that the responsible broker or dealer shall nonetheless be obligated to execute any such order as provided in paragraph[s] (b) [or (c)] of this rule at its revised bid or offer in any amount up to its published quotation size or revised quotation size.[; or]

[(ii) The order for the purchase or sale of a listed option is presented during a trading rotation in that listed option.]

(f) Each member on the floor shall abide by such rules and procedures adopted by the Exchange, in order to enable the Exchange to meet its quotation dissemination requirements.[24]

* * * Interpretations and Policies.

.01 With respect to subsection (b) of this Rule, if the disseminated bid (offer) is on behalf of an order represented by a Floor Broker, DPM, or OBO and is for less than the firm quote requirement applicable for that class of options, a responsible broker or dealer is obligated to buy or sell the necessary number of contracts needed to make the disseminated quote firm for the firm quote requirement for that class of options.

.02 Where a Floor Broker, DPM, or OBO has caused a bid or offer to be disseminated and the order is subsequently filled or canceled, the Floor Broker, DPM, or OBO will be responsible for causing such disseminated bid or offer to be removed. Failure to do so will result in the Floor Broker, DPM, or OBO being responsible for satisfying the firm disseminated quote commitment pursuant to subsection (b) [or (c)] of this Rule. Any member who has caused a bid or offer to be disseminated is equally responsible for removing such bid or offer when he leaves the trading crowd.

.03 Where a disseminated market quote is revised, as provided for in paragraph (e) of this Rule, it shall be considered conduct inconsistent with just and equitable principles of trade for a responsible broker or dealer immediately to re-display the previously disseminated market quote, unless such action is warranted by a change in market conditions.

.04 Floor Officials may, as provided for under Rules 6.20(c) and 17.50(g)(6), impose a fine on members of the trading crowd for violations of this Rule and its Interpretations and Policies.

.05 The requirement of paragraph[s] (b) [and (c)] of this Rule that the responsible broker or dealer must honor displayed quotations up to the firm quote requirement subject to the conditions of the Rule applies not only to orders to buy or to sell options, but also to two-part spread or straddle for all options orders which may be executed at displayed quotations for both parts of the order. This obligation of a responsible broker or dealer applies to two-part orders where the two sides are on opposite sides of the market in a one-to-one ratio, and extends to the amount of the firm quote requirement on each side of the order.

.06 Pursuant to Rule 6.20 Interpretation .09, the reference to any two Floor Officials in Rule 8.51 and its Interpretations and Policies includes, but is not limited to, members of the appropriate Market Performance Committee.

.07 Under paragraph (e) of this Rule, when two Floor Officials [may] determine that a market in a class of series of option is fast pursuant to Rule 6.6, the Floor Officials may determine the market constitutes a level of trading activity or such unusual market conditions that the Exchange is incapable of collecting, processing and making available to quotation vendors bids, offers and quotation sizes in a manner that accurately reflects the current state of the market on the floor, and thus, suspend the firm quote requirement.

.08 The trading crowd shall not be deemed to be a responsible broker or dealer with respect to a published bid or offer that is erroneous as a result of an error or omission made by the Exchange or any quotation vendor. If a published bid or published offer is accurate but the published quotation size (or published aggregate quotation size, as the case may be) associated with it is erroneous as a result of an error or omission made by the Exchange or any quotation vendor, then the [trading crowd] responsible broker or dealer is responsible for the published bid or published offer shall be obligated to the extent set forth in paragraph (c) of Rule 11Ac1–1 but only to the extent of one contract of the listed option in question.

C. ISE Proposed Rule Test

Rule 804. Market Maker Quotations

* * *

(d) Firm Quotes. Market maker bids and offers are firm for Public Customer Orders and Non-Customer Orders Both under this Rule and Rule 11Ac1–1 under the Exchange Act (''Rule 11Ac1–1'') for the number of contracts specified for each according to the requirements of paragraph (b) above. Market Maker bids and offers are not firm under this Rule and Rule 11Ac1–1 if:

[(i) the Exchange determines that an exception is warranted, on a case by case basis, because of an obvious error;]

[(ii)] (*i*) a system malfunction or other circumstance impairs the Exchange's ability to disseminate or update market quotes in a timely and accurate manner;

[(iii)] (*ii*) The level of trading activities or the existence of unusual market conditions is such that the Exchange is incapable of collecting, processing, and making available to quotation vendors the data for the option in a manner that accurately reflects the current state of the market on the Exchange, and as a result, the market in the option is declared to be ''fast'' pursuant to Rule 704;

[(iv] (*iii*) during trading rotations; or

[(v)] (*iv*) any of the circumstances provided in paragraph (c)(3) of Rule 11Ac1–1 exist.

* * * * *

D. PCX Proposed Rule Text

¶ 5221—Firm Quotes.

Rule 6.86(a)–(c)—No change.

(d) Exception for Unusual Market Conditions

(1) If the Exchange determinations, in accordance with the procedures set forth below, that the level of trading activity or the existence of unusual market conditions is such that the Exchange *is incapable of collecting, processing and making* [cannot collect, process and make] available to quotation vendors quotation data in a manner that accurately reflects the current state of the market at the Exchange, the Exchange will immediately notify the persons specified in SEC Rule 11Ac1–1(b)(3) and, upon such notification, the obligation imposed upon Exchange members under SEC Rule 11Ac1–1(c)(2) and the Exchange under subsection (b), above, will be suspended, until the Exchange determines that the unusual market activity or condition has terminated and the specified persons have been notified that the unusual market activity or condition has terminated.

* * *

E. Phlx Proposed Rule Text

Rule 1082 Firm Quotations.

(a) Definitions.

(i) The term ''disseminated price'' shall mean the bid (or offer) price for an options series that is made available by the Exchange and displayed by a quotation vendor on a terminal or other display device.

[24] See SEC Rule 11Ac1–1.

(ii) The term ''disseminated size'' shall mean with respect to the disseminated price for any quoted options series, the AUTO–X guarantee for the quoted option, except that the disseminated size of bids and offers of limit orders on the book shall be ten (10) contracts.

(iii) The term ''SEC Quote Rule'' shall mean Rule 11Ac1–1 under the Securities Exchange Act of 1934, as amended.

(iv) The terms ''customer,'' ''responsible broker or dealer,'' and ''specified persons'' shall have the meaning set forth in the SEC Quote Rule.

(b) Except as provided in paragraph (c) of this Rule, all quotations made available by the Exchange and displayed by quotation vendors shall be firm for customer orders at the disseminated price in an amount up to the disseminated size. Responsible brokers or dealers bidding (or offering) at the disseminated price shall be collectively required to execute orders presented to them at such price up to the disseminated size in accordance with Rule 1015, or, if the responsible broker or dealer is representing (as agent) a limit order, such responsible broker or dealer shall be responsible (as agent) up to the size of such limit order, but may be responsible as principal for all or a portion of the excess of the disseminated size over the size of such limit order to the extent provided in Rule 1015.

(c) The requirements of paragraph (b) or (d) of this Rule shall not apply to displayed quotations: (i) When the level of trading activities or the existence of unusual market conditions is such that the Exchange is incapable of collecting, processing, and making available to quotation vendors the data for a subject security required to be made available pursuant to the SEC Quote Rule in a manner that accurately reflects the current market on the Exchange as determined *in accordance with paragraph (f) of this Rule;* [by two Floor Officials, with the concurrence of the Director of Surveillance, or his designee] (ii) during a trading rotation; (iii) if any of the circumstances provided in paragraph (c)(3) of the SEC Quote Rule exist; or (iv) on a case by case basis where it is determined that an exemption is warranted for an obvious error in the posting of the disseminated price or disseminated size due to reporter error or system malfunction. [The Exchange shall immediately notify all specified persons of such a determination. Regular trading procedures shall be resumed when two Floor Officials determine that the conditions supporting that determination no longer exist. The Exchange shall immediately notify all specified persons of such a determination.] Any exemption granted pursuant to paragraph (c)(iv) shall be in writing and shall set forth the basis upon which the exemption is granted.

(d) In accordance with paragraph (d)(1)(ii) of the SEC Quote Rule, the quotation size for a disseminated price with respect to an order for the account of a broker or dealer (''broker-dealer order'') shall be one (1) contract (''quotation size''), and all quotations made available by the Exchange and displayed by quotation vendors shall be firm for broker-dealer orders at the disseminated price in an amount up to the quotation size. The quotation size for broker-dealer orders provided in this paragraph (d) shall be periodically published by the Exchange. Responsible brokers or dealers bidding (or offering) at the disseminated price shall be collectively required to execute broker-dealer orders at such price up to the quotation size.

(e) If responsible brokers or dealers receive an order to buy or sell a listed option at the disseminated price in an amount greater than the disseminated size (for customer orders) or the quotation size (for broker-dealer orders), such responsible broker or dealer shall, within thirty (30) seconds of receipt of the order, (i) execute the entire order at the disseminated price (or better), or (ii) execute that portion of the order equal to the disseminated size (in the case of a customer order) or the quotation size (in the case of a broker-dealer order) at the disseminated price (or better), and revise its bid or offer.

(f) *With respect to subparagraph (c)(i) of this Rule, two Floor Officials (''Initiating Officials''), with the concurrence of the Director of Surveillance (or his designee), may determine (either on their own motion or at the request of a responsible broker or dealer) that the level of trading activities or the existence of unusual market conditions is such that the Exchange is incapable of collecting, processing and making available to quotation vendors the data for a subject security required to be made available pursuant to the SEC Quote Rule in a manner that accurately reflects the current market on the Exchange. Upon the making of such a determination, the Exchange shall designate the market in such security to be ''non-firm,'' and shall immediately notify all specified persons of that determination through the Options Price Reporting Authority, using the industry agreed-upon indicator for ''non-firm'' status. Upon such notification, responsible brokers or dealers shall be relieved of their obligations under paragraph (c)(2) the SEC Quote Rule and this Rule 1082 with respect to such security until a determination by the Exchange that the unusual market conditions have terminated and the specified persons have been notified that the unusual market conditions have terminated. During any period that the market for a subject security is ''non-firm,'' the Exchange shall continue to the maximum extent practicable under the circumstances, to collect, process, and make available to quotation vendors data for that security as required under the SEC Quote Rule.*

During any period that the market in a subject security is ''non-firm,'' the Exchange shall monitor the activity or condition which formed the basis for such determination. Continuation of the ''non-firm'' designation for longer than 15 minutes shall require the reaffirmation of two floor officials (the ''Reviewing Floor Officials''), with the concurrence of the Director of Surveillance (or his designee). Such review and reaffirmation shall occur not less frequently than every 15 minutes thereafter while the quotations in the subject security are deemed ''non-firm.''

When the Exchange determines that the unusual market conditions have terminated, the Exchange shall immediately notify all specified persons that the Exchange is once again capable of collecting, processing and making available to quotation vendors the quotation data required by the SEC Quote Rule, and responsible brokers and dealers shall once again be obligated under the SEC Quote Rule and this Rule 1082 with respect to the subject security.

F–10 Unusual Market Conditions

In the interest of maintaining a fair and orderly market under unusual market conditions for one or more classes of options, [two Floor Officials, with the concurrence of the Director of Surveillance or his designee, may determine that the level of trading activities or the existence of unusual market conditions is such that the Exchange is incapable of collecting, processing, and making available to quotation vendors the data for a subject security required to be made available pursuant to the SEC Quote Rule in a manner that accurately reflects the current market on the Exchange. The Exchange shall immediately notify all specified persons of such a determination. Regular trading procedures shall be resumed when two Floor Officials determine that the

conditions supporting that declaration no longer exist.] *two Floor Officials (''Initiating Officials''), with the concurrence of the Director of Surveillance (or his designee), may determine (either on their own motion or at the request of a responsible broker or dealer) that the level of trading activities or the existence of unusual market conditions is such that the Exchange in incapable of collecting, processing and making available to quotation vendors the data for a subject security required to be made available pursuant to the SEC Quote Rule in a manner that accurately reflects the current market on the Exchange.*

Upon the making of such a determination, the Exchange shall designate the market in such security to be ''non-firm,'' and shall immediately notify all specified persons of that determination, the Exchange will notify specified persons through the Options Price Reporting Authority, using the agreed-upon indicator. Upon such notification, responsible brokers or dealers shall be relieved of their obligations under paragraph (c)(2) the SEC Quote Rule and Exchange Rule 1082 with respect to such security until a determination by the Exchange that the unusual market conditions have terminated and the specified persons have been notified that the unusual market conditions have terminated. During any period that the market for a subject security is ''non-firm,'' the Exchange shall continue, to the maximum extent practicable under the circumstances, to collect, process, and make available to quotation vendors data for that security as required under the SEC Quote Rule.

During any period that the market in a subject security is ''non-firm,'' the Exchange shall monitor the activity or condition which formed the basis for such determination. Continuation of the ''non-firm'' designation for longer than 15 minutes shall require the reaffirmation of two floor officials (the ''Reviewing Floor Officials''), with the concurrence of the Director of Surveillance (or his designee). Such review and reaffirmation shall occur not less frequently than every 15 minutes thereafter while the quotations in the subject security are deemed ''non-firm.''

When the Exchange determines that the unusual market conditions have terminated, the Exchange shall immediately notify all specified persons that the Exchange is once again capable of collecting, processing and making available to quotation vendors the quotation data required by the SEC Quote Rule, and responsible brokers and dealers shall once again be obligated under the SEC Quote Rule and this Advice with respect to the subject security.

During the period for which such a determination has been made, displayed quotes for the respective options are not firm (as required by Rule 1082) and volume guarantees of Advice A–11 and Rule 1015 are not applicable, but the respective specialists and trading crowds are required to use best efforts to update quotes and fill incoming orders in accordance with Advice A–11 and Rule 1015.

Fine Schedule—F–10

Fine Not Applicable

* * * * *

Rule 1015. Execution Guarantees

(a) Execution Guarantees—Customer market or marketable limit orders in any options series on the Exchange are to be filled at the best market, in accordance with Rule 1082, to a minimum of the disseminated size by floor traders (i.e., Specialists and ROTs) in the crowd as follows:

(i) If only one floor traders is quoting the availed upon best bid (or offer), that floor trader is responsible for providing a fill for the disseminated size.

(ii) If more than one floor trader is quoting the availed upon best bid (or offer), and their combined quote size is less than the disseminated size, participation for the additional contracts needed to meet the disseminated size requirement shall be decided upon agreement by those floor traders or otherwise divided proportionately among them.

(iii) If the availed upon best bid (or offer) is established by someone other than a floor trader and is not for at least the disseminated size, participation for the additional contracts needed to meet the disseminated size requirement shall be supplied at that same price by the floor trader with the immediately prior best bid (or offer). If more than one floor trader was on the prior bid (or offer), participation for the additional contracts shall be decided upon agreement by those floor traders or otherwise divided proportionately among them. For example, if a 2¼ or 2.25 bid by an ROT is followed by a 2½ or 2.50 bid for five contracts by a customer, the ROT who was bidding 2¼ or 2.25 will be responsible for buying the other five contracts at 2½ or 2.50.

(iv) The ''availed upon best bid (or offer)'' for purposes of this Rule shall be the disseminated price (as defined in Rule 1082).

[(v) Orders received by a member from a customer may not be unbundled for the primary purpose of availing upon the execution guarantee requirement, nor may a Firm solicit a customer to unbundle an order for the primary purpose of availing upon the execution guarantee.]

(v[i]) Floor Brokers must make reasonable efforts to ascertain whether each order entrusted to them is for the account of a customer or a broker-dealer. If it is ascertained that the order is for the account of a broker-dealer, the responsible Floor Broker must advise the crowd of that fact prior to bidding/offering on behalf of the order or executing the order. The responsible floor agent must legibly mark the floor ticket as ''B/D'' when it has been determined that the order is for an account of a broker/dealer.

(vi[i]) The disseminated size requirement shall not apply when Exchange quotations are not required to be firm pursuant to paragraph (c) of Rule 1082.

(b) Trade or Fade—When paragraph (e) of Rule 1082 is applicable to an order received by a responsible broker or dealer, participation by Specialists or ROTs above their stated size to fill the order completely or meet the disseminated size requirement (for customer orders) or the quotation size requirement (for broker-dealer orders) shall be decided upon agreement by such Specialists or ROTs or otherwise divided proportionately among them. Where the disseminated market quote of a responsible broker or dealer is revised, ad provided for in Rule 1082, it shall be considered conduct inconsistent with just and equitable principles of trade for such responsible broker or dealer to immediately re-display its previously disseminated market quote, unless such action is warranted by a change in market conditions.

* * * * *

A–11 Responsibility To Fill Customer Orders

(a) Execution Guarantees—Customer market or marketable limit orders in any options series on the Exchange are to be filled at the best market, in accordance with Rule 1082, to a minimum of the disseminated size by floor traders (i.e., Specialists and ROTs) in the crowd as follows:

(i) If only one floor trader is quoting the availed upon best bid (or offer), that floor trader is responsible for providing a fill for the disseminated size.

(ii) If more than one floor trader is quoting the availed upon best bid (or offer), and their combined quote size is less than the disseminated size, participation for the additional contracts needed to meet the disseminated size

requirement shall be decided upon agreement by those floor traders or otherwise divided proportionately among them.

(iii) If the availed upon best bid (or offer) is established by someone other than a floor trader and is not for at least the disseminated size, participation for the additional contracts needed to meet the disseminated size requirement shall be supplied at that same price by the floor trader with the immediately prior best bid (or offer). If more than one floor trader was on the prior bid (or offer), participation for the additional contracts shall be decided upon agreement by those floor traders or otherwise divided proportionately among them. For example, if a 2¼ or 2.25 bid by an ROT is followed by a 2½ or 2.50 bid for five contracts by a customer, the ROT who was bidding 2¼ or 2.25 will be responsible for buying the other five contracts at 2½ or 2.50.

(iv) The ''availed upon best bid (or offer)'' for purposes of this Advice shall be the disseminated price (as defined in Rule 1082).

[(iv Orders received by a member from a customer may not be unbundled for the primary purpose of availing upon the execution guarantee requirement, nor may a Firm solicit a customer to unbundle an order for the primary purpose of availing upon the execution guarantee.]

(v[i]) Floor Brokers must make reasonable efforts to ascertain whether each order entrusted to them is for the account of a customer or a broker-dealer. If it is ascertained that the order is for the account of a broker-dealer, the responsible Floor Broker must advise the crowd of that fact prior to bidding/offering on behalf of the order or executing the order. The responsible floor agent must legibly mark the floor ticket as ''B/D'' when it has been determined that the order is for an account of a broker/dealer.

(vi[i]) The disseminated size requirement shall not apply when Exchange quotations are not required to be firm pursuant to paragraph (c) of Rule 1082.

(b) Trade or Fade—When paragraph (e) of Rule 1082 is applicable to an order received by a responsible broker or dealer, participation by Specialists or ROTs above their stated size to fill the order completely or meet the disseminated size requirement (for customer orders) or the quotation size requirement (for broker-dealer orders) shall be decided upon agreement by such Specialists or ROTs or otherwise divided proportionately among them. Where the disseminated market quote of a responsible broker or dealer is revised, as provided for in Rule 1082, it shall be considered conduct inconsistent with just and equitable principles of trade for such responsible broker or dealer to immediately re-display its previously disseminated market quote, unless such action is warranted by a change in market conditions.

Fine Schedule—A–11

Fine Not Applicable

II. Description of the Proposals

A. Background

On November 17, 2000, the Commission adopted amendments to its Quote [25] to require options exchanges and options market markers to publish firm quotes beginning on April 1,2001. [26] As a result of the amendments to the Quote Rule, the Exchanges needed to make conforming amendments to their rules. Accordingly, the Exchanges submitted proposals to the Commission to conform their rules to the provisions of the Quote Rule. On April 2, 2001, the Commission approved portions of the Exchange's proposed rule changes for a 60-day pilot period expiring on June 1, 2001.[27] The Exchanges now seek permanent approval of their respective Pilot Programs. In addition, the Exchanges seek to make additional modifications to their proposals to conform their respective rules to the requirements of the Quote Rule.

A brief summary of the additional modification to the proposed rule changes filed by each of the Exchanges is provided below.

B. Amex

The Amex proposes a number of non-substantive revisions to its Pilot Program. Specifically, Amex proposes to delete the last sentence of Amex Rule 958A(b) because it is already an obligation of the responsible broker or dealer to communicate a quotation size or aggregate quotation size of not less than ten contracts. Amex also proposes to revise Amex Rule 958A(c)(i)(B) to codify the Commission's grant of exemptive relief to permit responsible brokers or dealers to be firm for foreign broker-dealers to the same extent that the rules require their quotes to firm for U.S. broker-dealers,[28] and to establish that the quotation size established by the Amex would be at least one contract.

In addition, Amex proposes to codify in its rules the provisions found in paragraph (c)(3) of the Quote Rule and to delete Commentary .01 to Amex Rule 958A because the Amex is now able to disseminate quotations with size for all option classes it trades. Finally, the Amex proposes to revise Commentary .02 to Amex Rule 958A to be consistent with Amex's requirement that responsible brokers or dealers be firm to customers for at least ten contracts.

C. CBOE

CBOE proposes to amend CBOE Rule 8.51 to delete paragraph (b)(3), which it proposed in its initial filing but which was not approved by the Commission as part of the Pilot Approval Order.[29] This proposal states that ''[w]hen orders for the same class (whether for the same series or different series) from the same beneficial owner are represented at the trading station at approximately the same time, then only the first of such orders that cumulatively equal or add up to less than the firm quote requirement shall be entitled to an execution pursuant to paragraphs (b) and (c) above.'' The Commission did not approve this proposed provision because it is not consistent with the Quote Rule. However, the CBOE, pursuant to paragraph (e) of Rule 11Ac1–1 under the Exchange Act, has submitted to the Commission a letter requesting on behalf of their members an exemption from the Quote Rule in such circumstances.[30]

D. ISE

ISE proposes to delete subparagraph (d)(i) from ISE Rule 804 to remove obvious errors from the circumstances under which market maker bids and offers are not firm under ISE Rule 804 and the Quote Rule. The Commission has separately approved ISE Rule 720 to address obvious errors and, therefore, reference to obvious errors under ISE Rule 804 is unnecessary.[31]

E. PCX

PCX proposes a non-substantive amendment to its rule text regarding an exception from its obligation to collect, process, and make available to quotation vendors quotation data. Specifically, the PCX proposes to amended PCX Rule 6.86(d)(1) by replacing the phrase

[25] Exchange Act Rule 11Ac1–1, 17 CFR 240.11Ac1–1.

[26] *See* Adopting Release, *supra* note 4.

[27] *See* Pilot Approval Order, *supra* note 12.

[28] *See* Letter from Annette L., Nazareth, Director, Division, Commission, to Timothy H. Thompson, Esq., Assistant General Counsel, CBOE, dated April 2, 2001.

[29] *See* Pilot Approval Order, *supra* note 12.

[30] *See* Letter to Annette L. Nazareth, Director, Division, Commission, from Timothy H. Thompson, Esq., Assistant General Counsel, CBOE, dated March 29, 2001.

[31] Securities Exchange Act Release No. 44376 (June 1, 2001).

''cannot collect, process, and make available'' with the phrase ''is incapable of collecting, processing, and making available.''

F. Phlx

In general, Phlx proposes two amendments to its rules. First, Phlx proposes to adopt Phlx Rule 1082(f) and to amend Options Floor Procedure Advice (''OFPA'') F–10 to: (1) Include procedures to be followed in making a determination that unusual market conditions exist with respect to an option; (2) grant relief from firm quote obligations during periods of unusual market conditions; (3) monitor the existence of unusual market conditions; and (4) provide notification to specified persons that unusual market conditions exist or that the conditions supporting that determination no longer exist. Second, Phlx proposes to amend Phlx Rule 1015 and OFPA A–11 by deleting Phlx Rule 1015(a)(v) and OFPA A–11(a)(v), relating to the unbundling of orders for the purpose of availing upon the execution guarantee requirement, and renumbering that subsequent sections of Phlx Rule 1015(a) and OFPA A–1(a).

III. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether Amex Amendment No. 3, CBOE Amendment Nos. 2 and 3, ISE Amendment No. 2, PCX Amendment No. 2, and Phlx Amendment Nos. 3, 4, and 5 are consistent with the Exchange 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 changes that are filed with the Commission, and all written communications relating to the proposed rule changes 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 Exchanges. All submissions should refer to the File Nos. SR–Amex–2001–18, SR–CBOE–2001–15, SR–ISE–2001–07, SR–PCX–2001–18, and SR–Phlx–2001–37 and should be submitted by June 29, 2001.

IV. Commission Findings and Order Granting Accelerated Approval of the Proposed Rule Changes on a Permanent Basis

After careful consideration, the Commission finds that the proposed rule changes, as amended, are consistent with the Exchange Act and the rules and regulations thereunder applicable to national securities exchanges,[32] and, in particular, Section 6(b)(5) of the Exchange Act.[33] As noted in the Adopting Release, the Commission believes that the application of the Quote Rule to the options market will provide significant and immediate benefits to investors. In particular, market participants, including customers and broker-dealers, will be able to rely on options quotes up to the published size when routing orders.

On April 2, 2001, the Commission granted accelerated approval to the Exchanges' sixty-day pilot rule proposals. During the sixty-day pilot period, the Commission received two comment letters on the proposals [34] and, after considering the operating of the Pilot Programs during the sixty-day period, has determined to approve the Pilot Programs, as amended, on a permanent basis.

A. Rule 11Ac1–1(b)(3) and (c)(3) Under the Exchange Act

The Commission approved the Exchanges' proposals to relieve responsible brokers or dealers from their obligations under the Quote Rule in unusual market conditions.[35] Paragraph (b)(3)(i) of the Quote Rule provides that responsible brokers or dealers on the Exchanges will be relieved of their obligations under their rules and the Quote Rule when the level of trading activities or the existence of unusual market conditions is such that the Exchange is incapable of collecting, processing, and making available to quotation vendors quotation data.[36] The Phlx now proposes to modify its rules regarding unusual market conditions to provide more detailed procedures for determining and monitoring when quotes are not firm.[37] The Commission believes that such rules are consistent with the Exchange Act, and expects that the Phlx will ensure that sufficient monitoring procedures are in place to fully implement the requirements of the Quote Rule.

In addition, Amex proposes to incorporate into its own rules the exceptions from the Quote Rule under Rule 11AC1–1(c)(3) regarding revised bids, offers, and quotation sizes. The Commission notes that CBOE Rule 8.51 contains similar provisions that were approved by the Commission in connection with the Pilot Programs, and the ISE and Phlx proposals incorporate by reference these Quote Rule provisions.[38] The Commission believes that including such provisions in the exchanges' rules is consistent with the Exchange Act, provided that the Exchanges interpret them in a manner consistent with paragraph (c)(3) of Rule 11AC1–1.

B. Proposed Deletion of CBOE Rule 8.51(b)(3), Phlx Rule 1015(a)(v) and Phlx Options Floor Procedure Advice A–11(a)(v)

As a part of its pilot program, the CBOE proposed to retain a provision of CBOE Rule 8.51 providing that when multiple orders for the same class from the beneficial owner are represented at the trading station approximately the same time, only the first of such orders that cumulatively equal or add up to less than the firm quote requirement would be entitled to an execution pursuant to CBOE's rules. Similarly, Phlx initially proposed to retain a provision in its rules that would prohibit orders from being ''unbundled'' for the primary purpose of availing

[32] In approving these proposals, the Commission has considered the proposals' impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[33] 15 U.S.C. 78f(b)(5).

[34] *See supra* note 13. One commenter raised concerns about the provisions of Amex, CBOE, and Phlx rules relating to when an order ''reaches'' the trading post. *See* Ianni Letter, *supra* note 13. The Commission notes that such provisions have been eliminated from the Amex, CBOE, and Phlx rules. *See supra* note 12.

[35] *See* Pilot Approval Order, *supra* note 12. The Commission notes that a determination that a market is ''fast'' does not necessarily indicate a level of trading activity or unusual market condition that would relieve an exchange's or responsible broker or dealer's obligation under the Quote Rule. *See e.g.,* Proposed CBOE Rule 8.51 Interpretation and Policy .07.

[36] The Commission notes that CBOE, ISE, and Phlx proposed to establish specific time parameters for reviewing market conditions. *See* Proposed CBOE Rule 8.51(e)4) (requiring review no more than thirty minutes after the market has been designated non-firm); Proposed ISE Rule 704(c)(3) (requiring review at least every thirty minutes after the market has been designated non-firm); and Proposed Phlx Rule 1082(f) (requiring review at least every fifteen minutes after the market has been designated non-firm). Amex and PCX have, instead, proposed to continuously monitor their markets *until* the market condition or activity has terminated. *See* Proposed Amex Rule 958A(d)(v) (requiring the exchange to ''monitor the unusual market activity or condition until it has terminated'') and Proposed PCX Rule 6.86(d)(1)(E) (requiring the exchange to ''monitor the unusual market activity or condition until it has terminated''). The Commission believes that both approaches are consistent with the Exchange Act.

[37] *See* Phlx Amendment Nos. 3 and 5, *supra* notes 19 and 21, respectively.

[38] *See* Proposed ISE Rule 804(d)(iv) and Phlx Rule 1082(c).

upon the execution guarantee requirement provided by the Phlx.

In the Pilot Approval Order, the Commission stated its belief that rules such as CBOE Rule 8.51(b)(3) and Phlx Rule 1015(a)(v) are inconsistent with the Quote Rule and cannot be used to relieve exchange members from their obligations under the Quote Rule.[39] The Commission noted that those provisions had been approved prior to the adoption of amendments to the Quote Rule that extended its application to the options market. Generally, the Quote Rule requires each responsible broker or dealer to ''execute *any* order to buy or sell a subject security * * * at a price at least as favorable to such buyer or seller as the responsible broker's or dealer's published bid or offer * * * in any amount up to its published quotation size.'' [40] Further, the Quote Rule does not expressly provide an exception for multiple orders submitted by the same beneficial owner. And, in fact, the Quote Rule requires, subject to certain limitations, a responsible broker or dealer to execute *any* up to its published size.

At the same time, the Commission specifically solicited comment on whether it would be appropriate for the Commission to grant an exception from the requirement of the Quote Rule for multiple orders submitted by the same beneficial owner at approximately the same time. One commenter addressed this issue, arguing that without providing an exemption from the Quote Rule, options market makers would be subject to unacceptable levels of risk.[41] In addition, CBOE submitted a letter to the Commission requesting exemptive relief from the requirements of the Quote Rule that, if granted, would relieve responsible brokers and dealers of their obligations under the Quote Rule in these circumstances,[42] The Commission has determined not to grant an exemption from the requirements of the Quote Rule at this time. Accordingly, the CBOE and Phlx now propose to eliminate these provisions from their rules.[43]

The Commission finds good cause, consistent with Section 19(b)(2) of the Exchange Act,[44] for granting the Exchanges' request for permanent approval of the Pilot Programs, as amended, prior to the thirtieth day after the day of publication of notice of filing thereof in the **Federal Register**. The Commission notes that the Changes' Pilot Program expire on June 1, 2001. The Commission believes that granting accelerated approval to the proposed amendments will allow the Exchanges to permanently implement their rules in compliance with the Quote Rule without delay. In addition, the Commission notes that the Exchanges reported no complaints or problems with the operation of the rules during the 60-day pilot period. Finally, the Commission notes that the proposed amendments to the Pilot Programs generally include only non-substantive revisions and technical corrections to the Exchanges' rule text.

It is therefore ordered, pursuant to Section 19(b)(2) of the Exchange Act,[45] the Exchanges' proposed rule changes (File Nos. SR–Amex–2001–18, SR–CBOE–2001–15, SR–ISE–2001–07, SR–PCX–2001–18, and SR–Phlx–2001–37), as amended, are approved on a permanent basis.

For the Commmission, by the Division of Market Regulation, pursuant to delegated authority.[46]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–14463 Filed 6–7–01; 8:45 am]

BILLING CODE 8080–01–M

[39] *See* Pilot Approval Order, *supra* note 12.

[40] 17 CFR 240.11Ac1–1(c)(2) (emphasis added).

[41] *See* Phlx Letter, *supra* note 13.

[42] *See supra* note 30.

[43] *See* CBOE Amendment No. 2 and Phlx Amendment No. 5.

[44] 15 U.S.C. 78s(b)(2).

[45] 15 U.S.C. 78s(b)(2).

[46] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–44385; File No. SR–CBOE–2001–17]

Self-Regulatory Organizations; Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change by the Chicago Board Options Exchange, Incorporated To Change the Voting Requirement for Approval of Membership Applications and to Clarify a Notice Requirement Relating to the Exercise of an Authorization To Sell a Membership

June 1, 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 April 5, 2001, the Chicago Board Options Exchange, Incorporated (''CBOE'' 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 CBOE. The CBOE submitted an amendment to the proposed rule change on May 22, 2001.[3] The Commission is publishing this notice to solicit comments from interested persons on the proposed rule change, as amended, and to approve the proposal, as amended, on an accelerated basis.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* letter from Arthur B. Reinstein, Deputy General Counsel, CBOE, to Sonia Patton, Attorney, Division of Market Regulation, Commission, dated May 22, 2001 (''Amendment No. 1''). Amendment No. 1 designated the proposed rule change for submission to the Commission under Section 19(b)(2) of the Act instead of under Section 19(b)(3)(A) of the Act.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The CBOE proposes to change the voting requirement for approval of CBOE membership applications and to clarify a notice requirement relating to the exercise of an Authorization to Sell a membership. Below is the text of the proposed rule change. New language is italicized, and deletions are bracketed.

* * * * *

Chicago Board Options Exchange, Incorporated Rules

* * * * *

Chapter III—Membership

* * * * *

Application Procedures and Approval or Disapproval

Rule 3.9.

(a)–(j) Unchanged.

(k) [Approval of an application requires a vote of the majority of the members of the Membership Committee then in office.] Any applicant that is approved to be a member by the Membership Committee must be approved by the Membership Committee to perform in at least one of the recognized capacities of a member as stated in Rule 3.1(b). Written notice of the action of the Membership Committee, specifying in the case of disapproval of an application the grounds therefore, shall be provided to the applicant.

* * * * *

Sale and Transfer of Membership

Rule 3.14.

(a)–(c) Unchanged.

(d) Authorizations to Sell. The owner of a transferable membership may voluntarily grant to another Exchange member an Authorization to Sell the membership. Authorizations to Sell shall be subject to the following provisions:

(i) An Authorization to Sell shall be effective only if it has been executed on a form prescribed by the Exchange and filed with the Membership Department.

(ii) A membership owner may not grant an Authorization to Sell a particular membership to more than one member.

(iii) The grantee of an Authorization to Sell shall have all of the authority granted under the Constitution and Rules relating to the sale of the membership that would otherwise be vested in the membership owner, including the sole authority to determine whether and when to submit an offer to sell the membership in accordance with the provisions of paragraph (a) of this Rule. Notwithstanding the foregoing, *unless the following notice requirement is waived as described below,* a grantee of an Authorization to Sell must (A) notify the membership owner in writing at least 3 business days prior to exercising the grantee's right to sell the membership of any decision by the grantee to exercise that right and (B) provide the Membership Department with written verification in a form and manner prescribed by the Exchange that the required notice has been provided to the membership owner. *The membership owner may waive the foregoing notice requirement in a form and manner prescribed by the Exchange.*

* * * * *

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 CBOE 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 CBOE 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 proposed rule change would (i) change the voting requirement for approval of CBOE membership applications by CBOE's Membership Committee to the same voting requirement that applies to other CBOE committee decisions and (ii) clarify that a membership owner that grants to another member an Authorization to Sell the membership may waive the requirement that the grantee of the Authorization to Sell provide at least 3 business days notice to the membership owner prior to exercising the grantee's right to sell the membership.

With respect to the proposed voting requirement change, CBOE Rule 3.9(k) currently requires a vote of the majority of the members of CBOE's Membership Committee then in office to approve a membership application. However, CBOE Rule 2.1(b) provides that, except as provided in CBOE's Constitution, CBOE's Rules, or by resolution of CBOE's Board of Directors, the vote of a majority of the members of a committee present at a meeting at which a quorum is present will be the act of the committee. The voting requirement set forth in CBOE Rule 2.1(b) is generally applicable to other CBOE committees and even to votes of the Membership Committee regarding issues other than whether to approve a membership application. In order to make the Membership Committee voting requirement for the approval of membership applications consistent with the voting requirement for other CBOE committee decisions, the Exchange is proposing to delete the special voting requirement for membership applications currently contained in CBOE Rule 3.9(k). by virtue of this deletion, the voting requirement contained in CBOE Rule 2.1(b) would apply to the approval of membership applications.

With respect to waiving the notice requirement that must be satisfied in order to exercise an Authorization to Sell a membership, CBOE Rule 3.14(d) currently permits an owner of a transferable membership to voluntarily grant to another member an Authorization to Sell the membership. The grantee of an Authorization to Sell is vested with all of the authority provided for under the Exchange's Constitution and Rules relating to the sale of the membership. The grantee of an Authorization to Sell also has the right upon the sale of the membership to submit claims against the membership owner pursuant to CBOE Rule 3.15(b), to be satisfied out of the proceeds of the sale of the membership, that are related to the membership owner's Exchange business activities. CBOE Rule 3.14(d)(iii) requires a grantee of an Authorization to Sell a membership (i) to notify the membership owner in writing at least 3 business days prior to exercising the grantee's right to sell the membership of any decision by the grantee to exercise that right, and (ii) to provide the Membership Department with written verification in a form and manner prescribed by the Exchange that the required notice has been provided to the membership owner. However, a membership owner may wish to waive this notice requirement if the grantee of the Authorization to Sell is exercising the grantee's right to sell the membership and the membership owner believes a higher sale price will be obtained if the membership is sold right away instead of three business days later. Because this notice requirement is for the sole benefit of the membership owner, the Exchange believes that it is fairly and reasonably implied that the membership owner may waive this notice requirement.

The Exchange is now proposing to amend CBOE Rule 3.14(d)(iii) to make explicit that the membership owner may waive the foregoing notice requirement in a form and manner prescribed by the Exchange. The Exchange believes that this codification would benefit members and would help to ensure that members are aware of the ability to waive the notice requirement.

2. Statutory Basis

The CBOE believes the proposed rule change is consistent with Section 6(b) of the Act [4] in general, and furthers the objectives of Section 6(b)(5) [5] in particular, in that it is designed to remove impediments to and perfect the mechanism of a free and open market and to protect investors and the public interest by improving the Exchange's approval process for membership applicants and by clarifying the Exchange's membership rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

The CBOE does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. 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

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, D.C. 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the CBOE. All submissions should refer to file number SR–CBOE–17 and should be submitted by June 29, 2001.

IV. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

After careful review, the Commission finds that the proposed rule change. as amended, is consistent with the requirements of the act and the rules and regulations thereunder applicable to a national securities exchange[6] and, in particular, the requirements of Section 6(b)(5) of the Act.[7] Specifically, the Commission finds that the proposed rule change will make the Exchange's approval process for membership applications consistent with the Exchange's generally applicable committee voting process. In addition, the Commission believes that clarifying that membership owners are permitted to waive the notice requirement relating to the exercise of an Authorization to Sell a membership will help ensure that members are aware of this right.

The Commission finds good cause for approving the proposed rule change prior to the thirtieth day after date of publication of the notice of filing thereof in the **Federal Register** pursuant to Section 19(b)(2) of the Act.[8] Accelerated approval will permit the Exchange to use its generally applicable committee voting process in approving membership applications, and will put membership owners on notice of their right to waive the notice requirement relating to Authorizations to Sell, without undue delay. Accordingly the Commission finds that it is consistent with Section 6(b)(5) of the Act[9] to approve the proposal on an accelerated basis.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[10] that the proposed rule change (SR–CBOE–2001–17), as amended, is hereby approved on an accelerated basis.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[11]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–14460 Filed 6–7–01; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–44382; File No. SR–Phlx–2001–55]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Philadelphia Stock Exchange, Inc. Relating to Short Sales

June 1, 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 May 16, 2001, the Philadelphia Stock Exchange, Inc. (''Phlx'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items the Phlx has prepared. 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 Phlx proposes to amend Phlx Rule 455, Short Sales, by adding new Supplementary Material .01. The text of the proposed rule change is below, with new language in italics.

Rule 455. Short Sales

(a)–(d) No change.

Supplementary Material

.01 This Rule 455 shall not prohibit any transaction or transactions which the Commission, upon written request or upon its motion, exempts, either unconditionally or on specified terms and conditions.

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 Phlx 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 Phlx 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

Rule 10a–1 under the Act[3] addresses short selling. Subsection (f) of Rule 10a–1 provides that Rule 10a–1 shall not prohibit any transaction or transactions that the Commission, upon written request or upon its own motion, exempts, either unconditionally or on specified terms and conditions.

Phlx Rule 455 also addresses short selling. proposed Supplementary Material .01 of Phlx Rule 455 would track the language of Rule 10a–1(f) to clarify that nothing in Phlx Rule 455 prohibits any transaction or transactions that the Commission has exempted from Rule 10a–1 pursuant to Rule 10a–1(f).

2. Statutory Basis

The Phlx believes the proposed rule change is consistent with the provisions of Section 6(b) of the Act[4] and furthers the objectives of Section 6(b)(5) of the Act[5] in that it is designed to perfect the mechanisms of a free and open market and the national market system, protect investors and the public interest and promote just and equitable principles of trade by clarifying and describing clearly in the Phlx's rules that nothing in Phlx Rule 455 prohibits any transaction or transactions which the Commission, upon written request or upon its own motion, has exempted pursuant to Rule 10a–1(f).

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not

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[6] In approving this rule, the Commission has considered its impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[7] 15 U.S.C. 78f(b)(5).

[8] 15 U.S.C. 78s(b)(2).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78s(b)(2).

[11] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.10a–1. *See also* Securities Exchange Act Release No. 42037 (October 20, 1999), 64 FR 57996 (October 28, 1999) (Concept Release on Short Sales).

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Phlx neither solicited nor received any written comments.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The proposed rule change has become effective pursuant to Section 19(b)(3)(A)(i) of the Act [6] and subparagraph (f)(1) of Rule 19b–4 thereunder [7] because it constitutes a stated policy, practice, or interpretation with respect to the meaning, administration, or enforcement of an existing rule. 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.

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 amendment, all written statement 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 that 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 Phlx. All submissions should refer to file number SR–Phlx–2001–55 and should be submitted by June 29, 2001.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[8]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–14461 Filed 6–7–01; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–44386; File No. SR–Phlx–2001–45]

Self-Regulatory Organizations; Philadelphia Stock Exchange, Inc.; Order Granting Approval of Proposed Rule Change Amending Rule 930

June 4, 2001.

On April 20, 2001, the Philadelphia Stock Exchange, Inc. (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend Rule 930 to add paragraph (k).

Rule 930(k) relates to the Exchange's ability to allow a member who leases a membership (''lessee'') to pay past-due fees owed to the Exchange by the lessor under a lease agreement, on behalf of the lessor. Rule 930(k) states that the Exchange is a third party beneficiary of the lease agreement, and shall have the right to permit payment by a lessee of past-due fees owed to the Exchange by the lessor. The Rule further states that should the lessee pay such past due amounts, the lessee shall provide written notice to the lessor and the Exchange. Once the lessee has elected to make such payments, the lessee may continue to make such payments for a period of up to three months and set off such amounts, with notice to the Exchange and lessor against amounts due the lessor by the lessee. Furthermore, Rule 930(k) states that notwithstanding the terms of the lease agreement, a lessee will not be considered in default of the lease agreement solely by virtue of having elected to make such payments. The Exchange also amended Rule 930 to make certain minor technical amendments to the text of the rule in order to make the various paragraphs contained in the rule more consistent.

The proposed rule change was published for comment in the **Federal Register** on May 2, 2001.[3] The Commission received no comments on the proposal.

The Commission finds that the proposed rule change is consistent with the Act and the rules and regulations under the Act 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 the requirement of Section 6(b)(5) [6] because it is designed to promote just and equitable principles of trade and to protect investors and the public interest by enabling lessees to continue trading on the Exchange even when their respective lessors fail to pay fees owed the Exchange when due.

The Commission is not required under Section 19(b)(2) of the Act [7] to find that a proposed rule change by a self-regulatory organization is lawful under state corporation law; in approving this proposal, the Commission is relying on the Phlx's representation that it has the general power under applicable provisions of Delaware law to modify Rule 930 by adding paragraph (k). The Commission is also relying on the Phlx's representations that proposed Rule 930(k) is permissible under Pennsylvania contract law. The Commission has not independently evaluated the accuracy of Phlx's representations regarding Delaware or Pennsylvania law.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[8] that the proposed rule change (SR–Phlx–2001–45) is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[9]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–14462 Filed 6–7–01; 8:45 am]

BILLING CODE 8010–01–M

[6] 15 U.S.C. 78s(b)(3)(A)(i).

[7] 17 CFR 240.19b–4(f)(1).

[8] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 44220 (April 25, 2001), 66 FR 22059.

[4] In approving this proposed rule change, the Commission has considered the proposal'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] 15 U.S.C. 78s(b)(2).

[8] 15 U.S.C. 78s(b)(2).

[9] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–44374; File No. SR–NASD–2001–17]

Self-Regulatory Organizations; Order Approving a Proposed Rule Change by the National Association of Securities Dealers, Inc. To Revise the Fees Associated With Appeals of Nasdaq Listing Determinations

May 31, 2001.

On March 13, 2001, the National Association of Securities Dealers, Inc. (''NASD''), through its subsidiary, the Nasdaq Stock Market, Inc. (''Nasdaq'') filed with the Securities and Exchange Commission (''Commission'') pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] a proposed rule change to revise the fees associated with appeals of Nasdaq Listing Determinations. The proposed rule change was noticed in the **Federal Register** on April 11, 2001.[3] No comments were received on the proposed rule change. This order approves the proposed rule change.

I. Description of the Proposal

Determinations by the Listing Qualifications Department or the Listing Investigations Department to limit or prohibit the initial or continued listing of an issuer's securities may be appealed by the issuer to the Listing Qualifications Panel (the ''Panel'') and thereafter to the Nasdaq Listing and Hearing Review Council (the ''Listing Council''). Nasdaq has proposed to revise the current fee schedules for issuer requests for the review of listing determinations to both the Panel and the Listing Council to cover the costs associated with the review.

Currently, the fee for an appeal to the Panel based on a written submission from the issuer is $1,400, and the fee for an oral hearing before the Panel is $2,300. In addition, the fee for an appeal to the Listing Council is $1,400.[4] Nasdaq has proposed to change the fee for an appeal to the Panel based on a written submission from the issuer to $4,000, and the fee for an oral hearing before the Panel to $5,000. In addition, Nasdaq has proposed to change the fee for an appeal to the Listing Council to $4,000.

The fees associated with appeals to the Panel were last revised in 1996.[5] Nasdaq asserts that since that time, there has been an increase in the various costs associated with the review process. Nasdaq asserts in particular that, in 1999, it expanded the review process in part in response to the Commission's findings, which required changes in the process of reviews and an increase in the amount of time spent by Nasdaq staff members dedicated to the review process.[6] Further, Nasdaq has identified other expenses related to the review process that are not covered by the current hearing fees.[7]

The proposed fee for an appeal to the Panel includes all costs of the Office of Listing Qualifications Hearings attributable to the processing of hearing requests and the associated expenses of the Panel.[8] In addition, the proposed fee for an appeal to the panel includes a large portion of the expenses associated with the Office of Appeals and Review,[9] and the Listing Council. The proposed fee for an appeal to the Listing Council under Marketplace Rule 4840(b) will cover the remainder of the expenses of the Office of Appeals and Review and the Listing Council, as well as the Office of General Counsel's time directly related to the appeals process.[10]

II. Discussion

The Commission finds that the proposed rule change is consistent with the provisions of Section 15A(b)(5) [11] and Section 15A(b)(6) [12] of the Act. The Commission believes that the proposed rule change is consistent with Section 15A(b)(5) because it helps to provide for the equitable allocation of reasonable dues, fees, and other charges among issuers using Nasdaq, by proposing fees for the review process that are revenue neutral and reflect the costs incurred by Nasdaq to process issuer requests. The Commission also believes that the proposed rule change is consistent with Section 15A(b)(6), which requires that the rules of the Exchange be designed to prevent fraudulent and manipulative acts and practices as well as to protect investors and the public interest. In particular, the Commission believes that the proposed fees will help Nasdaq to ensure that only qualified issuers are allowed to list or remain listed on Nasdaq.

III. Conclusion

It Is Therefore Ordered, pursuant to Section 19(b)(2) of the Act,[13] that the proposed rule change (SR–NASD–2001–17) is approved.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[14]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–14430 Filed 6–7–01; 8:45 am]

BILLING CODE 8010–01–M

SMALL BUSINESS ADMINISTRATION

[License No. 02/02–5377]

Elk Associates Funding Corporation; Notice Seeking Exemption Under Section 312 of the Small Business Investment Act, Conflicts of Interest

Notice is hereby given that Elk Associates Funding Corporation, 747 Third Avenue, New York, New York 10017, a Federal Licensee under the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 44153 (April 5, 2001), 66 FR 44153 (April 11, 2001) (SR–NASD–01–17).

[4] Pursuant to Marketplace Rule 4840(d), appeals to the Listing Council are based only on the written record unless the Listing Council exercises its discretion to hold an oral hearing. There is no additional fee for an oral hearing before the Listing Council.

[5] *See* Securities Exchange Act Release No. 37088 (April 9, 1996), 61 FR 16662 (April 16, 1996). In 1999, a $1,400 fee for appeals to the Listing Council was established, which matched the fee for appeals to the Panel based only on the written record. *See* Securities Exchange Act Release No. 41367 (May 4, 1999), 64 FR 25942 (May 13, 1999).

[6] *See* Securities Exchange Act Release No. 41367 (May 4, 1999), 64 FR 25942 (May 13, 1999).

[7] Nasdaq has represented that the other expenses relating to the review process that are not covered by the current hearing fees include the following: overhead, including telephones, supplies, depreciation and occupancy, computer system support, listing qualifications retention analyst and manager review, and a stipend for Panel and Listing Council members. Telephone conversation between John D. Nachmann, Senior Attorney, Office of General Counsel, Nasdaq, and Lisa Jones, Attorney, Division of Market Regulation, Commission (March 30, 2001).

[8] The additional variable fee allocated to issuers who request oral hearings before the panel is designed to recover the additional costs associated with such hearings; specifically, travel expenses for members of the Panel and court reporter time to maintain a transcript of these hearings.

[9] On March 22, 2001, Nasdaq filed a proposed rule change, SR–NASD–2001–02, with the Commission pursuant to Section 19(b)(3)(A) of the Act, and subparagraph (f) of Rule 19b–4 thereunder, that transfers certain responsibilities from the Nasdaq Office of General Counsel regarding the review process to the Office of Appeals and Review, a new unit in the Nasdaq's Listing Qualifications Department. The Office of Appeals and Review will receive requests for review from issuers and will keep records of proceedings.

[10] The fees proposed in this proposed rule change are designed to recover only the direct costs associated with the review process and do not include various indirect overhead costs that have been identified by Nasdaq as Senior Management, Finance, Human Resources, Administrative Services, Legal (excluding unrelated litigation and international expenses), Economic Research, Nas Tech and Strategic Development.

[11] 15 U.S.C. 78*o*–3(b)(5).

[12] 15 U.S.C. 78*o*–3(b)(6).

[13] 15 U.S.C. 78s(b)(2).

[14] 17 CFR 200.30–3(a)(12).

Small Business Investment Act of 1958, as amended (''the Act''), in connection with the financing of a small concern, has sought an exemption under section 312 of the Act and section 107.730, Financings which Constitute Conflicts of Interest of the Small Business Administration (''SBA'') rules and regulations (13 CFR 107.730 (2000). Elk Associates Funding Corporation proposes to provide loans to Concorde Cab Corp. and Queens Star Cab Corp. The financings are contemplated for the purchase of taxicab medallions, New York City transfer taxes and taxicab vehicles.

The financings are brought within the purview of sec. 107.730(a)(1) of the regulations because Meryl Sara and Lauren Abate, Associates of Elk Associates Funding Corporation, will own greater than 10 percent of Concorde Cab Corp. and Queens Star Cab Corp., and therefore, Concorde Cab Corp. and Queens Star Cab Corp. are considered Associates of Elk Associates Funding Corporation as defined in section 107.50 of the regulations.

Notice is hereby given that any interested person may submit written comments on the transaction to the Acting Associate Administrator for Investment, U.S. Small Business Administration, 409 Third Street, SW, Washington, DC 20416.

Dated: May 29, 2001.

Harry Haskins,

Acting Associate Administrator for Investment.

[FR Doc. 01–14511 Filed 6–7–01; 8:45 am]

BILLING CODE 8025–01–P

SOCIAL SECURITY ADMINISTRATION

President's Commission To Strengthen Social Security

AGENCY: Social Security Administration (SSA).

ACTION: Announcement of meeting location and time change.

DATES: June 11, 2001, 10 a.m.– 4 p.m.

ADDRESSES: Willard Inter-Continental Hotel, 1401 Pennsylvania Avenue, NW., Washington, DC 20004, (202) 628–9100.

SUPPLEMENTARY INFORMATION: The May 29, 2001 **Federal Register** notice (FR Doc. 01–13486, 66 FR 29200) announcing the June 11 meeting of the President's Commission to Strengthen Social Security did not include a meeting location. The purpose of this announcement is to provide the meeting location and to note that the meeting will end at 4 p.m. instead of 6 p.m., as previously reported.

The meeting will be open to the public at 11 a.m. The Commission will break for lunch at Noon, and the public meeting will reconvene at 1 p.m. and continue through 4 p.m. In accordance with the Government in the Sunshine Act, 5 U.S.C. 552b(c), the meeting will be closed to the public from 10 a.m. to 11 a.m. to conduct housekeeping business relating solely to Federal personnel rules and practices and other administrative matters.

Dated: June 4, 2001.

Larry G. Massanari,

Acting Commissioner of Social Security.

[FR Doc. 01–14527 Filed 6–5–01; 4:08 pm]

BILLING CODE 4191–02–U

DEPARTMENT OF STATE

[Public Notice 3691]

Bureau of Educational and Cultural Affairs Request for Grant Proposals: Ukrainian Media Partnership Program

SUMMARY: The Europe/Eurasia Division in the Office of Citizen Exchanges of the Bureau of Educational and Cultural Affairs announces an open competition for the Ukrainian Media Partnership Program. Public and private non-profit organizations meeting the provisions described in IRS regulation 26 CFR 1.501(c) may submit proposals to conduct this program. Grants are subject to availability of funds. Overall grant making authority for this program is contained in the Mutual Educational and Cultural Exchange Act of 1961, Public Law 87–256, as amended, also known as the Fulbright-Hays Act. The purpose of the Act is ''to enable the Government of the United States to increase mutual understanding between the people of the United States and the people of other countries * * *; to strengthen the ties which unite us with other nations by demonstrating the educational and cultural interests, developments, and achievements of the people of the United States and other nations * * * and thus to assist in the development of friendly, sympathetic and peaceful relations between the United States and the other countries of the world.'' The funding authority for the program cited above is provided through the Fulbright-Hays Act and the FREEDOM Support Act.

Programs and projects must comply with Bureau requirements and guidelines outlined in the Solicitation Package: the Request for Grant Proposals (RFGP) and the Proposal Submission Guidelines (PSI).

Announcement Title and Number

All communications with the Bureau concerning this Request for Grant Proposals (RFGP) should refer to the announcement title ''The Ukrainian Media Partnership Program'' and reference number ECA/PE/C/EUR–01–77.

Program Information

Overview

The Bureau of Educational and Cultural Affairs (the Bureau) invites applicants to submit proposals for a project to create and foster long-term relationships between selected American media outlets and Ukrainian media outlets of similar size and between the individual professionals that work at both outlets. Within the framework of these partnerships, Ukrainian professionals in print and broadcast media will have the opportunity to interact with US counterparts and to take part in practical training experiences organized by their US partner. This project seeks to promote the development of free and independent Ukrainian media outlets on the assumption that independent media is critical for the further democratic development of Ukraine.

The Bureau would like to see five partnerships developed under this program. Each Ukrainian media outlet should be matched with an appropriate U.S. media outlet for partnership activities. Proposals should demonstrate geographic diversity by including media outlets from throughout Ukraine. While partnerships should primarily include media outlets in regional capitals or larger regional cities, a Kiev media outlet may be included in one of the proposed partnerships. Applicants should propose at least three partnerships in their submission, but are encouraged to propose all five. When only three or four partnerships are proposed by the applicant, the Public Affairs Section in at the American Embassy in Kiev (PAS) will identify the remaining Ukrainian media outlets who will then be partnered with American media outlets already selected by the applicant. Applicants should explain how proposed matches support the program's objectives and why they expect that the partnerships they are proposing will be sustained beyond the life of the grant. The grantee should work closely with the Bureau and PAS throughout the grant period; specific partnerships will be approved by the Bureau and PAS.

Applicants should explain how partnerships will be structured and what activities they will include. The

Bureau would like to see each partnership include a combination of trips to the U.S. for Ukrainian participants, trips to Ukraine for American participants, and on-going activities and electronic interactions throughout the grant period. Exchanges in both directions, while meeting the program's objectives, should be tailored to meet the specific needs of the Ukrainian partners. U.S.-based visits for Ukrainian participants should expose Ukrainian media professionals to the American media industry, including business practices, work style, and culture. These visits should also demonstrate the important role journalism plays in an open and democratic society by providing accurate and unbiased news to the public.

U.S. visits for Ukrainian participants should consist primarily of substantive internships and/or job shadowing experiences at U.S. partner media outlets. In addition, visits may include consultations; workshops and/or intensive training on specific topics; and other appropriate activities. The program should emphasize hands-on experience that will build professional expertise and strengthen links between the two partners. The program may include such topics as use of the Internet as a news tool, web design for media outlets, business practices, management, journalistic ethics, the relationship of journalists and editors, and licensing and other legal issues as they pertain to media. The proposal should identify the individuals who will be responsible for the partnership at each U.S. media outlet, and should, wherever possible, identify personnel that will participate from both the U.S. and Ukrainian sides. Roundtable discussions should not be a component of the training activities, but grantees are encouraged, time allowing, to arrange activities that will enable Ukrainian participants to speak to community/business and other groups that are interested in contemporary Ukraine and the Ukrainian media.

For the visits to Ukraine, activities should focus on complementing those activities conducted in the U.S. and increasing the professional capacity of the Ukrainian participants and their colleagues who may not travel to the U.S. This aspect of the program should also strengthen the sustainable relationship between the two outlets.

The Bureau encourages applicants to submit proposals for programs that provide for a minimum of two visits to both the U.S. and Ukraine within each institutional partnership. Applicants are encouraged to propose visits with two or more participants in each direction.

A detailed program timeline for the entire grant period that outlines how components will unfold and complement each other must be included in the proposal.

Applicants should explain the rationale for proposed partnerships as well as for individual participants with particular emphasis on explaining how proposed partnerships will contribute to the sustainability of both the Ukrainian media outlet, and to the partnership. The names of proposed Ukrainian participants must be reviewed and approved in advance of U.S. travel by PAS. The Bureau anticipates that the majority of Ukrainian participants will not have a working-level competency in English language. Applicants should describe the provisions that will be made for these non-English speaking participants.

Guidelines

Programs should begin in January 2002 and last from one to two years. The Executive Summary and Narrative of the proposal should be no more than 20 pages in length, double-spaced, single-sided, and unbound. Programs must comply with J–1 visa regulations. Please refer to the Solicitation Package for further information.

In the Solicitation Package, you will also find forms required by Federal regulations and Bureau policy. Please follow the guidelines; complete and return the necessary forms with the submission. Please refer to the Technical Format and Instructions page in the PSI.

Budget Guidelines

The Bureau anticipates awarding one grant in the amount of $427,000 to support program and administrative costs required to implement this program. Bureau grant guidelines state that organizations that are unable to demonstrate at least four years of experience in conducting international exchange programs are limited to $60,000 in Bureau support. Therefore, organizations with less than four years of experience in conducting international exchanges would not be eligible to apply under this competition. The Bureau encourages applicants to provide maximum levels of cost-sharing and funding from private sources in support of its programs.

Applicants must submit a comprehensive budget for the entire program. There must be a summary budget as well as breakdowns reflecting both administrative and program budgets. Applicants may provide separate sub-budgets for each program component, phase, location, or activity to provide clarification. Allowable costs for the program include the following:

1. *International and domestic air fares* (per the ''Fly America Act''). Including visas, transit costs, and ground transportation costs.

2. *Per Diem.* Current USG per diem rates may be accessed at: *http://www.state.gov/m/a/als/prdm/* (foreign), and *http://policyworks.gov/org/main/mt/homepage/mtt/perdiem/travel.shtml* (domestic). For activities in Ukraine, however, the Bureau strongly encourages the applicant to budget realistic costs that reflect the local economy.

3. *Interpreters.* Locally-based interpreters should be hired to assist with training when necessary. Interpreters' salaries should reflect the local economy. Per diem and transportation costs for interpreters should be included in the budget when needed.

4. *Consultants.* Consultants may be used to provide specialized expertise or to make presentations. Daily honoraria cannot exceed $250 per day. Subcontracting organizations may also be used, in which case the written agreement between the prospective grantee and subcontractor should be included in the proposal. Subcontracts should be itemized in the budget.

5. *Room rental.* Room rental may not exceed $250 per day. The Bureau encourages the applicant to cost share room rental and meeting space with local partners, when possible.

6. *Materials development.* The proposal may contain costs to purchase, develop, and translate materials for participants.

7. *Equipment.* The proposal may contain costs to purchase equipment for Ukraine-based programming such as computers and fax machines. Costs to purchase furniture are not allowed. Equipment costs must be kept to a minimum.

8. *Working meal.* Only one working meal may be provided during the program. Per capita costs may not exceed $5–8 for a lunch and $14–20 for a dinner, excluding room rental. The number of invited guests may not exceed participants by more than a factor of two-to-one. Interpreters must be included as participants.

9. *Administrative costs.* Costs necessary for the effective administration of the program may include salaries for grant organization employees, benefits, and other direct and indirect costs per detailed instructions in the Application Package. While this solicitation does not

proscribe a rigid ratio of administrative to program costs, the Bureau encourages the applicant to spend no more than twenty-five (25) per cent of the total funds requested from The Bureau on administrative expenses. The proposal should show cost-sharing contributions from the applicant, partners, and other sources.

The Bureau will provide health insurance for Ukrainian participants during U.S.-based program activities. Therefore, applicants do not need to include costs of insurance coverage for these individuals.

Please refer to the Solicitation Package for complete budget guidelines and formatting instructions.

Announcement Title and Number

All correspondence with the Bureau concerning this RFGP should reference the program title and grant reference number ECA/PE/C/EUR–01–77.

FOR FURTHER INFORMATION CONTACT: The Office of Citizen Exchanges, ECA/PE/C/EUR, Room 224, U.S. Department of State, 301 4th Street, SW., Washington, DC 20547, telephone 1–202–619–5327, e-mail *hscott@pd.state.gov* to request a Solicitation Package. The Solicitation Package contains detailed award criteria, required application forms, specific budget instructions, and standard guidelines for proposal preparation. Please specify Bureau program officer Henry Scott on all other inquiries and correspondence.

Please read the complete **Federal Register** announcement before sending inquiries or submitting proposals. Once the RFGP deadline has passed, Bureau staff may not discuss this competition with applicants until the proposal review process has been completed.

To Download a Solicitation Package Via Internet

The entire Solicitation Package may be downloaded from the Bureau's website at *http://exchanges.state.gov/education/RFGPs.* Please read all information before downloading.

Deadline for Proposals

All proposal copies must be received at the Bureau of Educational and Cultural Affairs by 5 p.m. Washington, DC time (Eastern Daylight Time) on July 26, 2001. Faxed documents will not be accepted at any time. Documents postmarked the due date but received on a later date will not be accepted. Each applicant must ensure that the proposals are received by the above deadline.

Applicants must follow all instructions in the Solicitation Package. The original and eight (8) copies of the application should be sent to: U.S. Department of State, SA–44, Bureau of Educational and Cultural Affairs, Ref.: ECA/PE/C/EUR–01–77, Program Management, ECA/EX/PM, Room 534, 301 4th Street, SW., Washington, DC 20547.

Diversity, Freedom, and Democracy Guidelines

Pursuant to the Bureau's authorizing legislation, programs must maintain a non-political character and should be balanced and representative of the diversity of American political, social, and cultural life. ''Diversity'' should be interpreted in the broadest sense and encompass differences including, but not limited to ethnicity, race, gender, religion, geographic location, socio-economic status, and physical challenges. Applicants are strongly encouraged to adhere to the advancement of this principle both in program administration and in program content. Please refer to the review criteria under the 'Support for Diversity' section for specific suggestions on incorporating diversity into the total proposal. Public Law 104–319 provides that ''in carrying out programs of educational and cultural exchange in countries whose people do not fully enjoy freedom and democracy,'' the Bureau ''shall take appropriate steps to provide opportunities for participation in such programs to human rights and democracy leaders of such countries.'' Public Law 106–113 requires that the governments of the countries described above do not have inappropriate influence in the selection process. Proposals should reflect advancement of these goals in their program contents, to the full extent deemed feasible.

Review Process

The Bureau will acknowledge receipt of all proposals and will review them for technical eligibility. Proposals will be deemed ineligible if they do not fully adhere to the guidelines stated herein and in the Solicitation Package. All eligible proposals will be reviewed by the program office, as well as the Public Affairs Section in Kiev. Eligible proposals will be subject to compliance with Federal and Bureau regulations and guidelines and forwarded to grant panels for advisory review. Proposals may also be reviewed by the Office of the Legal Adviser or by other Department elements. Final funding decisions are at the discretion of the Department of State's Acting Assistant Secretary for Educational and Cultural Affairs. Final technical authority for assistance awards resides with the Bureau's Grants Officer.

Review Criteria

Technically eligible applications will be competitively reviewed according to the criteria stated below. These criteria are not rank ordered and all carry equal weight in the proposal evaluation:

1. *Program planning and ability to achieve objectives:* A detailed agenda and relevant work plan should demonstrate substantive undertakings and logistical capacity. Agenda and plan should adhere to the program overview and guidelines described above. Objectives should be reasonable, feasible, and flexible. Proposals should clearly demonstrate how the institution will meet the program's objectives and plan.

2. *Impact:* Proposed programs should strengthen long-term mutual understanding, including maximum sharing of information, and the establishment of long-term institutional and individual linkages.

3. *Support of diversity:* Proposals should demonstrate substantive support of the Bureau's policy on diversity. Achievable and relevant features should be cited in both program administration (selection of participants, program venue, and program evaluation) and program content (orientation and wrap-up sessions, program meetings, resource materials and follow-up activities).

4. *Institutional capacity:* Proposals should demonstrate an institutional record of successful exchange programs, including responsible fiscal management and full compliance with all reporting requirements for past Bureau-supported grants as determined by staff of the Grants Office. The Bureau will consider the past performance of prior recipients and the demonstrated potential of new applicants.

5. *Follow-on activities:* Proposals should provide a plan for continued follow-on activity (without Bureau support) ensuring that supported programs are not isolated events.

6. *Project evaluation:* Proposals should include a plan to evaluate the activity's success, both as the activities unfold and at the end of the program. A draft survey questionnaire or other technique plus description of a methodology to use to link outcomes to original project objectives is recommended. Successful applicants will be expected to submit intermediate reports after each project component is concluded or quarterly, whichever is less frequent.

7. *Cost-effectiveness:* The overhead and administrative components of the proposal, including salaries and honoraria, should be kept as low as possible. All other items should be

necessary and appropriate. The Bureau encourages the applicant to spend no more than twenty-five (25) per cent of the total funds requested from The Bureau on administrative expenses. The proposal should show cost-sharing contributions from the applicant, partners, and other sources.

Authority

Overall grant making authority for this program is contained in the Mutual Educational and Cultural Exchange Act of 1961, Public Law 87–256, as amended, also known as the Fulbright-Hays Act. The purpose of the Act is ''to enable the Government of the United States to increase mutual understanding between the people of the United States and the people of other countries * * *; to strengthen the ties which unite us with other nations by demonstrating the educational and cultural interests, developments, and achievements of the people of the United States and other nations * * * and thus to assist in the development of friendly, sympathetic and peaceful relations between the United States and the other countries of the world.'' The funding authority for the program above is provided through The funding authority for the program cited above is provided through the Fulbright-Hays Act and the FREEDOM Support Act.

Notice

The terms and conditions published in this RFGP are binding and may not be modified by any Bureau representative. Explanatory information provided by the Bureau that contradicts published language will not be binding. Issuance of the RFGP does not constitute an award commitment on the part of the Government. The Bureau reserves the right to reduce, revise, or increase proposal budgets in accordance with the needs of the program and the availability of funds. Awards made will be subject to periodic reporting and evaluation requirements.

Notification

Final awards cannot be made until funds have been appropriated by Congress, allocated and committed through internal Bureau procedures.

Dated: June 1, 2001.

Helena Kane Finn,

Acting Assistant Secretary for Educational and Cultural Affairs, U.S. Department of State.

[FR Doc. 01–14508 Filed 6–7–01; 8:45 am]

BILLING CODE 4710–05–U

DEPARTMENT OF STATE

[Public Notice No. 3678]

Advisory Committee on International Economic Policy; Open Meeting Notice

The Advisory Committee on International Economic Policy (ACIEP) will meet from 9 am to 12 pm on Tuesday, June 12, 2001, in Room 1107, U.S. Department of State, 2201 C Street, NW., Washington, DC 20520. The meeting will be hosted by Committee Chairman R. Michael Gadbaw and Assistant Secretary of State for Economic and Business Affairs E. Anthony Wayne.

The ACIEP serves the U.S. Government in a solely advisory capacity concerning issues and problems in international economic policy. The objective of the ACIEP is to provide expertise and insight on these issues that are not available within the U.S. Government.

Topics for the June 12 meeting will be:

- A New WTO Round
- Responding to the HIV/AIDS Crisis
- The International Implications of U.S. Energy Policy

The public may attend these meetings as seating capacity allows. The media is welcome but discussions are off the record. Admittance to the Department of State building is by means of a pre-arranged clearance list. In order to be placed on this list, please provide your name, title, company or other affiliation if appropriate, social security number, date of birth, and citizenship to the ACIEP Executive Secretariat by fax (202) 647–5936 (Attention: Cecilia Walker) or email: (walkercr@state.gov) by October 27th. On the date of the meeting, persons who have registered should come to the 23rd Street entrance. One of the following valid means of identification will be required for admittance: a U.S. driver's license with photo, a passport, or a U.S. Government ID.

For further information about the meeting, contact Deborah Grout, ACIEP Secretariat, U.S. Department of State, Bureau of Economic and Business Affairs, Room 3526, Main State, Washington, DC 20520. Tel: 202–647-1826; or Carol Thompson, Email: thompsonce@state.gov.

Dated: June 5, 2001.

Carol E. Thompson,

Executive Secretary, Advisory Committee on International, Economic Policy, U.S. Department of State.

[FR Doc. 01–14622 Filed 6–6–01; 3:01 pm]

BILLING CODE 4710–07–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Reports, Forms and Recordkeeping Requirements; Agency Information Collection Activity Under OMB Review

AGENCY: Office of the Secretary, DOT.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for renewal and comment. The ICR describes the nature of the information collection and its expected cost and burden. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on March 23, 2001 [66 FR 16309]. No comments were received.

DATES: Comments must be submitted on or before (insert: date 30 days after publishing in the **Federal Register**) to: Attention DOT/OST Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Jack Schmidt, Competition and Policy Analysis Division, Office of Aviation Analysis; Office of the Secretary, U.S. Department of Transportation, 400 7th Street, SW., Washington DC 20590–0002. Telephone (202) 366–5420.

SUPPLEMENTARY INFORMATION:

Office of the Secretary (OST).

Title: Passenger Manifest Information.

OMB Control Number: 2105–0534.

Affected Public: US and foreign direct air carriers

Annual Estimated Burden: 1.05 million hours.

Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Issued in Washington, DC on June 5, 2001.

Michael Robinson,

Information Resource Management, United States Department of Transportation.

[FR Doc. 01–14492 Filed 6–7–01; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on Application To Impose and Use the Revenue From a Passenger Facility Charge (PFC) at Central Illinois Regional Airport, Bloomington, IL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent to rule on application.

SUMMARY: The FAA proposes to rule and invites public comment on the application to impose and use the revenues from a PFC at Central Illinois Regional Airport under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Public Law 101–508) and Part 158 of the Federal Aviation Regulations (14 CFR Part 158).

DATES: Comments must be received on or before July 9, 2001.

ADDRESSES: Comments on this application may be mailed or delivered in triplicate to the FAA at the following address: Federal Aviation Administration, Great Lakes Region, Chicago Airports District Office, 2300 E. Devon Avenue, Room 320, Des Plaines, Illinois 60018.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to the Bloomington-Normal Airport Authority at the following address: Mr. Michael La Pier, A.A.A., Executive Director, Central Illinois Regional Airport, 2901 East Empire, Suite 200, Bloomington, Illinois 61704.

Air carriers and foreign air carriers may submit copies of written comments previously provided to the Bloomington-Normal Airport Authority under section 158.23 of Part 158.

FOR FURTHER INFORMATION CONTACT: Denis Rewerts, Civil Engineer, Federal Aviation Administration, Great Lakes Region, Chicago Airports District Office, 2300 E. Devon Avenue, Room 320, Des Plaines, IL 60018, (847) 294–7195. The application may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the application to impose and use the revenue from a PFC at Central Illinois Regional Report under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Public Law 101–508) and Part 158 of the Federal Aviation Regulations (14 CFR part 158).

On May 22, 2001, the FAA determined that the application to use the revenue from a PFC submitted by the Bloomington-Normal Airport Authority was substantially complete within the requirements of section 158.25 of Part 158. The FAA will approve or disapprove the application, in whole or in part, no later than August 22, 2001.

The following is a brief overview of the application.

Level of the proposed PFC: $4.50.

Proposed charge effective date: October 1, 2017.

Proposed charge expiration date: June 1, 2018.

Total estimated PFC revenue: $1,161,019.00.

Brief description of proposed projects: PFC program development, construction of air carrier apron and taxiways to support new passenger terminal building, and purchase two passenger loading bridges.

Any person may inspect the application in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT**

In addition, any person may, upon request, inspect the application, notice and other documents germane to the application in person at the Central Illinois Regional Airport.

Issued in Des Plaines, Illinois on May 31, 2001.

Gary E. Nielsen,

Acting Manager, Planning and Programming Branch, Airports Division, Great Lakes Region.

[FR Doc. 01–14490 Filed 6–7–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on Application To Impose and Use the Revenue From a Passenger Facility Charge (PFC) at Delta County Airport, Escanaba, MI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Intent to rule on application.

SUMMARY: The FAA proposes to rule and invites public comment on the application to impose and use the revenue from a PFC at Delta County Airport under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Public Law 101–508) and Part 158 of the Federal Aviation Regulations (14 CFR Part 158).

DATES: Comments must be received on or before July 9, 2001.

ADDRESSES: Comments on this application may be mailed or delivered in triplicate to the FAA at the following address: Federal Aviation Administration, Detroit Airports District Office, Willow Run Airport, East, 8820 Beck Road, Belleville, Michigan 48111.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Mr. Richard Severson of the Delta County Airport at the following address: Delta County Airport, 3300 Airport Road, Escanaba, Michigan 49829.

Air carriers and foreign air carriers may submit copies of written comments previously provided to the Delta County Airport under section 158.23 of Part 158.

FOR FURTHER INFORMATION CONTACT: Arlene Draper, Program Manager, Federal Aviation Administration, Detroit Airports District Office, Willow Run Airport, East, 8820 Beck Road, Belleville, Michigan 48111 (734–487–7282). The application may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the application to impose and use the revenue from a PFC at Delta County Airport under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Public Law 101–508) and Part 158 of the Federal Aviation Regulations (14 CFR part 158).

On April 10, 2001, the FAA determined that the application to impose and use the revenue from a PFC submitted by Delta County was substantially complete within the requirements of section 158.25 of Part 158. The FAA will approve or disapprove the application, in whole or in part, no later than August 1, 2001.

The following is a brief overview of the application.

PRC Application No.: 01–06–C–00–ESC.

Level of the proposed PFC: $3.00.

Proposed charge effective date: July 1, 2001.

Proposed charge expiration date: January 1, 2003.

Total estimated PFC revenue: $117,900.00.

Brief description of proposed projects: Impose and Use—Construct and light North/South parallel taxiway (5,000 feet by 50 feet); design for rehabilitation of runway 9/27; wildlife management plan.

Impose Only—Construct runway safety area for runway 9.

Class or classes of air carriers which the public agency has requested not be required to collect PFCs: Air taxis and charter operators.

Any person may inspect the application in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT.**

In addition, any person may, upon request, inspect the application, notice, and other documents germane to the application in person at the Delta County Airport.

Issued in Des Plaines, Illinois, on May 31, 2001.

Gary E. Nielsen,

Acting Manager, Planning/Programming Branch, Airports Division, Great Lakes Region.

[FR Doc. 01–14491 Filed 6–7–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement: Berrien County, Benton Charter Township, Michigan

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Intent.

SUMMARY: The FHWA is issuing this notice to advise the public that a supplement to a final environmental impact statement will be prepared to identify a recommended route for the US–31 freeway between Napier Avenue and I–94 in Berrien County, Michigan.

FOR FURTHER INFORMATION CONTACT: Mr. James Kirschensteiner, Environmental Programs and Field Operations Engineer, Federal Highway Administration, 315 W. Allegan Street, Room 207, Lansing, Michigan 48933, Telephone (517) 702–1835 or Mr. Paul Wisney, Project Manager, Design Division, Michigan Department of Transportation, P.O. Box 30050, Lansing, Michigan 48909, Telephone (517) 394–8680.

SUPPLEMENTARY INFORMATION: The FHWA in cooperation with the Michigan Department of Transportation (MDOT) is preparing a supplement to a final environmental impact statement to reevaluate the recommended alternative alignment identified in the final environmental impact statement (EIS) for the US–31 freeway, and examine potential alternative improvements and alignments. The recommended alternative identified in the June 9, 1981 FEIS, (FHWA–MI–78–02–F) consisted of a freeway alignment which traversed the Blue Creek and the adjoining fen habitat areas and provided a direct connection with I–96.

The US–31 freeway connection to the I–94 study area is generally bounded by Napier Avenue to the south, Benton Center Road to the west, Blue Creek Road to the east, and I–94 and I–96 to the north. South of the proposed study area, US–31 has been constructed as a freeway facility from the Michigan-Indiana state line to a point just south of the St. Joseph River in Berrien Springs. North of Berrien Springs, US–31 is in various stages of construction and a limited-access freeway facility is planned to be completed up to Napier Avenue by 2003. US–31 is a principal arterial serving north-south traffic in Michigan's western lower peninsula, extending approximately 356 miles from the Michigan-Indiana state line north to a point just south of Mackinaw City. This route serves commercial and recreational areas along the western side of the state of Michigan.

A wide range of transportation improvement alternatives will be analyzed within the study area. Alternatives will include a: do nothing alternative, evaluating a potential connection of US–31 with I–94 in the vicinity of the existing Benton harbor/St. Joseph Business Loop I–94 interchange, comparing these alternatives to the approved 1981 final EIS limited access freeway alignment, and evaluation of various Transportation Systems Management improvements including a new eastbound I–94 off ramp to Business Loop I–94. The entire process of determining a recommended alternative is expected to take approximately eighteen months.

Letters and scoping information describing the proposed action will be prepared to solicit comments from appropriate federal, state, cooperating agencies, and local agencies. Citizen involvement will also be solicited throughout this process. A public hearing will be held on the draft supplement to the final environmental impact statement. Public notice will be given of the time and place of the hearing. The draft supplement to the final EIS will be available for public and agency review and comment prior to the public hearing.

To ensure that the full range of issues related to this proposed action are addressed and all potentially significant issues identified, comments and suggestions are invited from all interested parties. Comments or questions concerning this proposed action and the supplement to the final EIS should be directed to the FHWA at the address provided above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Research, Planning, and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Issued on: May 31, 2001.

James J. Steele,

Division Administrator, Lansing, Michigan.

[FR Doc. 01–14412 Filed 6–7–01; 8:45 am]

BILLING CODE 4910–22–M

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2001–8672]

Agency Information Collection Activities Under OMB Review: OMB Control No. 2126–0014 (Transportation of Hazardous Materials; Highway Routing)

AGENCY: Federal Motor Carrier Safety Administration, DOT.

ACTION: Notice; request for comments.

SUMMARY: The FMCSA announces that the Information Collection Request (ICR) described in this notice is being sent to the Office of Management and Budget (OMB) for review and approval. The FMCSA is requesting OMB's continued approval of the information that is required for Transportation of Hazardous Materials; Highway Routing. The ICR describes the information collection and its expected burden. The **Federal Register** notice announcing a 60-day comment period on this information collection was published on March 6, 2001 (66 FR 13620). We are required to send ICRs to OMB under the Paperwork Reduction Act.

DATES: Please submit comments by July 9, 2001.

FOR FURTHER INFORMATION CONTACT: Mr. Richard Swedberg (303) 969–5772 ext. 363, or Mr. William Quade (202) 366–2172, Hazardous Materials Division (MC–ECH), Federal Motor Carrier Safety Administration, 400 Seventh Street SW., Washington, DC 20590. Office hours are from 7:30 a.m. to 4 p.m., e.t., Monday through Friday, except Federal holidays.

ADDRESSES: Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 Seventeenth Street NW., Washington, DC 20503, *Attention:* DOT Desk Officer. We particularly request your comments on whether the collection of information is necessary for the FMCSA to meet its goal of reducing truck crashes, including whether the information is useful to this goal; the accuracy of the estimate of the burden of the information collection; ways to enhance the quality, utility and clarity of the information collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology. OMB wants to receive comments within 30 days of publication of this notice in order to act on the ICR quickly.

SUPPLEMENTARY INFORMATION:

Title: Transportation of Hazardous Materials; Highway Routing.

OMB Approval Number: 2126–0014.

Background: The data for the Transportation of Hazardous Materials; Highway Routing designations are collected under authority of 49 U.S.C. 5112 and 5125. That authority places responsibility on the Secretary of Transportation to specify and regulate standards for establishing, maintaining, and enforcing routing designations. Under 49 CFR 397.73, the Administrator has the authority to request that each state and Indian tribe, through its routing agency, provide information identifying hazardous materials (HM) routing designations within their respective jurisdictions. That information will be consolidated by the FMCSA and published annually in whole or as updates in the **Federal Register**.

The FMCSA published the required notice offering a 60-day comment period on the ICR on March 6, 2001 (66 FR 13620). We received two comments. The first commenter, the Institute of Makers of Explosives (IME), did not dispute the need for FMCSA to collect information they characterized as ''essential.'' It did, however, point out there have been errors in past publications of the information and made suggestions for improving the quality of the information and its presentation to the public. IME suggested that FMCSA should request each state to review, revise, and re-submit information. IME also requested that FMCSA be open to suggestions about other delivery mechanisms to make this information available and suggested FMCSA use the mechanism of the ''Uniform Program.'' IME also requested that FMCSA update the HM routing website as changes occur.

FMCSA does periodically request that each state review, revise, and re-submit information in preparation for publication of routes in the **Federal Register**. We also ask states to inform us when routing changes are made. FMCSA updates the HM routing website as we become aware of problems. For example, the Maryland I–95 error mentioned in IME's letter was corrected after FMCSA was made aware of the problem. FMCSA accepts suggestions about other delivery mechanisms to make this information available and will consider using the ''Uniform Program,'' although it is not clear how that specific mechanism would work. FMCSA invites IME to submit further elaboration of how FMCSA could use the ''Uniform Program'' to deliver information about HM routes.

The second commenter, the American Trucking Associations (ATA), made comments similar to those submitted by IME. ATA stated that the information being collected is essential and pointed out that publication of the information in the past has contained errors. In addition, ATA recommended that, to remedy past problems, the responsibility for the HM Routing program should be transferred to the Research and Special Programs Administration.

FMCSA recognizes that there have been errors in the routing program in the past and that notices have not been published annually in the **Federal Register**, as required by 49 CFR part 397. However, FMCSA is a new organization and has published a **Federal Register** notice every year we have been in existence. FMCSA also continually updates the list of routes by way of an Internet website, *http://hazmat.fmcsa.dot.gov,* and corrects errors as we are made aware of them. Because we have already addressed ATA's concerns, we believe transfer of the program to the Research and Special Programs Administration is not necessary.

Respondents: The reporting burden is shared by the 50 States, the District of Columbia, Puerto Rico, American Samoa, Guam, Northern Marianas, and the Virgin Islands; as applicable.

Estimated Total Annual Burden: The annual reporting burden is estimated to be 13 hours, calculated as follows: (53 respondents × 1 response × 15 minutes/60 minutes = 13.25 hours, rounded to 13 hours).

Frequency: There is one response annually from approximately 53 respondents.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.73.

Issued on: June 1, 2001.

Stephen E. Barber,

Acting Deputy Administrator.

[FR Doc. 01–14523 Filed 6–7–01; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Discretionary Cooperative Agreements To Assist in the Development of Crash Outcome Data Evaluation System

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Notice of availability—discretionary cooperative agreements to assist in the development and use of Crash Outcome Data Evaluation System.

SUMMARY: The National Highway Traffic Safety Administration (NHTSA) announces a discretionary cooperative agreement program to assist states in the development and use of Crash Outcome Data Evaluation System (CODES) and solicits applications for projects under this program from states that have not previously been funded to develop CODES. Under this program, states will link their existing statewide traffic records with medical outcome and charge data. The linked data will be used to support highway safety decision-making at the local, regional, and state levels to reduce deaths, non-fatal injuries, and health care costs resulting from motor vehicle crashes.

DATES: Applications must be received at the office designated below by 3:00 PM on or before August 7, 2001.

ADDRESSES: Applications must be submitted to DOT/National Highway Traffic Safety Administration, Office of Contracts and Procurement (NAD–30), ATTN: Mr. Joe Comella, 400 7th Street SW., Room 5301, Washington, DC 20590.

All applications submitted must include a reference to NHTSA Cooperative Agreement Program No. DTNH22–H–01–07241. Interested applicants should contact Mr. Comella to obtain the application packet. Included in the application packet are reports about data linkage and applications for linked data developed by the CODES project.

FOR FURTHER INFORMATION CONTACT: General administrative questions may be directed to Joe Comella, Office of Contracts and Procurement. All questions and requests for copies may

be directed by e-mail at jcomella@nhtsa.dot.gov or, by telephone, at (202) 366–9568. Programmatic questions relating to this cooperative agreement program should be directed to Barbara Rhea, CODES Contracting Officer's Technical Representative (COTR), at NHTSA, Room 6125, (NRD–33) 400 7th Street SW., Washington, DC 20590, or by e-mail at brhea@nhtsa.dot.gov, or by telephone at (202) 366–2714.

SUPPLEMENTARY INFORMATION:

Statement of Work

Background

Crash data alone are unable to convey the magnitude of the medical and financial consequences of the injuries resulting from motor vehicle crashes or the success of highway safety decision-making to prevent them. Outcome information describing what happens to all persons involved in motor vehicle crashes, regardless of injury, are needed.

Person-specific outcome information is collected at the crash scene and en route by EMS personnel, at the emergency department, in the hospital, and after discharge. When these data are computerized and merged statewide, they generate a source of population-based data that is available for use by state and local traffic safety and public health professionals. Linking these records to statewide crash data collected by police at the scene is the key to developing relationships among specific vehicles, crashes, and occupant behavior characteristics and their medical and financial outcomes.

The feasibility of linking crash and medical outcome (EMS, emergency department, hospital discharge, death certificate, claims, etc.) data was demonstrated by the CODES project. This project evolved from the Intermodal Surface Transportation Efficiency Act of 1991, which mandated that NHTSA prepare a Report to Congress about the benefits of safety belt and motorcycle helmet use. NHTSA provided funding to the States of Hawaii, Maine, Missouri, New York, Pennsylvania, Utah, and Wisconsin to link their state data and use the linked data to analyze the effectiveness of safety belts and motorcycle helmets. The Report was delivered to Congress in February 1996. In 1996, three CODES states (New York, Pennsylvania, and Wisconsin) and three states which linked crash and medical data without CODES funding (Alaska, Connecticut, and New Mexico) were awarded NHTSA research funds to develop state-specific applications for linked data. In 1997, NHTSA awarded grants for CODES linkage to Connecticut, New Hampshire, Maryland, North Dakota, South Dakota, Oklahoma, and Nevada. Iowa, Kentucky, Massachusetts, Nebraska, and South Carolina were funded to implement the CODES linkage in 1998. Arizona, Delaware, Minnesota and Tennessee were funded in 1999. Georgia and Rhode Island were funded in 2000. The CODES project also demonstrated that linked data have many uses for decision-making related to highway safety and injury control. In addition to demonstrating the effectiveness of safety belts and motorcycle helmets in preventing death, injury, and costs, the linked data were used to identify populations at risk for increased injury severity or high health care costs, the impact of different occupant behaviors on outcome, the safety needs at the community level, the allocation of resources for emergency medical services, the injury patterns by type of roadway and geographic location, and the benefits of collaboration on data quality. When crash, vehicle, and behavior characteristics were linked to outcome information, decision-makers could identify those prevention programs that had the most impact on preventing or reducing the medical and financial costs associated with motor vehicle crashes.

Data linkage fulfills expanded data needs without the additional expense and delay of new data collection. The linkage process itself provides feedback about data quality and content problems, which leads to improvement in the state data. Thus, it is in NHTSA's interest to encourage states to qualify for CODES funding. NHTSA benefits from the improved quality of the state data, while the states benefit from state-specific medical and financial outcome information about motor vehicle crashes.

Objective

The objective of this Cooperative Agreement program is to provide resources to the applicant to:

1. Coordinate the development and institutionalization of the capability to link state crash and medical outcome data to identify the medical and financial consequences of motor vehicle crashes.

2. Utilize this information in crash analysis, problem identification, and program evaluation to improve decision-making at the local, state, and national levels related to preventing or reducing deaths, injuries, and direct medical costs associated with motor vehicle crashes.

3. Provide NHTSA with population-based linked crash and injury data to analyze specific highway safety issues of interest to NHTSA in collaboration with the CODES states.

4. Develop data linkage capabilities as a means of improving the quality of state data that support NHTSA's national data. State data systems are stronger and more likely to survive when developed and supported by state funds. So, this cooperative agreement is not intended to fund basic development of state data systems, but rather to create linkages among existing state data. States with insufficient state data to perform the CODES linkages are encouraged to expedite the improvement of their state data with state resources to become eligible for CODES funding.

General Project Requirements

The grantees of this cooperative agreement will be required to:

1. Link statewide population-based crash to injury data for any two calendar years available since 1997, to produce a linked data file that, if not statewide, reflects a contiguous geographical area that contains at least three (3) million residents in which the residents obtain all levels of emergency medical care without the need to be transferred elsewhere, except in rare occurrences, when involved in motor vehicle crashes. The linked data must be representative and generalizable for highway traffic safety purposes in the state or within an area in the state. All applicants must be able to clearly document what data are available and what data are missing and the significance of the missing data for highway traffic safety planning efforts.

a. Develop a state/state-wide CODES that includes outcome information for all persons, injured and uninjured, involved in police reported motor vehicle crashes.

(1) The CODES should consist of crash data linked to hospital and either EMS or emergency department data, preferably both. States without EMS or emergency department data are eligible if this type of outpatient information can be obtained from insurance claims data for everyone involved in a crash that is treated at an outpatient center.

(2) Additional state/area-wide data (driver licensing, vehicle registration, citation/conviction records, insurance claims, HMO/managed care, outpatient records, etc.) should be linked as necessary to meet state/area-wide objectives.

b. Set up processes for collaboration among the technical experts who manage the data files being linked.

c. Assign an agency to be responsible for:

(1) Obtaining a computer and linkage software to be dedicated to CODES activities (the computer and software resources may not be permanently tied to an existing computer network in such a way as to preclude their movement in the future, as directed by the CODES Board of Directors, to another organization more interested in continuing the linkage and application for the linked data);

(2) Implementing probabilistic linkage methodology to facilitate tracking the crash victim from the scene to final disposition/recovery using existing computerized state/area-wide population-based databases;

(3) Validating the linkage results by evaluating the rate of false positives and false negatives among the linked and unlinked records;

(4) Analyzing the linked data; and

(5) Cross-training sufficient staff to ensure continuation of the linkage capability in spite of changes in organizational priorities or personnel during or after the project period.

d. Document the file preparation, linkage and validation processes so that the linkage can be repeated efficiently during subsequent years after Federal funding ends and provide evidence of this documentation.

e. Provide NHTSA a version of the linked data file with supporting documentation that conforms to State laws and regulations governing patient/provider confidentiality, yet satisfies minimum NHTSA data needs.

2. Use the linked data to influence highway traffic safety and injury control decision-making by implementing at least one application of linked data that is expected to have a positive impact on reducing death, injury, and direct medical costs.

3. Use the linked data to prepare management reports using a format standardized by NHTSA for a national CODES report.

4. Develop the computer programs needed to translate the linked data into information useful for highway traffic safety and injury control at the local, regional, or state/area-wide level.

a. Develop, for access within the State, a public-use version of the linked data, copies of which will be distributed upon request.

b. Develop the resources necessary to produce and distribute routine reports, respond to data requests, and provide access to the linked data for analytical, management, planning, and other purposes after Federal funding ends.

c. Use the Internet and other electronic mechanisms to efficiently distribute and share information generated from the linked data.

5. Promote collaboration between the owners and users of the state/area-wide data to facilitate data linkage and applications for linked data.

a. Establish a state/area-wide CODES collaborative network.

(1) Convene a Board of Directors consisting of the data owners and major users of the state/area-wide data. The CODES Board of Directors will be responsible for managing and institutionalizing the linked data, establishing the data release policies for the linked data, supporting the activities of the grantee, ensuring that data linkage and application activities are appropriately coordinated within the state/area, and resolving common issues related to data accessibility, availability, completeness, quality, confidentiality, transfer, ownership, fee for service, management, etc. The CODES Board of Directors shall meet bi-monthly.

(2) Convene a CODES Advisory Group consisting of the CODES Board of Directors and other stakeholders interested in the use of linked data to support highway safety, injury control, EMS, etc. The CODES Advisory Group will be informed of the results of the data linkage, application of the data for decision-making, the quality of the state/area-wide data for linkage and the quality of the linked data for analysis. The CODES Advisory Group shall meet twice a year.

b. Promote coordination of the various stakeholders through use of the Internet, teleconferencing, joint meetings, and other mechanisms to ensure frequent communication among all parties to minimize the expense of travel.

6. Work collaboratively with NHTSA to implement the Cooperative Agreement.

a. Attend Initial Briefing Meeting. Each grantee shall attend a briefing meeting (date and time to be scheduled within 30 days after the award) in Washington, DC with NHTSA staff. The purpose of the meeting will be to review the goals and objectives of the project, discuss implementation of the linkage software, review the tasks to be specified in the action plan for the data linkage and applications of the linked data for highway safety or injury control decision-making and discuss the agendas for the Board of Directors and Advisory Group.

b. Submit Detailed Action Plan and Schedule. Within 30 days after the briefing meeting, the grantee shall deliver a detailed action plan and schedule, covering the remaining funding period, for accomplishing the data linkage and incorporating information generated from linked data into the processes for highway safety or injury control decision-making. The action plan shall be subject to the technical direction and approval of NHTSA.

c. Attend Technical Workshops. All grantees together shall attend two technology transfer workshops during project performance at locations convenient to the majority of CODES grantees. The first meeting, to be scheduled during the ninth or tenth month of funding, will be organized to share data linkage experiences, discuss standardized formats for management reports, review the proposed state-specific highway safety applications of linked data, and resolve common problems. The second meeting will be scheduled approximately 12 months after the first technical assistance meeting, at the end of the funding period, for the purpose of sharing results and making recommendations for future CODES projects.

d. Attend National Meeting. At the direction of the COTR, Grantee shall attend one National Meeting to report on progress or results from their CODES project.

e. Progress Report. Grantee shall submit quarterly progress reports. During the period of performance, the grantee will provide letter-type written reports to the COTR. These reports will compare what was proposed in the Action Plan with actual accomplishments during the past quarter; what commitments have been generated; what follow up and state-level support is expected; what problems have been experienced and what may be needed to overcome the problems; and what is specifically planned to be accomplished during the next quarter. These reports will be submitted seven days after the end of each quarter.

f. Develop a plan to institutionalize the data linkage and applications for linked data after Federal funding ends. By the end of the 15th month of funding, each grantee shall submit a long-range plan and schedule to institutionalize data linkage and the use of linked data for highway safety and injury control decision-making within the state.

g. Project Report. The grantee shall deliver to NHTSA, at the end of the project, a final report describing the results of the data linkage process, and the applications of the linked data generated during the project.

NHTSA Involvement

NHTSA will be involved in all activities undertaken as part of the Cooperative Agreement program and will:

1. Provide a Contracting Officer's Technical Representative (COTR) to participate in the planning and management of the Cooperative Agreement and coordinate activities between the grantee and NHTSA.

2. Provide, at no cost to the grantee, training and technical assistance by a CODES expert for up to two weeks on-site and off-site during the project to assist the grantee in preparing the files for linkage, implementing probabilistic linkage techniques, validating the linkage results, developing applications for the linked data, and organizing the CODES Board of Directors and Advisory Group.

3. Develop a format in which the linked data and supporting documentation will be delivered to NHTSA.

4. Conduct Initial Briefing at NHTSA Headquarters in Washington, DC (Date and time to be scheduled within 30 days after the award.) The purpose of the meeting will be to review the goals and objectives of the project, discuss implementation of the linkage software, identify the tasks to be specified in the action plan for the data linkage and applications of the linked data for highway safety or injury control decision-making, and discuss agendas for the Board of Directors and Advisory Group.

5. Conduct two Technical Assistance meetings for the purpose of technology transfer. The first meeting, to be scheduled during the ninth or tenth month of funding, will be organized to share data linkage experiences, develop a standardized format for management reports, review the proposed state-specific highway traffic safety applications of linked data, and resolve common problems. The second meeting will be scheduled at the end of the funding period for the purpose of sharing results and making recommendations for future CODES projects. Locations for the Workshops will be determined based on the location of the Grantees. However, for the purpose of cost estimation, assume the workshops will be held in Washington, DC.

6. Collaboratively work with the state when using the state's linked data to analyze and report on specific highway safety issues.

7. When appropriate, NHTSA will publish state-specific reports on CODES applications.

Period of Support

The project study effort described in this announcement will be supported through the award of up to three (3) Cooperative Agreements, depending upon the merit of the applications received and the availability of funding. It is anticipated that individual award amounts will range from $250,000–$300,000. Project efforts involving linkage of the state/area-wide data and applications for the linked data must be completed within twenty-one months after funding.

Eligibility Requirements

The grantee must be a state agency involved with highway traffic safety, such as a State Highway Safety Office, Department of Transportation or other State agency with demonstrated activities in the highway traffic safety areas, to ensure active involvement by highway traffic safety stakeholders. States that have previously been funded to develop CODES are not eligible. Only one application should be submitted for a state or area within a state. Because this Cooperative Agreement program requires extensive collaboration among the data owners in order to achieve the program objectives, it is envisioned that the grantee agency may need to actively involve the data owners in the development of the formal application and may need to sub-contract activities with at least one of them to implement a successful CODES.

While the general eligibility requirements are broad, applicants are advised that this Cooperative Agreement program is not designed to support basic developmental efforts. Although no single organization within any state or area within the state has all of the required data capabilities, the application should demonstrate strong collaborative agreements with the data owners and access to at least the state/area-wide crash, hospital, and either EMS or emergency department data, or both, by the time of the award. States/areas that collect at least the date of birth and zip code of residence on their crash data and have state/area-wide health and/or vehicle insurance claims information may be eligible, in spite of the lack of EMS or emergency department information, if the claims data include everyone involved in motor vehicle crashes. In addition, it is important that the applicant indicate the level of commitment, with state or area within the state funding and/or shared resources, by the data owners to meet program objectives, particularly institutionalization of the data linkage and applications for linked data.

Application Procedure

Each applicant must submit one original and two (2) copies of the application package to: DOT/National Highway Traffic Safety Administration, Office of Contracts and Procurement (NAD–30), ATTN: Joe Comella, 400 7th Street, SW., Room 5301, Washington, DC 20590. Applications must be typed on one side of the page only.

An additional two (2) copies will facilitate the review process, but are not required. Applications must include a reference to NHTSA Cooperative Agreement Program Number DTNH22–01–H–07241. Only complete application packages received on or before 3 p.m. on (60 days) will be considered.

Application Contents

1. The application package must be submitted with OMB Standard Form 424 (REV. 7–97, including 424A and 424B), Application for Federal Assistance, with the required information filled in and assurances signed (SF 424B). While the Form 424A deals with budget information and Section B identifies Budget Categories, the available space does not permit a level of detail, which is sufficient to provide for a meaningful evaluation of the proposed total costs. A supplemental sheet shall be provided which presents a detailed breakdown of the proposed costs (direct labor, including labor category, level of effort, and rate; direct materials including itemized equipment; travel and transportation, including projected trips and number of people traveling; subcontractors/subgrants, with similar detail, if known; and overhead), as well as any costs the applicant proposes to contribute or obtain from other sources in support of the project. Applicants shall assume that awards will be made during September 2001 and should prepare their applications accordingly.

2. The application shall include a program narrative statement of not more than 20 pages, which addresses the following as a minimum:

a. A brief description of the state/area in terms of its highway safety and injury control decision-making processes for planning, performance monitoring and other functions aimed at reducing death, injury, and costs of injuries resulting from motor vehicle crashes. This description should indicate how linked data would make a difference to the decision-making processes.

b. A brief description of the existing crash and medical outcome data files Applicants will link state/area-wide population-based crash data to EMS (and/or emergency department or insurance claims) and hospital discharge data to obtain medical and financial outcomes for persons injured in motor vehicle crashes for any two calendar years of data available since 1997. Linkages to census, other traffic

records (vehicle registration, driver licensing, roadway, conviction/citation, etc.), insurance claims, etc., are encouraged to meet priorities for highway safety and injury control decision-making. The following information should be included describing the state/area-wide data:

(1) The total crashes, total persons involved in crashes, total victims with injuries caused by a motor vehicle crash as identified or estimated and a descriptive profile of the total injuries by severity level, if available, state/area-wide.

(1) Information about the current status of the data files to be linked, recorded using the format below:

Data files	Reporting threshold (A)	Rate of compliance with (A)	Data years to be linked (19XX–19XX)	Month and year when most recent data year will become available	Percent of records computerized	Can remaining records be computerized? (Y/N)
Crash						
EMS						
ED						
Hospital						
Other						

(2) The data elements chosen to identify persons and crashes and, for each, the missing data rate.

(3) The data elements indicating type of injury, severity of injury, total charges, a payer source and, for each, the missing data rate.

c. A brief description of the proposed sequence for linking the data files.

d. A brief description of how staff from the various data owners will be cross-trained in the CODES linkage to compensate for potential future changes in organizational priorities and personnel.

e. A brief description of the process to be used to ensure adequate documentation of the data files and linkage process.

f. A brief description of how the linked data will be converted into information useful for the highway safety and injury control decision-making processes for the purpose of reducing death, injury, and costs resulting from motor vehicle crashes.

Describe:

(1) The different types of decision-making processes, currently being utilized in the state/area, that identify highway traffic safety and injury control objectives and prioritize prevention programs that have the most impact on reducing death, injury and direct medical costs associated with motor vehicle crashes; and

(2) Why linked data are needed to make these decision-making processes more effective and how the data will be incorporated.

g. A brief description of each member of the CODES Board of Directors and the proposed arrangements describing the management and use of the linked data.

2. The application shall include an appendix. A large appendix is strongly discouraged. Materials not listed below should be included only if it is necessary to support information about data linkage, applications for linked data or institutionalization discussed in the application. Do not send copies of brochures, documents, etc., developed as the result of a collaborative effort in the state/area. The appendix should include the following:

a. Letters of support from each proposed member of the CODES Board of Directors. A letter of support should reflect the signer's level of commitment to the CODES project and thus should not be a form letter.

The letter of support should document:

(1) Why linked data are important to the agency.

(2) The priority assigned by the agency to obtain linked data compared to other responsibilities.

(3) The agency's level of commitment in terms of the number of staff and the dollars or shared resources, which will be available to support and institutionalize CODES.

(4) The agency's willingness to collaborate with other data owners to support shared ownership of the linked data.

(5) The agency's permission to collaborate with NHTSA during the project and to release the linked data (or description of policies which would restrict transfer) to NHTSA at the end of the project.

b. A brief description or letters of support should be included for the other stakeholders to be represented on the CODES Advisory Group. The letters of support should indicate the stakeholder's need for the linked data, and willingness to facilitate the linkage of state/area-wide data or use of linked data for decision-making.

c. A list of activities in chronological order and a time line to show the expected schedule of accomplishments and their target dates.

d. Descriptions of the proposed project personnel as follows:

(1) Project Director: Include a resume along with a description of the director's leadership capabilities to make the various stakeholders work together.

(2) Key personnel proposed for the data linkage and applications of linked data, and other personnel considered critical to the successful accomplishment of this project: include a brief description of qualifications, employment status (permanent, temporary) in the organization, and respective organizational responsibilities. The proposed level of effort in performing the various activities should also be identified.

e. A brief description of the applicant's organizational experience in performing similar or related efforts, and the priority that will be assigned to this project compared to the organization's other responsibilities.

f. A brief description of any potential delays in implementing the project because of requirements for legislative approval before CODES funds can be expended.

g. Data Use Agreement. A description of the existing State laws and regulations governing patient/provider confidentiality in the data files being linked that would restrict use of the data for linkage and/or for transfer of the CODES linked data to NHTSA and conditions under which the linked data file may be used by NHTSA.

Application Review Process and Evaluation Factors

Initially, all application packages will be reviewed to confirm that the applicant is an eligible recipient and to ensure that the application contains all of the items specified in the Application Content section of this announcement. Each complete application from an eligible recipient will then be evaluated by an Evaluation committee. The applications will be evaluated using the following criteria which are listed in descending order of importance:

1. Understanding the intent of the program (30%). The applicant's

recognition of the importance of CODES to obtain medical and financial outcome data which are necessary for a comprehensive evaluation of the impact of highway safety and injury control countermeasures. The applicant's understanding of the importance of developing CODES as a meaningful and appropriate strategy for improving traffic records capabilities and ensuring the continuation of CODES after completion of this project.

2. Technical approach for project completion (30%). The reasonableness and feasibility of the applicant's approach for successfully achieving the objectives of the project within the required time frame. The appropriateness and feasibility of the applicant's proposed plans for data linkage and applications for the linked data. Evidence that the applicant has the necessary authorization and support from data owners to access medical and non-medical state/area-wide data, particularly total charges and information about type and severity of injury, which are not routinely available for highway safety analyses and the necessary authorization to data.

3. Project personnel (20%). The adequacy of the proposed personnel to successfully perform the project study, including qualifications and experience (both general and project related), the various disciplines represented, and the relative level of effort proposed for the professional, technical and support staff.

4. Organizational capabilities (20%). The adequacy of organizational resources and experience to successfully manage and perform the project, particularly to support the collaborative network and respond to the increasing demand for access to the linked data. The proposed coordination with and use of other organizational support and resources, including other sources of financial support. Depending upon the results of the evaluation process, NHTSA may choose to alter the number of awards. In addition, NHTSA may suggest revisions to applications as a condition of further consideration to ensure the most efficient and effective performance consistent with the objectives of the project. An organizational representative of the National Association of Governors' Highway Safety Representatives will be assisting in NHTSA's technical evaluation process.

Special Award Selection Factors

After evaluating all applications received, in the event that insufficient funds are available to award to all meritorious applicants, NHTSA may consider the following special award factors in the award decision:

1. Priority may be given to those applicants that have statewide data available for linkage.

2. Priority may be given to applicants who have the highest probability of maintaining the collaborative network of data owners and users, of institutionalizing the linkage of the crash and medical outcome data on a routine basis, and of continuing to respond to data requests after the project is completed.

3. Priority may be given to an applicant on the basis that the application fits a profile of providing NHTSA with a broad range of population densities (rural through metropolitan) with different highway safety needs.

Terms and Conditions of the Award

1. Prior to award, each grantee must comply with the certification requirements of 49 CFR part 20, Department of Transportation New Restrictions on Lobbying, and 49 CFR part 29, Department of Transportation Government-wide Debarment and Suspension (Non-procurement) and Government-wide Requirements for Drug Free Workplace (Grants). In addition, grantees must certify that data release agreements have been signed by the owners of the data files being linked to transfer the CODES linked database to NHTSA, according to NHTSA specifications.

2. Reporting Requirements and Deliverables:

a. Detailed Action Plan and Schedule. Within 30 days after the briefing meeting, the grantee shall deliver a detailed action plan and schedule for accomplishing the data linkage and applications of linked data for decision-making, showing any revisions to the approach proposed in the grantee's application. This detailed action plan will be subject to the technical direction and approval of NHTSA and will describe the following:

(1) The personnel who will perform the tasks.

(2) The time period for obtaining the different files required for linkage.

(3) The milestones for completing the various phases of the probabilistic linkage and validation processes.

(4) The milestones for proposed meeting schedules and actions by the Board of Directors and Advisory Group.

(5) Date(s) for providing the linked data to NHTSA.

(6) The milestones for implementing the applications.

b. Quarterly Progress Report. During the performance, the grantee will provide letter-type written reports to the NHTSA COTR. These reports will compare what was proposed in the Plan of Action with actual accomplishments during the past quarter; what commitments have been generated; what follow-up and state-level support is expected; what problems have been experienced and what may be needed to overcome the problems; and what is specifically planned to be accomplished during the next quarter. These reports will be submitted seven days after the end of each quarter.

c. Board of Directors and Advisory Group Meetings. Copies of the agenda and minutes for each Board of Directors and Advisory Group Meeting will be attached to the Progress Report submitted to NHTSA immediately following the meeting.

d. Institutionalization Plan. The grantee shall deliver to NHTSA, by the end of the 15th month of funding, a long-range plans and schedule to institutionalize data linkage and the use of linked data for highway safety and injury control decision-making within the state.

e. Project Report. The grantee shall deliver to NHTSA, at the end of the project, a final report that describes the results of the data linkage process, and the applications of the linked data. The report shall follow the content outline mandated by NHTSA and include the following:

(1) A description of the state/area wide linked crash and injury data;

(2) A description of the file preparation;

(3) A description of the linkage, validation processes and results;

(4) A description of the extent of the documentation and how the documentation will facilitate linkage in subsequent years;

(5) A discussion of the limitations of the linked data and subsequent applications of these data;

(6) A description of the applications of linked data implemented for decision-making and results of the decision-making;

(7) A description of how the data linkage and use of linked data for decision-making has been institutionalized for decision-making;

(8) A description of the documentation created to facilitate repeating of the linkage process and an estimate of how much time is needed to repeat the linkage in subsequent years;

(9) A copy of the public-use formats that were successful for incorporating linked data into the decision-making processes for highway safety and injury control; and

(10) A copy of the management reports prepared using the standardized format for the national CODES report.

f. CODES Linked Database. The grantee shall deliver to NHTSA after linkage, at the date specified in the Action Plan, the CODES linked databases. NHTSA will use the data to help facilitate the development of data linkage capabilities at the state/area-wide level and to encourage use of the linked data for decision-making.

The deliverables will include:

(1) The database in an electronic media and format acceptable to NHTSA, including all persons, regardless of injury severity (none, fatal, non-fatal), involved in a reported motor vehicle crash for any two calendar years of available data since 1997, and including medical and financial outcome information for those who are linked.

(2) A copy of the file structure for the linked data file.

(3) Documentation of the definitions and file structure for each of the data elements contained in the linked data files.

(4) An analysis of the quality of the linked data and a description of any data bias, which may exist, based on an analysis of the false positive and false negative linked records.

3. During the effective performance period of Cooperative Agreements awarded as a result of this announcement, the agreement as applicable to the grantee shall be subject to the National Highway Traffic Safety Administration's General Provisions for Assistance Agreements.

H. Keith Brewer,

Acting Associate Administrator for Research and Development, National Highway Traffic Safety Administration.

[FR Doc. 01–14493 Filed 6–7–01; 8:45 am]

BILLING CODE 4910–12–U

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

[Docket No. RSPA–00–7126 (PD–24(R))]

New Jersey Restrictions on Transportation of Blasting Caps With Other Commercial Explosives

AGENCY: Research and Special Programs Administration (RSPA), DOT.

ACTION: Notice of administrative determination of preemption by RSPA's associate administrator for hazardous materials safety.

Applicant: Institute of Makers of Explosives (IME).

Local Laws Affected: New Jersey Statutes Annotated (N.J.S.A.) 21:1A–137(F); New Jersey Administrative Code (N.J.A.C.) 12:190–6.5(d).

Applicable Federal Requirements: Federal hazardous material transportation law, 49 U.S.C. 5101 *et seq.*, and the Hazardous Materials Regulations (HMR), 49 CFR Parts 171–180.

Mode Affected: Highway.

SUMMARY: Federal hazardous material transportation law preempts N.J.S.A. 21:1A–137F and N.J.A.C. 12:190–6.5(d) when those provisions are interpreted and applied to prohibit the transportation of blasting caps (including electric blasting caps) on the same motor vehicle with more than 5,000 pounds of explosives, while on a public road or during activities on private property that are incidental to the movement of property and involve a safety aspect of transportation on a public road.

FOR FURTHER INFORMATION CONTACT: Frazer C. Hilder, Office of the Chief Counsel, Research and Special Programs Administration, U.S. Department of Transportation, Washington, DC 20590–0001 (Tel. No. 202–366–4400).

SUPPLEMENTARY INFORMATION:

I. Background

In this determination, RSPA considers whether Federal hazardous material transportation law, 49 U.S.C. 5101 *et seq.*, preempts New Jersey statutory and regulatory restrictions against the transportation of blasting caps on the same motor vehicle with more than 5,000 pounds of other commercial explosives.

In a notice published in the **Federal Register** on April 7, 2000, 65 FR 18422, RSPA invited interested persons to comment on an application by IME for a determination that New Jersey's statutory and regulatory restrictions are preempted on two grounds. IME stated that these restrictions (1) concern the ''handling'' of a hazardous material in transportation and are not substantively the same as requirements in the HMR, and (2) are an obstacle to the accomplishing and carrying out the Federal hazardous material transportation law and the HMR. In the notice, RSPA observed that IME's application did not indicate ''whether New Jersey's restrictions cause shipments of blasting caps and other explosives to be routed around the State of New Jersey, rather than on highways through the State,'' and RSPA requested an explanation of ''the manner in which the New Jersey requirements are applied and enforced.'' 65 FR at 18423, 18424–25. The full text of IME's application was set forth in Appendix A to the notice.

In response to the April 7, 2000 notice, comments were submitted by the Hazardous Materials Advisory Council (HMAC) and the International Society of Explosives Engineers (ISEE) in support of IME's application, and further comments were submitted by IME. No comments were received from the State of New Jersey or any of its agencies, and no person has opposed IME's application.

II. Federal Preemption

Section 5125 of Title 49 U.S.C. contains several preemption provisions that are relevant to IME's application. Subsection (a) provides that—in the absence of a waiver of preemption by DOT under 5125(e) or specific authority in another Federal law—a requirement of a State, political subdivision of a State, or Indian tribe is preempted if

(1) Complying with a requirement of the State, political subdivision, or tribe and a requirement of this chapter or a regulation issued under this chapter is not possible; or

(2) The requirement of the State, political subdivision, or tribe, as applied or enforced, is an obstacle to accomplishing and carrying out this chapter or a regulation prescribed under this chapter.

These two paragraphs set forth the ''dual compliance'' and ''obstacle'' criteria that RSPA had applied in issuing inconsistency rulings prior to 1990, under the original preemption provision in the Hazardous Materials Transportation Act (HMTA). Pub. L. 93–633, 112(a), 88 Stat. 2161 (1975). The dual compliance and obstacle criteria are based on U.S. Supreme Court decisions on preemption. *Hines* v. *Davidowitz,* 312 U.S. 52 (1941); *Florida Lime & Avocado Growers, Inc.* v. *Paul,* 373 U.S. 132 (1963); *Ray* v. *Atlantic Richfield, Inc.,* 435 U.S. 151 (1978).

Subsection (b)(1) of 49 U.S.C. 5125 provides that a non-Federal requirement concerning any of the following subjects, that is not ''substantively the same as'' a provision of Federal hazardous material transportation law or a regulation prescribed under that law, is preempted unless it is authorized by another Federal law or DOT grants a waiver of preemption:

(A) The designation, description, and classification of hazardous material.

(B) The packing, repacking, handling, labeling, marking, and placarding of hazardous material.

(C) The preparation, execution, and use of shipping documents related to hazardous material and requirements related to the number, contents, and placement of those documents.

(D) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material.

(E) The design, manufacturing, fabricating, marking, maintenance, reconditioning, repairing, or testing of a packaging or a container represented, marked, certified, or sold as qualified for use in transporting hazardous material.

To be ''substantively the same,'' the non-Federal requirement must conform ''in every significant respect to the Federal requirement. Editorial and other similar de minimis changes are permitted.'' 49 CFR 107.202(d).

Subsection (c)(1) of 49 U.S.C. 5125 provides that, beginning two years after DOT prescribes regulations on standards to be applied by States and Indian tribes in establishing requirements on highway routing of hazardous materials,

A State or Indian tribe may establish, maintain, or enforce a highway routing designation over which hazardous material may or may not be transported by motor vehicles, or a limitation or requirement related to highway routing, only if the designation, limitation, or requirement complies with section 5112(b).

Pursuant to 49 U.S.C. 5112(b), the Federal Motor Carrier Safety Administration (FMCSA) has issued standards that a State or Indian tribe must follow in establishing highway routing requirements for nonradioactive materials, in 49 CFR part 397, subpart C, which apply to any designations that are established or modified after November 14, 1994. 49 CFR 397.69(a).

These preemption provisions in 49 U.S.C. 5125 carry out Congress's view that a single body of uniform Federal regulations promotes safety in the transportation of hazardous materials. In considering the HMTA, the Senate Commerce Committee ''endorse[d] the principle of preemption in order to preclude a multiplicity of State and local regulations and the potential for varying as well as conflicting regulations in the area of hazardous materials transportation.'' S. Rep. No. 1102, 93rd Cong. 2nd Sess. 37 (1974). When it amended the HMTA in 1990, Congress specifically found that:

(3) Many States and localities have enacted laws and regulations which vary from Federal laws and regulations pertaining to the transportation of hazardous materials, thereby creating the potential for unreasonable hazards in other jurisdictions and confounding shippers and carriers which attempt to comply with multiple and conflicting registration, permitting, routing, notification, and other regulatory requirements,

(4) Because of the potential risks to life, property, and the environment posed by unintentional releases of hazardous materials, consistency in laws and regulations governing the transportation of hazardous materials is necessary and desirable,

(5) In order to achieve greater uniformity and to promote the public health, welfare, and safety at all levels, Federal standards for regulating the transportation of hazardous materials in intrastate, interstate, and foreign commerce are necessary and desirable.

Pub. L. 101–615 section 2, 104 Stat. 3244.

A Federal Court of Appeals has found that uniformity was the ''linchpin'' in the design of the HMTA, including the 1990 amendments that expanded the original preemption provisions. *Colorado Pub. Util. Comm'n* v. *Harmon,* 951 F.2d 1571, 1575 (10th Cir. 1991). (In 1994, Congress revised, codified and enacted the HMTA ''without substantive change,'' at 49 U.S.C. chapter 51. Pub. L. 103–272, 108 Stat. 745.) To also achieve safety through consistent Federal and State requirements, Congress has authorized DOT to make grants to States ''for the development or implementation of programs for the enforcement of regulations, standards, and orders'' that are ''compatible'' with the highway-related portions of the HMR. 49 U.S.C. 31102(a). In this fiscal year, $155 million is available for grants to States under the Federal Motor Carrier Safety Assistance Program. *See* 49 CFR parts 350 & 355 and the preamble to FMCSA's March 21, 2000 final rule, 65 FR 15092, 15095–96.

Under 49 U.S.C. 5125(d)(1), any directly affected person may apply to the Secretary of Transportation for a determination whether a State, political subdivision or Indian tribe requirement is preempted. The Secretary of Transportation has delegated to RSPA the authority to make determinations of preemption, except for those concerning highway routing (which have been delegated to FMCSA). 49 CFR 1.53(b)

Section 5125(d)(1) requires that notice of an application for a preemption determination must be published in the **Federal Register**. Following the receipt and consideration of written comments, RSPA publishes its determination in the **Federal Register**. *See* 49 CFR 107.209(c). A short period of time is allowed for filing of petitions for reconsideration. 49 CFR 107.211(a). Any party to the proceeding may seek judicial review in a Federal district court. 49 U.S.C. 5125(f).

Preemption determinations do not address issues of preemption arising under the Commerce Clause, the Fifth Amendment or other provisions of the Constitution or under statutes other than the Federal hazardous material transportation law unless it is necessary to do so in order to determine whether a requirement is authorized by another Federal law, or whether a fee is ''fair'' within the meaning of 49 U.S.C. 5125(g)(1). A State, local or Indian tribe requirement is not authorized by another Federal law merely because it is not preempted by another Federal statute. *Colorado Pub. Util. Comm'n* v. *Harmon,* above, 951 F.2d at 1581 n.10.

In making preemption determinations under 49 U.S.C. 5125(d), RSPA is guided by the principles and policies set forth in Executive Order No. 13132, entitled ''Federalism.'' 64 FR 43255 (August 10, 1999). Section 4(a) of that Executive Order authorizes preemption of State laws only when a statute contains an express preemption provision, there is other clear evidence that Congress intended to preempt State law, or the exercise of State authority directly conflicts with the exercise of Federal authority. Section 5125 contains express preemption provisions, which RSPA has implemented through its regulations.

III. Discussion

Blasting caps and electric blasting caps are classified in the HMR as ''detonators, non electric, *for blasting*'' and ''detonators, electric, *for blasting,*'' respectively, in Division 1.1B, 1.4B, or 1.4S (depending on their explosive properties). *See* 49 CFR 172.101 (Hazardous Materials Table) and 173.52 (classification codes for explosives).[1] The HMR include specific provisions for packaging detonators for transportation, including the exceptions set forth in 49 CFR 173.63(f), (g). The HMR also provide that detonators and explosives may be transported on the same motor vehicle when certain conditions are met with regard to the manner in which the detonators are packaged and the containers on the vehicle in which packages are carried. 49 CFR 177.835(g) (set out in full in Appendix A).

New Jersey has adopted the HMR as State law, in regulations of its Department of Transportation at N.J.A.C. 16:49–1.3(i), but the State separately prohibits the transportation of blasting caps on the same motor vehicle with more than 5,000 pounds of commercial explosives. The Explosives Act, as codified in N.J.S.A. 21:1A–128 *et seq.*, contains provisions governing the

[1] The words ''for blasting'' italicized in the Hazardous Materials Table are not part of the proper shipping name, 49 CFR 172.101(c), but are used in the Table to distinguish blasting caps from other detonators for ammunition and detonating relays. *See* 49 CFR 173.59 (description of the term ''detonators''). As used in this determination, the term ''blasting caps'' includes ''detonators for blasting, both electric and non-electric'' *Id.*

''Transportation of explosives'' at N.J.S.A. 21:1A–137, including the following restriction:

F. Blasting caps or electric blasting caps, or both, may be transported in the same vehicle with other commercial explosives only when the net weight of the other commercial explosives does not exceed 5,000 pounds.

The Explosives Act provides that the Commissioner of the Department of Labor shall enforce that Act, prosecute violations, and ''state the items which are in violation of the provisions of the act or the precautions which he deems reasonably necessary to be taken.'' N.J.S.A. 21:1A–130. The Explosives Act also provides in N.J.S.A. 21:1A–141 that it does not apply

to explosives which are in transit upon vessels, railroad cars or vehicles or while being held for delivery, when such transportation and delivery are under jurisdiction of and in conformity with regulations adopted by the Interstate Commerce Commission, the United States Coast Guard or the Civil Aeronautics Board, * * *[2]

According to IME, in 1998, the New Jersey Department of Labor (NJDL) adopted and began enforcing regulations governing ''off-highway'' transportation of explosives in N.J.A.C. 12:190–6.5, including:

(d) Blasting caps or electric blasting caps, or both, may be transported in the same vehicle with other commercial explosives only when the net weight of the other commercial explosives does not exceed 5,000 pounds.

IME stated that a person using both blasting caps and more than 5,000 pounds of other commercial explosives at a site within New Jersey must use separate vehicles to transport the blasting caps and the other commercial explosives, from the origin of the transportation to the job site. It stated that this requires the use of additional trucks and, ''the more trucks on the road, irrespective of the cargo, the higher likelihood of an accident.'' With its application, IME provided affidavits from three companies stating that they transport blasting caps and explosives in separate vehicles to comply with New Jersey's requirements.

In one of these affidavits, the president of Maurer & Scott, Inc. stated that this practice ''leads to more explosives vehicles on the road, trucks not loaded to capacity, inefficient transportation, excess handling of hazardous materials, and greater exposure to the public'' as well as ''more vehicles * * * at the minesite which creates an increased safety hazard.'' Attached to the affidavit from Maurer & Scott were copies of that company's applications for an exception to the restriction against transporting blasting caps in the same vehicle with more than 5,000 pounds of explosives, and letters from NJDL denying an exception.

IME stated that the only alternative would be to transfer either the blasting caps or the other commercial explosives to a separate vehicle at some point before leaving the public highway at the job site. However, IME indicated that this would violate a prohibition in the HMR against the transfer of Division 1.1, 1.2, or 1.3 explosive materials between vehicles ''on any public highway, street, or road, except in case of emergency.'' 49 CFR 177.835(j).[3] IME stated that transferring the blasting caps or explosives to another vehicle would involve ''the added risk from the unnecessary handling during loading or re-loading to conform explosive/detonator shipments to New Jersey's restrictions.''

IME, HMAC, and ISEE all stated that New Jersey's statutory and regulatory prohibitions against transporting blasting caps on the same motor vehicle with more than 5,000 pounds of commercial explosives are preempted because they are not substantively the same as requirements in the HMR on the ''handling * * * of hazardous material.'' 49 U.S.C. 5125(b)(1)(B). Alternatively, IME stated that these restrictions are ''a detriment to safety'' and are preempted as an ''obstacle to accomplishing and carrying out'' the HMR. 49 U.S.C. 5125(a)(2).

IME acknowledged ''the authority of the State to regulate the movement of explosives that is outside the scope of'' Federal hazardous material transportation law and the HMR, but stated that NJDL does not interpret its regulation to apply only to ''vehicles transporting explosives between locations on one site where a public way is never entered or crossed.'' According to IME, that agency's position is that vehicles carrying both blasting caps and more than 5,000 pounds of explosives would be in violation of N.J.A.C. 12:190–6.5(d) ''the moment they left a public road.''

HMAC stated that the ''critical'' issue in this proceeding is whether N.J.A.C. 12:190–6.5(d) applies to transportation ''in commerce.'' It commented that, because ''the New Jersey off-highway regulation is not limited to transportation occurring entirely on private property,'' it affects motor vehicles transporting Class 1 materials ''over the public roads of the State to consignee sites where these materials are unloaded/loaded prior to further commercial movement of the vehicle on those public ways.''

In its further comments, IME stated that NJDL appears to define ''off-highway'' in a manner that applies the prohibition in N.J.A.C. 12:190–6.5(d) to ''sites where the vehicle is being loaded or unloaded, [and] also off-highway locations where a driver may stop for food, fuel, rest or comfort.'' Unfortunately, no representative of the State of New Jersey submitted comments to explain how the exception for ''explosives which are in transit'' in N.J.S.A. 21:1A–141 is interpreted and applied to the transportation of detonators and explosives on the same vehicle in accordance with 49 CFR 177.835(g).

The HMR ''govern safety aspects of the transportation of hazardous material [DOT] considers appropriate.'' 49 U.S.C. 5103(b)(1)(B). They apply to the ''offering of hazardous materials for transportation and transportation of hazardous materials in interstate, intrastate, and foreign commerce by * * * motor vehicle.'' 49 CFR 171.1(a)(1). The HMR set forth specific provisions on the manner in which hazardous materials are packaged for transportation and loaded on a motor vehicle, including the conditions in 49 CFR 177.835(g) under which detonators and explosives may be carried on the same motor vehicle. The HMR also contain provisions on the manner in which hazardous materials are unloaded from a motor vehicle. These requirements for loading hazardous materials on a vehicle, and which materials may be carried on the same vehicle, are clearly within the HMR's provisions on the ''handling'' of hazardous materials.

Whenever the loading or unloading of hazardous materials is ''incidental to the movement'' of those materials on a public roadway, that loading or unloading is a ''safety aspect'' and part of the transportation of the hazardous materials ''in commerce,'' subject to the requirements of the HMR, regardless of whether the loading or unloading takes

[2] The residual safety-related authority of the Interstate Commerce Commission and the Civil Aeronautics Board, both of which no longer exist, is now exercised by agencies within DOT.

[3] According to IME, NJDL seems to take the position that the restriction in the Explosives Act ''applies to any transportation in the State,'' but it is uncertain whether that prohibition is self-executing or whether NJDL must issue regulations under the authority conferred in N.J.S.A. 21:1A–130 before the restriction applies to an explosives carrier. If the restriction in the Explosives Act is self-executing, it would also not allow blasting caps and explosives to be transported into New Jersey and then separated onto different vehicles before leaving the highway to enter the job site.

place on private property. *See* 49 U.S.C. 5102(12) (defining ''transportation'').

In this case, the affidavits submitted with IME's application state, without contradiction from NJDL, that New Jersey's prohibitions against carrying blasting caps on the same motor vehicle with more than 5,000 pounds of explosives affect and restrict the transportation of those hazardous materials on the public roadways. Those affidavits and the comments in this proceeding also support a conclusion, without contradiction from NJDL, that greater safety results when blasting caps and explosives are transported on the same vehicle in accordance with the conditions in 49 CFR 177.835(g), than when blasting caps and explosives must be transported on separate vehicles or transferred between vehicles at some point before leaving a public road to enter the delivery location.

To the extent that New Jersey's restrictions are interpreted and applied only to on-site storage, either before transportation begins or after transportation ends, they are not preempted by Federal hazardous materials transportation law. However, these restrictions are preempted when they are interpreted and applied to prohibit the transportation of detonators on the same motor vehicle with more than 5,000 pounds of explosives, while on a public road or during activities on private property that are incidental to the movement of property and involve a safety aspect of transportation on a public road. In the latter situations, New Jersey's restrictions in N.J.S.A. 21:1A–137F and N.J.A.C. 12:190–6.5(d) are preempted by 49 U.S.C. 5125(a)(2) and 5125(b)(1)(B), because these prohibitions are an obstacle to carrying out and accomplishing the safe transportation of hazardous materials as permitted by 49 CFR 177.835(g) and they are not substantively the same as the requirements in 49 CFR 177.835(g) on the handling of hazardous materials.

Because New Jersey's restrictions in N.J.S.A. 21:1A–137F and N.J.A.C. 12:190–6.5(d) are preempted by 49 U.S.C. 5125(a)(2) and 5125(b)(1)(B), it is unnecessary to address the separate issue, raised in RSPA's April 7, 2000 notice, whether these restrictions are preempted by 49 U.S.C. 5125(c)(1) as a highway routing limitation that fails to comply with FMCSA's standards in 49 CFR part 397.

IV. Ruling

Federal hazardous material transportation law preempts N.J.S.A. 21:1A–137F and N.J.A.C. 12:190–6.5(d) when those provisions are interpreted and applied to prohibit the transportation of blasting caps (including electric blasting caps) on the same motor vehicle with more than 5,000 pounds of explosives, while on a public road or during activities on private property that are incidental to the movement of property and involve a safety aspect of transportation on a public road.

V. Petition for Reconsideration/Judicial Review

In accordance with 49 CFR 107.211(a), any person aggrieved by this decision may file a petition for reconsideration within 20 days of publication of this decision in the **Federal Register**. Any party to this proceeding may seek review of RSPA's decision ''in an appropriate district court of the United States * * * not later than 60 days after the decision becomes final.'' 49 U.S.C. 5125(f). New Jersey is considered a party to this proceeding concerning a State law and a regulation issued by an agency of the State, despite the fact that NJDL did not submit comments.

This decision will become RSPA's final decision 20 days after publication in the **Federal Register** if no petition for reconsideration is filed within that time. The filing of a petition for reconsideration is not a prerequisite to seeking judicial review of this decision under 49 U.S.C. 5125(f).

If a petition for reconsideration of this decision is filed within 20 days of publication in the **Federal Register**, the action by RSPA's Associate Administrator for Hazardous Materials Safety on the petition for reconsideration will be RSPA's final decision. 49 CFR 107.211(d).

Issued in Washington, DC on June 4, 2001.

Robert A. McGuire,

Associate Administrator for Hazardous Materials Safety.

Appendix A

49 CFR 177.835 Class I (explosive materials)

* * * * *

(g) No detonator assembly or booster with detonator may be transported on the same motor vehicle with any Division 1.1, 1.2 or 1.3 material (except other detonator assemblies, boosters with detonators or detonators), detonating cord Division 1.4 material or Division 1.5 material. No detonator may be transported on the same motor vehicle with any Division 1.1, 1.2 or 1.3 material (except other detonators, detonator assemblies or boosters with detonators), detonating cord Division 1.4 material or Division 1.5 material unless—

(1) It is packed in a specification MC 201 (§ 178.318 of this subchapter) container; or

(2) The package conforms with requirements prescribed in § 173.63 of this subchapter, and its use is restricted to instances when—

(i) There is no Division 1.1, 1.2, 1.3 or 1.5 material loaded on the same motor vehicle; and

(ii) A separation of 61 cm (24 inches) is maintained between each package of detonators and each package of detonating cord; or

(3) It is packed and loaded in accordance with a method approved by the Department. One method approved by the Department requires that—

(i) The detonators are in packagings as prescribed in § 173.63 of this subchapter which in turn are loaded into suitable containers or separate compartments; and

(ii) That both the detonators and the container or compartment meet the requirements of the Institute of Makers of Explosives' Safety Library Publication No. 22 (incorporated by reference, see § 171.7 of this subchapter).

[FR Doc. 01–14496 Filed 6–7–01; 8:45 am]

BILLING CODE 4910–60–U

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

June 1, 2001.

The Department of the Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 2110, 1425 New York Avenue, NW., Washington, DC 20220.

DATES: Written comments should be received on or before July 9, 2001 to be assured of consideration.

Internal Revenue Service (IRS)

OMB Number: 1545–1374.

Form Number: IRS Form 8834.

Type of Review: Extension.

Title: Qualified Electric Vehicle Credit.

Description: Form 8834 is used to compute an allowable credit for qualified electric vehicles placed in service after June 30, 1993. Section 1913(b) under Pub. L. 102–1018 created new section 30.

Respondents: Individuals or households, Business or other for-profit.

Estimated Number of Respondents/Recordkeepers: 500.

Estimated Burden Hours Per Respondent/Recordkeeper:

Recordkeeping—7 hrs., 10 min.

Learning about the law or the form—30 min.

Preparing, copying, assembling, and sending the form to the IRS—38 min.

Frequency of Response: Annually.

Estimated Total Reporting/Recordkeeping Burden: 4,155 hours.

Clearance Officer: Garrick Shear, Internal Revenue Service, Room 5244, 1111 Constitution Avenue, NW., Washington, DC 20224.

OMB Reviewer: Alexander T. Hunt, (202) 395–7860, Office of Management and Budget, Room 10202, New Executive Office Building, Washington, DC 20503.

Mary A. Able,

Departmental Reports, Management Officer.

[FR Doc. 01–14411 Filed 6–7–01; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

[Docket No. 919; ATF O 1130.17]

Delegation Order—Delegation of the Director's Authorities in 27 CFR Part 30, Gauging Manual

To: All Bureau Supervisors

1. *PURPOSE.* This order delegates certain authorities of the Director to subordinate ATF officers.

2. *CANCELLATION.* ATF O 1100.126B, Delegation Order—Delegation of Authorities of the Director in 27 CFR part 30, Gauging Manual, dated 11/03/87, is hereby canceled.

3. *BACKGROUND.* Under current regulations, the Director has authority to take final action on matters relating to the gauging manual. We have determined that certain of these should, in the interest of efficiency, be delegated to a lower organizational level.

4. *DELEGATIONS.* Under the authority vested in the Director, Bureau of Alcohol, Tobacco and Firearms, by Treasury Department Order No. 120–1 (formerly 221), dated June 6, 1972, and by 26 CFR 301.7701–9, this ATF order delegates certain authorities to take final action prescribed in 27 CFR part 30 to subordinate officers. The attached table identifies the regulatory sections, documents and authorized ATF officers. The authorities in the table may not be redelegated. An ATF organization chart showing the directorates involved in this delegation order has been attached.

5. *QUESTIONS.* Any questions concerning this order should be directed to the Regulations Division at 202–927–8210.

Bradley A. Buckles,

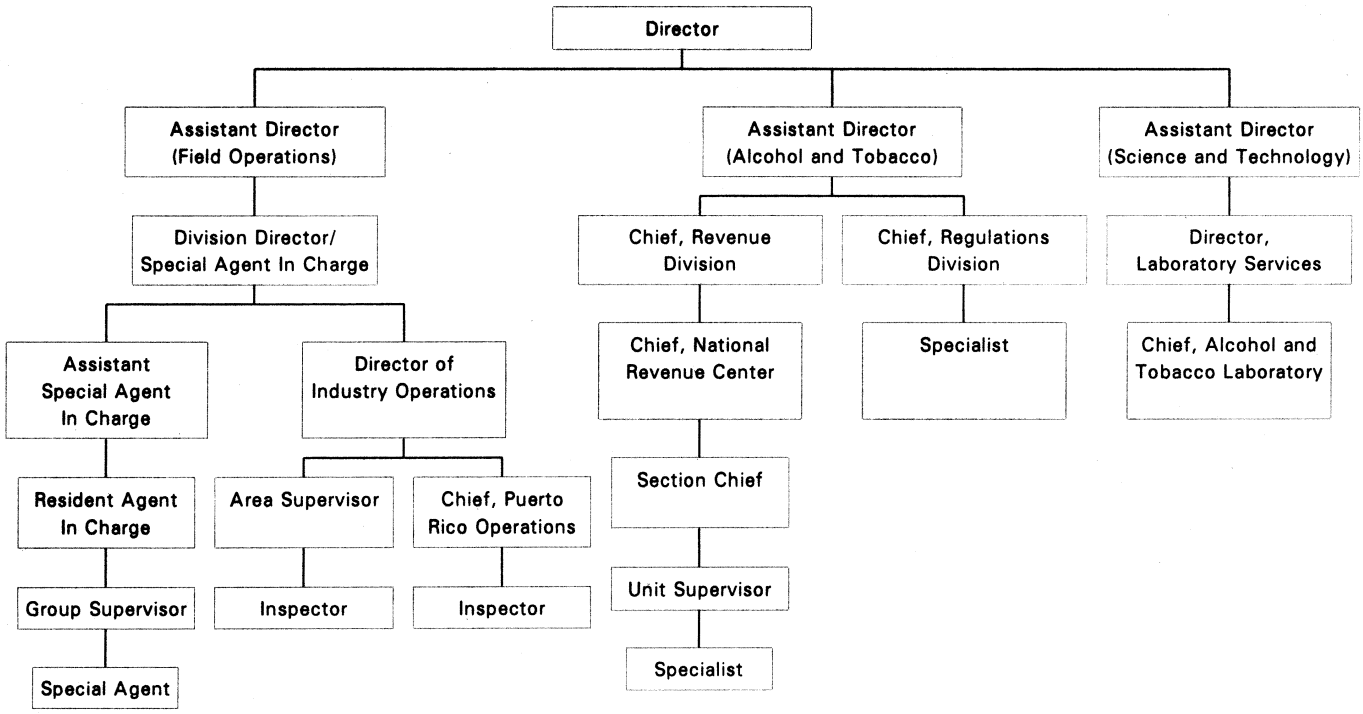
Director.

TABLE OF AUTHORITIES, DOCUMENTS TO BE FILED, AND AUTHORIZED OFFICIALS

Regulatory section	Officer(s) authorized to act or receive document.
§ 30.11—Bulk conveyance.	Chief, National Revenue Center (NRC), to approve containers for bulk quantities upon recommendation of Area Supervisor or Chief, Puerto Rico Operations.
§ 30.21(c)	Inspector, Specialist, or Special Agent, to use instruments and to verify accuracy of hydrometers and thermometers used by proprietor.
§ 30.21(c)	Chief, Alcohol and Tobacco Laboratory, to approve other methods for determination of specific gravity and for gauging.
§ 30.24(a)	Inspector, Specialist or Special Agent
§ 30.24(b)	Inspector, Specialist or Special Agent
§ 30.31(b)	Chief, Alcohol and Tobacco Laboratory
§ 30.36	Chief, Regulations Division
§ 30.43	Chief, Regulations Division
§ 30.51	Chief, Regulations Division

BILLING CODE 4810–31–P

ATF Organization



This is not a complete organizational chart of ATF

[FR Doc. 01–14469 Filed 6–7–01; 8:45 am]
BILLING CODE 4810–31–C

UNITED STATES INSTITUTE of PEACE

Sunshine Act Meeting

AGENCY: United States Institute of Peace

DATE/TIME: Thursday—June 21, 2001 (4 p.m.–9 p.m.) Friday—June 22, 2001 (9 a.m.–6 p.m.) Saturday—June 23, 2001 (9 a.m.–12 noon)

LOCATION: Westfields Marriott Conference Center Chantilly, Virginia

STATUS: Open Session—Portions may be closed pursuant to Subsection (c) of Section 552(b) of Title 5, United States Code, as provided in subsection 1706(h)(3) of the United States Institute of Peace Act, Public Law 98–525.

AGENDA: June 2001 Board Meeting; Approval of Minutes of the Ninety-Ninth Meeting (March 22, 2001) of the Board of Directors; Chairman's Report; President's Report; Review and Discussion of Individual Grants and Fellowships; Review Essay Finalists and Select Winners; Committee Reports; Discuss Research & Studies project Reports; Review Fellowship Program; Report on Peace Scholars; Update on Training Program; Update on Education Program; Other General Issues

CONTACT: Dr. Sheryl Brown, Director, Officer of Communications, Telephone: (202) 457–1700.

Dated: June 4, 2001.

Charles E. Nelson,

Vice President for Management and Finance United States Institute of Peace.

[FR Doc. 01–14569 Filed 6–6–01; 10:20 am]
BILLING CODE 6820–AR–M

Federal Register

Friday,
June 8, 2001

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 5
Delegations of Authority and Organization; Reorganization and Republication; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Delegations of Authority and Organization; Reorganization and Republication

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revising its regulation for its delegations of authority, to improve information retrieval, ensure consistency, clarify redelegation statements, update the legal citations and position and organizational titles, and, in some instances, redelegate authorities to additional agency officials and employees. This action is necessary to ensure the continued accuracy of the regulations.

DATES: This rule is effective April 2, 2001.

FOR FURTHER INFORMATION CONTACT: Donna Page or Robin Phipps, Division of Management Programs (HFA–340), Food and Drug Administration, 301–827–4816 or 301–827–4806, respectively.

SUPPLEMENTARY INFORMATION: FDA is revising its regulations for delegation of authority and organization in part 5 (21 CFR part 5) to improve information retrieval by agency officials and employees, the public, and affected industries; to ensure the accuracy of the regulation by removing or correcting obsolete references to legislation, organizational and position titles; and to improve consistency in the display of the information. This regulation includes revisions to § 5.10 to clarify that the authority of the Secretary of Health and Human Services (the Secretary) is delegated directly to the Commissioner of Food and Drugs (the Commissioner), as well as to correct or remove outdated statutory citations. In 21 CFR, subpart B has been substantially reorganized, made into additional subparts, and updated.

Prior to November 1995, the Commissioner had reported to the Assistant Secretary for Health (ASH), and the Commissioner exercised authority delegated from the Secretary through the ASH. In November 1995, the Secretary designated U.S. Public Health Service agencies, including FDA, as Operating Divisions within the Department of Health and Human Services that report directly to the Secretary, and deleted the Office of the ASH (60 FR 56605, November 9, 1995). In this revision, we have therefore modified the introductory language of § 5.10(a) to indicate that the delegations are from the Secretary directly to the Commissioner, and we have moved the delegations formerly listed in § 5.10(c), (d), and (f) into § 5.10(a).

In this revision, we have also removed or corrected obsolete citations to legislation in § 5.10 and in the agency delegations. Following are the legal citations that we removed or corrected, as appropriate:

(1) In § 5.10(a)(1) and in § 5.32 (formerly § 5.35), we removed references to the Tea Importation Act, which Congress repealed by Public Law 104–128, section 2.

(2) We removed § 5.10(a)(3), which pertained to electronic product radiation control under the PHS Act (PHS Act), because Congress transferred these provisions from the PHS Act to the Federal Food, Drug and Cosmetic Act (the act) by Public Law 101–629, section 19(a). Additionally in §§ 5.800, 5.601, 5.602, 5.603, 5.604, 5.605, and 5.606 (formerly §§ 5.45, 5.87, 5.88, 5.89, 5.90, 5.91, and 5.92), we revised citations for electronic product radiation control to the act instead of the PHS Act.

(3) In § 5.10(a)(19) (formerly § 5.10(a)(20)), we updated the reference to the acceptance of gifts, which was formerly codified under the PHS Act (at 42 U.S.C. 219) and is now codified at 42 U.S.C. 238 by Public Law 103–43, title XX, section 2010(a)(1)–(3).

(4) We removed § 5.10(a)(22), which pertained to waiving matching requirements on state and local governments under title X of the Public Works and Economic Development Act of 1965 (42 U.S.C. 3246b(b)(3)), because Congress repealed section 1003(b)(3), title X, of that act by Public Law 105–393, title I, section 102(c).

(5) In § 5.10(a)(22) (formerly § 5.10(a)(24)), we removed the reference to section 1704(6) of the PHS Act, because Congress repealed it by Public Law 98–551, section 2(b).

(6) We removed § 5.10(a)(28), which pertained to a registry for cardiac pacemaker devices and leads under section 1862(h)(1), (2)(A), and (3) of the Social Security Act (42 U.S.C. 1395y(h)(1), (2)(A), and (3)) because Congress repealed section 1862(h) (42 U.S.C. 1395y(h)) by Public Law 104–224, section 1. Additionally, we removed former § 5.28, regarding payments for cardiac pacemaker devices and pacemaker leads, because Congress repealed the statutory provision.

(7) In § 5.10(a)(26) (formerly § 5.10(a)(29)), we updated citations under the Stevenson-Wydler Technology Innovation Act of 1980, because Congress placed what had been section 11(b)(3) into 11(b)(3)(D) and what had been section 11(b)(4) into 11(b)(3)(C) by Public Law 104–113, section 4.

At the end of each section of the reorganized §§ 5.20 through 5.1000, we have added the appropriate redelegation statements. Although the officials under § 5.20(b) (the Deputy Commissioner; Senior Associate Commissioner; Deputy Commissioner for International and Constituent Relations; Senior Associate Commissioner for Management and Systems; Senior Associate Commissioner for Policy, Planning, and Legislation; and the Associate Commissioner for Regulatory Affairs) have all the authorities of the Commissioner, their titles appear in other sections of the reorganized §§ 5.21 through 5.1000, generally to indicate that they are the agency officials who would principally exercise the authority. Further, in some instances, the Commissioner has delegated authorities to additional agency officials to ensure more efficient operations.

For the convenience of the user, we have established additional subparts to categorize the information about delegations within FDA by functional areas. In this revision, the subparts are Subpart B, General Redelegations of Authority; Subpart C, Human Drugs, Redelegations of Authority; Subpart D, Biologics, Redelegations of Authority; Subpart E, Food and Cosmetics, Redelegations of Authority; Subpart F, Medical Devices, Redelegations of Authority; Subpart G, Animal Drugs, Redelegations of Authority; Subpart H, Radiation Control, Redelegations of Authority; Subpart I, Product Designation, Redelegations of Authority; Subpart J, Imports and Exports, Redelegations of Authority; Subpart K, Orphan Products, Redelegations of Authority; Subpart L, Mammography Facilities, Redelegations of Authority; and Subpart M, Organization. We have cross-referenced (in the attached Appendix) the former subparts and sections to the new subparts and sections; and we are displaying the entire text of the revised part 5.

The agency is issuing this rule as a final rule without publishing a general notice of proposed rulemaking because such notice is not required for this rule of agency organization, procedure, or practice under 5 U.S.C. 533(b)(A).

The agency has determined under 21 CFR 25.30 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.

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.

FDA has examined the impacts of this final rule under Executive Order 12866. 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). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or more, or adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. The agency finds that this final rule, which reorganizes, updates, and clarifies the agency's internal delegations, is not a significant rule as defined by Executive Order 12866. No analysis is required under the Regulatory Flexibility Act (5 U.S.C. 601–612) because the agency is issuing it without publishing a general notice of proposed rulemaking, as explained previously in this document.

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

The agency plans to migrate to an Intra/Internet-based system for publishing the delegations of authority and eventually remove them from part 5. The agency will publish a notice to make that change effective and provide the Internet website address.

The Commissioner hereby ratifies and affirms any actions taken by the delegates and their subordinates, which in effect, involved the exercise of the authorities delegated herein prior to the effective date of this notice.

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, title 21 CFR part 5 is revised to read as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. Part 5 is revised in its entirety to read as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

Subpart A—Delegations of Authority to the Commissioner of Food and Drugs

Sec.

5.10 Delegations from the Secretary for Health and Human Services to the Commissioner of Food and Drugs.
5.11 Reservation of authority.

Subpart B—General Redelegations of Authority

Sec.

5.20 General redelegations of authority from the Commissioner to other officers of the Food and Drug Administration.
5.21 Emergency functions.
5.22 Certification of true copies and use of Department seal.
5.23 Disclosure of official records and authorization of testimony.
5.24 Authority relating to technology transfer.
5.25 Research, investigation, and testing programs and health information and promotion programs.
5.26 Service fellowships.
5.27 Patent term extensions for human drug products, medical devices, and food and color additives; and authority to perform due diligence determinations and informal hearings.
5.28 Hearings.
5.29 Petitions under part 10.
5.30 Authority to select temporary voting members for advisory committees and authority to sign conflict of interest waivers.
5.31 Enforcement activities.
5.32 Certification following inspections.
5.33 Issuance of reports of minor violations.
5.34 Issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment.
5.35 Officials authorized to make certification under 5 U.S.C. 605(b) for any proposed and final rules.

Subpart C—Human Drugs; Redelegations of Authority

Sec.

5.100 Issuance of notices implementing the provisions of the Drug Amendments of 1962.
5.101 Termination of exemptions for new drugs for investigational use in human beings.
5.102 Authority to approve and to withdraw approval of a charge for investigational new drugs.
5.103 Approval of new drug applications and their supplements.
5.104 Responses to Drug Enforcement Administration temporary scheduling notices.
5.105 Issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and their supplements.
5.106 Submission of and effective approval dates for abbreviated new drug applications and certain new drug applications.
5.107 Extensions or stays of effective dates for compliance with certain labeling requirements for human prescription drugs.
5.108 Authority relating to waivers or reductions of prescription drug user fees.
5.109 Issuance of written notices concerning patent information, current good manufacturing practices and false or misleading labeling of new drugs.

Subpart D—Biologics; Redelegations of Authority

Sec.

5.200 Functions pertaining to safer vaccines.
5.201 Redelegation of the Center for Biologics Evaluation and Research Director's program authorities.
5.202 Issuance of notices of opportunity for a hearing on proposals for denial of approval of applications for licenses, suspension of licenses, or revocation of licenses and certain notices of revocation of licenses.
5.203 Issuance and revocation of licenses for the propagation or manufacture and preparation of biological products.
5.204 Notification of release for distribution of biological products.

Subpart E—Foods and Cosmetics; Redelegations of Authority

Sec.

5.300 Food standards, food additives, generally recognized as safe (GRAS) substances, color additives, nutrient content claims, and health claims.
5.301 Issuance of initial emergency permit orders and notices of confirmation of effective date of final regulations on food for human and animal consumption.
5.302 Detention of meat, poultry, eggs, and related products.
5.303 Establishing standards and approving accrediting bodies under the National Laboratory Accreditation Program.
5.304 Approval of schools providing food-processing instruction.

Subpart F—Medical Devices and Radiological Health; Redelegations of Authority

Sec.

5.400 Issuance of **Federal Register** documents to recognize or to withdraw recognition of a standard to meet premarket submission requirements.

5.401 Issuance of **Federal Register** documents pertaining to exemptions from premarket notification.
5.402 Detention of adulterated or misbranded medical devices.
5.403 Authorization to use alternative evidence for determination of the effectiveness of medical devices.
5.404 Notification of petitioners of determinations made on petitions for reclassification of medical devices.
5.405 Determination of classification of devices.
5.406 Notification to sponsors of deficiencies in petitions for reclassification of medical devices.
5.407 Approval, disapproval, or withdrawal of approval of product development protocols and applications for premarket approval for medical devices.
5.408 Determinations concerning the type of valid scientific evidence submitted in a premarket approval application.
5.409 Determinations that medical devices present unreasonable risk of substantial harm.
5.410 Orders to repair or replace, or make refunds for, medical devices.
5.411 Medical device recall authority.
5.412 Temporary suspension of a medical device application.
5.413 Approval, disapproval, or withdrawal of approval of applications and entering into agreements for investigational device exemptions.
5.414 Postmarket surveillance.
5.415 Authority relating to medical device reporting procedures.
5.416 Medical device tracking.
5.417 Authority pertaining to accreditation functions for medical devices.

Subpart G—Animal Drugs; Redelegations of Authority.

Sec.
5.500 Issuance of **Federal Register** documents pertaining to the determination of safe levels, notice of need for development of an analytical method, notice of availability of a developed analytical method, and prohibition of certain extralabel drug use.
5.501 Approval of new animal drug applications, medicated feed mill license applications and their supplements.
5.502 Issuance of notices, proposals, and orders relating to new animal drugs and medicated feed mill license applications.
5.503 Submission of and effective approval dates for abbreviated new animal drug applications and certain new animal drug applications.
5.504 Issuance of written notices concerning patent information, current good manufacturing practices and false or misleading labeling of new animal drugs and feeds bearing or containing new animal drugs.
5.505 Termination of exemptions for new drugs for investigational use in animals.

Subpart H—Radiation Control; Redelegations of Authority

Sec.
5.600 Variances from performance standards for electronic products.
5.601 Exemption of electronic products from performance standards and prohibited acts.
5.602 Testing programs and methods of certification and identification for electronic products.
5.603 Notification of defects in, and repair or replacement of, electronic products.
5.604 Manufacturers requirement to provide date to ultimate purchasers of electronic products.
5.605 Dealer and distributor direction to provide data to manufacturers of electronic products.
5.606 Acceptance of assistance from State and Local authorities for enforcement of radiation control legislation and regulations.

Subpart I—Product Designation; Redelegations of Authority

Sec.
5.700 Authority relating to determination of product primary jurisdiction.
5.701 Premarket approval of a product that is or contains a biologic, a device, or a drug.

Subpart J—Imports and Exports; Redelegations of Authority

Sec.
5.800 Imports and exports.
5.801 Export of unapproved drugs.
5.802 Manufacturer's resident import agents.

Subpart K—Orphan Products; Redelegations of Authority

Sec. 5.900 Orphan products.

Subpart L—Mammography Facilities; Redelegations of Authority

Sec.
5.1000 Authority to ensure that mammography facilities meet quality standards.

Subpart M—Organization

Sec.
5.1100 Headquarters.
5.1105 Chief Counsel, Food and Drug Administration.
5.1110 Food and Drug Administration Public Information Offices.
5.1115 Field Structure.

Authority: 5 U.S.C. 504, 552, App. 2 605; 7 U.S.C. 138a, 2217; 15 U.S.C. 638, 1261–1282, 1451–1461, 3701–3711a; 21 U.S.C., 61–63, 141–149, 301–394, 467f, 679(b), 801–886, 1031–1309, 1401–1403; 35 U.S.C. 156; 42 U.S.C. 238, 241, 242, 242a, 242l, 242n, 242o, 243, 262, 263, 264, 265, 300u–300u–5, 300aa–1, 300ar–25–28, 300cc, 300ff, 1395y, 4332, 4831(a), 10007–10008; E.O. 11921, 41 FR 24294, 3 CFR, 1977 Comp., p. 124–131; E.O. 12591, 52 FR 13414, 3 CFR, 1988 Comp., p. 220–223.

Subpart A—Delegations of Authority to the Commissioner of Food and Drugs

§ 5.10 Delegations from the Secretary of Health and Human Services to the Commissioner of Food and Drugs.

(a) The Secretary of Health and Human Services (the Secretary) has redelegated to the Commissioner of Food and Drugs (Commissioner), with authority to redelegate (except when specifically prohibited), all authority as follows:

(1) Functions vested in the Secretary under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*), as amended, the Filled Milk Act (21 U.S.C. 61–63), the Federal Import Milk Act (21 U.S.C. 141 *et seq.*), the Federal Caustic Poison Act (44 Stat. 1406; see also Public Law 86–613, section 19, formerly section 18) and The Fair Packaging and Labeling Act (15 U.S.C. 1451 *et seq.*), under section 12 of Reorganization Plan No. IV and Reorganization Plan No. 1 of 1953, including authority to administer oaths vested in the Secretary of Agriculture by 7 U.S.C. 2217.

(2) Functions vested in the Secretary under section 301 (Research and Investigations); section 307 (International Cooperation); and section 311 (Federal-State Cooperation) of the Public Health Service Act (the PHS Act) (42 U.S.C. 241, 242l, 243), as amended, which relate to the functions of the Food and Drug Administration.

(3) Functions vested in the Secretary under section 361 of the PHS Act (42 U.S.C. 264), as amended, which relate to the law enforcement functions of the Food and Drug Administration concerning the following products and activities: Biologicals (including blood and blood products); interstate travel sanitation (except interstate transportation of etiologic agents under 42 CFR part 72); food (including milk and food service sanitation and shellfish sanitation); and drugs, devices, cosmetics, electronic products, and other items or products regulated by the Food and Drug Administration.

(4) Functions vested in the Secretary under sections 351 and 352 of part F, subpart 1 of the PHS Act (42 U.S.C. 262 and 263), as amended (Biological Products), insofar as they relate to the functions assigned to the Food and Drug Administration.

(5) Functions vested in the Secretary under section 302(a) of the PHS Act (42 U.S.C. 242(a)), as amended, which relate to the determination and reporting requirements with respect to the medicinal and scientific requirements of the United States for controlled substances.

(6) Functions vested in the Secretary under section 303 of the PHS Act (42 U.S.C. 242a), as amended, which relate to the authorization of persons engaged in research on the use and effect of drugs to protect the identity of their research subjects with respect to drugs scheduled under Public Law 91–513 for which an investigational new drug

application is filed with the Food and Drug Administration and with respect to all drugs not scheduled under Public Law 91–513.

(7) Functions vested in the Secretary pertaining to section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Public Law 91–513, 84 Stat. 1241) which relate to the determination of the safety and effectiveness of drugs or to approve new drugs to be used in the treatment of narcotic addicts.

(8) Functions vested in the Secretary pertaining to section 303(f) of the Controlled Substances Act (21 U.S.C. 823(f)), which relate to the merits of the research protocol and to the determination of the qualifications and competency of practitioners wishing to conduct research with controlled substances listed in Schedule I of the Act.

(9) Functions vested in the Secretary pertaining to provisions of the Controlled Substances Act (21 U.S.C. 801 *et seq.*), which relate to administration of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*).

(10) Functions vested in the Secretary under section 409(b) of the Federal Meat Inspection Act (21 U.S.C. 679(b)), which relate to the detention of any carcass, part thereof, meat, or meat product of cattle, sheep, swine, goats, or equines.

(11) Functions vested in the Secretary under section 24(b) of the Poultry Products Inspection Act (21 U.S.C. 467f(b)), which relate to the detention of any poultry carcass, part thereof, or poultry product.

(12) Functions vested in the Secretary under the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

(13) Functions vested in the Secretary by amendments to the foregoing statutes subsequent to Reorganization Plan No. 1 of 1953.

(14) Function of issuing all regulations of the Food and Drug Administration, except as provided in § 5.11. The reservation of authority contained in Chapter 2–000 of the Department Organization Manual shall not apply.

(15) Functions vested in the Secretary under section 1103 of Executive Order 11490, as amended by Executive Order 11921, which relate to emergency health functions as they pertain to the operations and functional responsibilities assigned to the agency. This authority shall be exercised in accordance with section 102 and pertinent sections of part 30 of Executive Order 11490 and guidelines issued by the Federal Preparedness Agency of the General Services Administration and the Office of the Secretary.

(16) Function vested in the Secretary of authorizing and approving miscellaneous and emergency expenses of enforcement activities.

(17) Functions vested in the Secretary under the Federal Advisory Committee Act, Public Law 92–463, to:

(i) Renew, recharter, amend and terminate established Federal Advisory Committees;

(ii) Authority to approve waivers to appoint committee members to established Federal Advisory Committees;

(iii) Authority to close review meetings following approval by the Office of the General Counsel based on a determination that the Advisory Committee meeting or a portion thereof may be closed to the public under the provisions of 5 U.S.C. 552b(c) and section 10(d) of the Federal Advisory Committee Act. These authorities are to be exercised in accordance with the requirements of 5 U.S.C. 552b; the Federal Advisory Committee Act (Public Law 92–463); Departmental regulations (45 CFR part 11, superseded by 41 CFR part 101–6); and any other applicable statutes and regulations. These authorities may be redelegated.

(18) Functions vested in the Secretary under the second sentence of section 310(a) and under section 310(b) (Health Conferences and Health Education Information) of the PHS Act (42 U.S.C. 242o), as amended, to call for a conference and invite as many health authorities and officials of State or local public or private agencies or organizations as deemed necessary or proper on subjects related to the functions of the Food and Drug Administration, and to issue information related to health for the use of the public and other pertinent health information for the use of persons and institutions concerned with health services when such information is related to the functions of the Food and Drug Administration.

(19) Functions vested in the Secretary under section 2701 of the PHS Act (42 U.S.C. 238), as amended, to accept offers of gifts, excluding the acceptance of gifts of real property. Only the authority to accept unconditional gifts of personal property valued at $5,000 or less may be redelegated.

(20) Functions vested in the Secretary under section 362 of the PHS Act (42 U.S.C. 265), as amended, which relate to the prohibition of the introduction of foods, drugs, devices, cosmetics, electronic products, and other items or products regulated by the Food and Drug Administration into the United States when it is determined that it is required in the interest of public health when such functions relate to the law enforcement functions of the Food and Drug Administration.

(21) Functions vested in the Secretary under section 401(a) of the Lead-Based Paint Poisoning Prevention Act, as amended by Public Law 94–317 (42 U.S.C. 4831(a)), relating to the prohibition of the application of lead-based paint to cooking, drinking, or eating utensils.

(22) Functions vested in the Secretary for the health information and health promotion program under title XVII of the PHS Act (42 U.S.C. 300u *et seq.*), as amended, insofar as the authorities pertain to functions assigned to the Food and Drug Administration. The delegation includes, but is not limited to, the authorities under: Section 1702(a)(1) and (3) and section 1704(1) and (2) (42 U.S.C. 300u–1(a) and (3) and 300u–3(1) and (2)). The delegation excludes the authority to select all Senior Executive Service, supergrade and equivalent, and Schedule C (GS–12 and above) positions; issue regulations; and submit reports to the President.

(23) To administer a Small Business Innovation Research Program under section 9 of the Small Business Act (15 U.S.C. 638), as amended. The delegation excludes the authority to issue regulations, establish advisory councils and committees, appoint members to advisory councils and committees, and submit reports to Congress.

(24) Functions vested in the Secretary under sections 982 and 983 of the Consumer-Patient Radiation Health and Safety Act of 1981 (the Act) (42 U.S.C. 10007 and 10008), as amended. The delegation excludes the authority to issue regulations and submit reports to Congress. The authority delegated under section 983 of the Act may only be exercised as it relates to functions assigned to the Food and Drug Administration.

(25) Functions vested in the Secretary under section 156 of title 35 of the U.S. Code (35 U.S.C. 156), as amended, which allows for the extension of patent terms for human drug products, medical devices, food additives, and color additives subject to the Federal Food, Drug, and Cosmetic Act (the act). These authorities may be redelegated, except the authority to make due diligence determinations under section 156(d)(2)(B), which may not be redelegated to an Office below the Office of the Commissioner of Food and Drugs.

(26) Functions vested in the Secretary under the Stevenson-Wydler Technology Innovation Act of 1980 (15

U.S.C. 3701 *et seq.*) (the Act), as amended, and under Executive Order 12591 of April 10, 1987, as they pertain to the functions of the Food and Drug Administration. The delegation excludes the authority to issue regulations and submit reports to Congress; under section 11(a)(2) of the Act (15 U.S.C. 3710a(a)(2)) to approve agreements and contracts with invention management organizations; and under section 11(c)(3)(B) of the Act (15 U.S.C. 3710a(c)(3)(B)) to propose necessary statutory changes regarding conflict of interest.

(i) The authorities under sections 11(c)(5) (A) and (B) of the Act (15 U.S.C. 3710a (c)(5) (A) and (B)) to disapprove or require the modification of cooperative research and development agreements and licensing agreements after the agreement is presented to the Commissioner by the head of the laboratory concerned, and to transmit written explanation of such disapproval or modification to the head of the laboratory concerned, may be redelegated only to a senior official in the immediate Office of the Commissioner.

(ii) The following authorities may not be redelegated: The authority under section 11(b)(3)(D) of the Act (15 U.S.C. 3710a(b)(3)(D)) to waive a right of ownership which the Federal Government may have to an invention made under a cooperative research and development agreement; the authority under section 11(b)(3)(C) of the Act (15 U.S.C. 3710a(b)(3)(C)) to permit employees or former employees to participate in efforts to commercialize inventions they made while in the service of the United States; the authority under section 11(c)(3)(A) of the Act (15 U.S.C. 3710a(c)(3)(A)) to review employee standards of conduct for resolving potential conflicts of interest; the authority under section 13(a)(1) of the Act (15 U.S.C. 3710c(a)(1)) to retain any royalties or other income, except as provided in section 13(a)(2) of the Act (15 U.S.C. 3710c(a)2)); and the authority under section 13(a)(1)(A)(i) of the Act (15 U.S.C. 3710c(a)(1)(A)(i)) to pay royalties or other income the agency receives on account of an invention to the inventor if the inventor was an employee of the agency at the time the invention was made.

(iii) Any authorities under paragraph (a)(26) of this section delegated by the Commissioner may not be further redelegated.

(27) Functions vested in the Secretary under sections 4702, 4703, and 4704 of the Pesticide Monitoring Improvements Act of 1988 (21 U.S.C. 1401–1403) that relate to pesticide monitoring and enforcement information, foreign pesticide information, and pesticide analytical methods. The delegation excludes the authority to submit reports to Congress.

(28) Functions vested in the Secretary under sections 2312(a)(1) and (2)(B), (b), and (c) (Use of Investigational New Drugs with Respect to Acquired Immunodeficiency Syndrome); 2314(c) (Scientific and Ethical Guidelines for Certain Treatments); and 2317(d) and (e) (Information Services) of title XXIII of the PHS Act (42 U.S.C. 300cc–12(a)(1) and (2)(B), (b) and (c), 300cc–14(c) and 300cc–17 (d) and (e)), as amended, insofar as these authorities pertain to the functions assigned to the Food and Drug Administration. The delegation excludes the authority to issue regulations, submit reports to the Congress, establish advisory committees or national commissions, and appoint members to such committees or commissions.

(29) Functions vested in the Secretary under section 2672(a)(1) (A) and (B) (Provisions Relating to Blood Banks) and section 2672(a)(2) (Information and Training Programs) of the PHS Act (42 U.S.C. 300ff–72(a)(1)(A) and (B) and (a)(2) *et seq.*), as amended, insofar as these authorities pertain to the functions assigned to the Food and Drug Administration. The delegations exclude the authority to issue regulations, submit reports to the Congress, establish advisory committees or national commissioners, and appoint members to such committees or commissions.

(30) Functions vested in the Secretary under sections 1322(b) and (c) of the Food, Agriculture, Conservation, and Trade Act of 1990 (the National Laboratory Accreditation Program) (7 U.S.C. 138a), as amended hereafter, which relate to setting standards for the National Laboratory Accreditation Program and approving State agencies or private, nonprofit entities as accrediting bodies to implement certification and quality assurance programs in accordance with the requirements of this section. The delegation excludes the authority to submit reports to Congress.

(31) Functions vested in the Secretary under part C, subtitle 2 of title XXI of the PHS Act (42 U.S.C. 300aa–25 *et seq.*), as amended, and the National Childhood Vaccine Injury Act of 1986 (42 U.S.C. 300aa–1 note), as amended hereafter, as follows:

(i) Section 2125 of the PHS Act (42 U.S.C. 300aa–25)—Recording and reporting of information.

(ii) Section 2127 of the PHS Act (42 U.S.C. 300aa–27)—-Mandate for safer childhood vaccines.

(iii) Section 2128 of the PHS Act (42 U.S.C. 300aa–28)—Manufacturer recordkeeping and reporting.

(iv) Section 312 of the National Childhood Vaccine Injury Act of 1986—Related studies (42 U.S.C. 300aa–1 note).

(v) Section 313 of the National Childhood Vaccine Injury Act of 1986—Study of other vaccine risks (42 U.S.C. 300aa–1 note).

(vi) Section 314 of the National Childhood Vaccine Injury Act of 1986—Review of warnings, use instructions, and precautionary information (42 U.S.C. 300aa–1 note).

(vii) The delegation excludes the authority to issue regulations and submit reports to Congress.

(32) Functions vested in the Secretary under section 201(h)(4) of the Controlled Substances Act (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended) (21 U.S.C. 811(h)(4)) to provide responses to the Drug Enforcement Administration's temporary scheduling notices. The delegation excludes the authority to submit reports to Congress.

(33) Functions vested in the Secretary under the Safe Medical Devices Act of 1990 (Pub. L. 101–629), as amended hereafter (e.g., 21 U.S.C. 360c note, 360i note, and 360j note). The delegation excludes the authority to submit reports to Congress.

(34) Functions vested in the Secretary under section 601 of Effective Medication Guides of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 1997 (Public Law 104–180), as amended hereafter. The delegation excludes the authority to issue reports to Congress.

(35) The Secretary has redelegated to the Commissioner of Food and Drugs, or his designee, the authority to take final action on matters pertaining to section 203 of the Equal Access to Justice Act (5 U.S.C. 504), and to develop procedures and regulations where necessary to supplement the Department's regulations, 45 CFR part 13.

(36) The Secretary has delegated to the Commissioner, the authority to administer and make decisions regarding the invention and patent program as they pertain to the functions of the Food and Drug Administration and to make determinations of rights in inventions and patents in which the Department has an interest. This delegation excludes the authority to

submit reports to Congress and further, it excludes those authorities under the Stevenson-Wydler Technology Innovation Act of 1980, as amended by the Federal Technology Transfer Act of 1986 and the National Technology Transfer and Advancement Act of 1995, which are governed by a separate delegation (under § 5.10(a)(26)). All authorities other than the authority under 35 U.S.C. section 203 (March-In Rights) may be redelegated.

(37) Functions vested in the Secretary under title III, Section 354, of the PHS Act (42 U.S.C. 262 *et seq.*), as amended. The authority pertains to the Food and Drug Administration's oversight of mammography facilities.

(38) The Deputy Assistant Secretary for Health Management Operations, Public Health Service, has redelegated to the Commissioner of Food and Drugs, with authority to redelegate, the authority to certify true copies of any books, records, or other documents on file within the Food and Drug Administration, or extracts from such; to certify that true copies are true copies of the entire file of the Administration; to certify the complete original record or to certify the nonexistence of records on file within the Administration; and to cause the Seal of the Department to be affixed to such certifications and to agreements, awards, citations, diplomas, and similar documents.

(39) The Secretary of Health and Human Services has redelegated to the Commissioner, of Food and Drugs, under 45 CFR 5b.8 regulations, appeal authority to take final action upon an individual's appeal of a refusal to correct or amend the individual's record when the appeal has been made by the individual under Privacy Act regulations (part 21 of this chapter and 45 CFR part 5b). The authority may not be redelegated.

(b) The Chief Counsel of the Food and Drug Administration has been authorized to report apparent violations to the Department of Justice for the institution of criminal proceedings, under section 305 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335), section 4 of the Federal Import Milk Act (21 U.S.C. 144), and section 9(b) of the Federal Caustic Poison Act.

§ 5.11 Reservation of authority.

(a) Notwithstanding provisions of § 5.10 or any previous delegations of authority to the contrary, the Secretary of Health and Human Services (Secretary) reserves the authority to approve regulations of the Food and Drug Administration, except regulations to which sections 556 and 557 of title 5 U.S.C. apply, which:

(1) Establish procedural rules applicable to a general class of foods, drugs, cosmetics, medical devices, or other subjects of regulation; or

(2) Present highly significant public issues involving the quality, availability, marketability, or cost of one or more foods, drugs, cosmetics, medical devices, or other subjects of regulation.

(b) Nothing in this section precludes the Secretary from approving a regulation, or being notified in advance of an action, to which sections 556 and 557 of title 5 U.S.C. apply, which meets one of the criteria in paragraph (a) of this section.

(c) This reservation of authority is intended only to improve the internal management of the Department of Health and Human Services, and it is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, the Department of Health and Human Services, the Food and Drug Administration, any agency, officer, or employee of the United States, or any person. Regulations issued by the Food and Drug Administration without the approval of the Secretary are to be conclusively viewed as falling outside the scope of this reservation of authority.

Subpart B—General Redelegations of Authority

§ 5.20 General redelegations of authority from the Commissioner to other officers of the Food and Drug Administration.

(a) Final authority of the Commissioner of Food and Drugs (Commissioner) is redelegated as set forth in these subparts. The Commissioner may continue to exercise all authority delegated in subparts B through L.

(b) The following officials are authorized to perform all of the functions of the Commissioner. These officials may not further redelegate this authority, or any part of this authority, except as elsewhere specified:

(1) Deputy Commissioner;

(2) Associate Commissioner for Regulatory Affairs;

(3) Senior Associate Commissioner;

(4) Senior Associate Commissioner for Management and Systems;

(5) Senior Associate Commissioner for Policy, Planning, and Legislation; and

(6) Deputy Commissioner for International and Constituent Relations.

(c)(1) During the absence or disability of the Commissioner or in the event of a vacancy in that position, the first official who is available in the following positions, or who has been designated by the Commissioner to act in such position, shall act as Commissioner:

(i) Deputy Commissioner;

(ii) Associate Commissioner for Regulatory Affairs; or

(iii) Senior Associate Commissioner.

(2) These officials may not further redelegate this authority. However, for a planned period of absence, the Commissioner (or someone ''acting'' on his/her behalf) may specify a different order of succession.

(d) Authority delegated to a position by title may be exercised by a person officially designated to serve in that position in an acting capacity or on a temporary basis, unless prohibited by a restriction in the document designating him/her as ''acting'' or unless not legally permissible.

(e)(1) The Senior Associate Commissioner is authorized to make determinations that advisory committee meetings are concerned with matters listed in 5 U.S.C. 552(b) and therefore may be closed to the public in accordance with 5.10(a)(17).

(2) The Senior Associate Commissioner is authorized to perform other associated advisory committee functions (e.g., establishing technical and scientific review groups (advisory committees)); appointing and paying members; approving waivers to appoint members to established advisory committees; renewing and rechartering of established advisory committees; amending charters of established advisory committees; and terminating established advisory committees.

(3) The Senior Associate Commissioner is authorized to approve conflict of interest waivers for special Government employees serving on advisory committees in accordance with 18 U.S.C. 208(b)(3), as amended.

(4) The Senior Associate Commissioner is authorized to select temporary members to advisory committees if such voting members are serving on an advisory committee managed by another center.

(5) The Senior Associate Commissioner may not further redelegate these authorities.

(f)(1) The Senior Associate Commissioner for Policy, Planning, and Legislation (SACPPL) and the Associate Commissioner for Policy (ACP) are authorized to perform any of the functions of the Commissioner with respect to the issuance of **Federal Register** notices and proposed and final regulations of the Food and Drug Administration. These officials may not further redelegate this authority.

(2) The SACPPL and the ACP are authorized to issue responses to the following matters under part 10 of this chapter as follows and these officials

may not further redelegate this authority:

(i) Requests for waiver, suspension, or modification of procedural requirements under § 10.19 of this chapter;

(ii) Citizen petitions under § 10.30 of this chapter;

(iii) Petitions for reconsideration under § 10.33 of this chapter;

(iv) Petitions for stay under § 10.35 of this chapter; or

(v) Requests for advisory opinions under § 10.85 of this chapter.

(3) With respect to any matter delegated to the SACPPL and the ACP under this paragraph, the SACPPL and the ACP are authorized to perform the function of the Commissioner under §§ 10.40, 10.45, 10.50, 10.55, 10.60, 10.65, 10.80, 10.90, and 10.95 of this chapter and of the Deputy Commissioner under § 10.206(g) and (h) of this chapter. These officials may not further redelegate this authority.

(4) The SACPPL and the ACP are authorized under the Regulatory Flexibility Act (5 U.S.C. 605(b)) to certify that a proposed or final rule, if issued, will not have a significant economic impact on a substantial number of small entities. The SACPPL and the ACP may further redelegate this authority.

(g) The following officials are authorized to perform all the functions of the officials under them in their respective offices and they may not further redelegate this authority:

(1) Senior Associate Commissioner;

(2) Deputy Commissioner for International and Constituent Relations;

(3) Senior Associate Commissioner for Management and Systems; or

(4) Senior Associate Commissioner for Policy, Planning, and Legislation.

(h)(1) The Chief Mediator and Ombudsman and the Deputy Chief Mediator and Ombudsman are authorized to act upon requests for reconsideration of any user fee decisions under section 735 of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 379h) made by such officers and the former Deputy User Fee Waiver Officer prior to July 1, 1999. These officials may not further redelegate this authority. (See subpart C, § 5.108 for the user fee-related redelegation to officials within the Center for Drug Evaluation and Research.)

(2) The Senior Associate Commissioner for Management and Systems and the Director, Office of Financial Management, are authorized to perform the functions of the Commissioner under section 736(d)(1)(c) of the act (21 U.S.C. 379h(d)(1)(C)), as amended, to waive or reduce prescription drug user fees in situation where he or she finds that ''the fees will exceed the anticipated present and future costs.'' These officials may not further redelegate this authority.

(3) The Deputy Commissioner, or in the event of a vacancy in that position, the Senior Associate Commissioner, Office of the Commissioner, is designated as the User Fee Appeals Officer. The User Fee Appeals Officer is authorized to hear and decide user fee waiver appeals. The decision of the User Fee Appeals Officer will constitute final agency action on such matters. The User Fee Appeals Officer may not further redelegate this authority.

(i) The Senior Associate Commissioner for Management and Systems is authorized to perform all of the administrative authorities (i.e., financial, personnel, facilities management, property management, etc.) of the Commissioner. These authorities may be further redelegated, except when specifically prohibited.

(j) Unless specifically noted, the persons to whom the Commissioner has delegated authority in subparts B through L of this part may not further redelegate that authority.

§ 5.21 Emergency functions.

(a) Each Regional Food and Drug Director is authorized, during any period when normal channels of direction are disrupted between the Food and Drug Administration headquarters and his or her region to:

(1) Fully represent the Food and Drug Administration within his or her region in cooperation with the Department of Health and Human Services regional emergency plans, and

(2) Exercise the authority of the Commissioner of Food and Drugs for supervision of and direction to all Food and Drug Administration activities and use of resources within his or her region for continuity and for Federal Emergency Health Service operations.

(b) These same officials are authorized to provide in Regional Emergency Plans for the delegation of Food and Drug Administration regional authorities to heads of field activities when such activities are cut off from national and regional headquarters. These officials may not further redelegate this authority.

§ 5.22 Certification of true copies and use of Department seal.

(a) The following officials are authorized to certify true copies of, or extracts from, any books, records, papers, or other documents on file within the Food and Drug Administration, to certify that copies are true copies of the entire file, to certify the complete original record, or to certify the nonexistence of records on file within the Food and Drug Administration, and to cause the seal of the Department to be affixed to such certifications:

(1) The Deputy Commissioner, the Senior Associate Commissioner, the Deputy Commissioner for International and Constituent Relations, the Senior Associate Commissioner for Management and Systems, and the Senior Associate Commissioner for Policy, Planning, and Legislation.

(2) The Associate and Deputy Associate Commissioners and the Chief Counsel and Deputy Chief Counsels.

(3) The Director, Office of the Executive Secretariat, Office of the Senior Associate Commissioner, Office of the Commissioner (OC).

(4) The Director, Office of Executive Operations, Office of the Senior Associate Commissioner, OC.

(5)(i) The Director and Deputy Director, Office of Enforcement, Office of Regulatory Affairs (ORA).

(ii) The Director and Deputy Director, Office of Regional Operations, ORA.

(iii) The Director and Deputy Director, Office of Resource Management (ORM), ORA.

(iv) The Director, Division of Management Operations, ORM, ORA.

(v) Team Leader, FDA History Staff, ORM, ORA.

(6)(i) The Director, Office of Human Resources and Management Services (OHRMS), Office of Management and Systems (OMS), OC.

(ii) The Director, Division of Management Programs (DMP), OHRMS, OMS, OC.

(iii) The Chief, Dockets Management Branch, DMP, OHRMS, OMS, OC.

(7) The Associate Commissioner for Public Affairs, Office of Public Affairs (OPA), Office of the Senior Associate Commissioner (OSAC), OC.

(8)(i) The Chief Information Officer, Office of Information Resources Management (OIRM), Office of Management and Systems (OMS), OC.

(ii) The Director, Freedom of Information Staff, OIRM, OMS, OC.

(9)(i) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(ii) The Director, Office of Management, CBER.

(iii) The Director and Deputy Directors of the Office of Compliance and Biologics Quality, CBER.

(iv) The Director and Deputy Director, Office of Communication, Training, and Manufacturer's Assistance, CBER.

(v) The Director and Branch Chiefs, Division of Case Management, Office of

Compliance and Biologics Quality (OCBQ), CBER; and the Consumer Safety Officers, OCBQ, CBER.

(10)(i) The Director and Deputy Director, Center for Food Safety and Applied Nutrition (CFSAN).

(ii) The Director of Regulations and Policy, CFSAN.

(iii) The Director, Office of Management Systems, CFSAN.

(iv) The Director, Office of Cosmetics and Colors, CFSAN.

(v) The Director, Office of Plant and Dairy Foods and Beverages, CFSAN.

(vi) The Director, Office of Seafood, CFSAN.

(vii) The Director, Office of Nutritional Products, Labeling, and Dietary Supplements, CFSAN.

(viii) The Director, Office of Special Research Skills, CFSAN.

(ix) The Director, Office of Constituent Operations, CFSAN.

(x) The Director, Office of Field Programs, CFSAN.

(xi) The Director, Office of Premarket Approval, CFSAN.

(xii) The Director, Office of Scientific Analysis and Support, CFSAN.

(11)(i) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH).

(ii) The Associate Director and Deputy Associate Director for Management and Systems, CDRH.

(iii) The Director and Deputy Director, Office of Compliance, CDRH.

(iv) For medical devices assigned to their respective divisions, the Division Directors, Office of Compliance, CDRH.

(v) The Director and Deputy Director, Office of Surveillance and Biometrics (OSB), CDRH, and the Director and Deputy Director, Division of Surveillance Systems (DSS), OSB, CDRH.

(vi) The Director, Office of Systems and Management, CDRH.

(vii) Freedom of Information Officers, CDRH.

(12)(i) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(ii) The Director and Deputy Director, Office of Management and Communications, CVM.

(iii) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(iv) The Director, Division of Compliance, Office of Surveillance and Compliance, CVM.

(13)(i) The Director and Deputy Director for Washington Operations, National Center for Toxicological Research (NCTR).

(ii) The Deputy Center Director, Office of Management (OM), NCTR, and the Associate Director, Office of Management Services, OM, NCTR.

(iii) The Deputy Center Director, Office of Research, NCTR.

(14)(i) The Director and Deputy Director, the Directors, Office of Review Management and Office of Pharmaceutical Science, the Associate Director for Regulatory Policy, and the Associate Director for Medical Policy, Center for Drug Evaluation and Research (CDER).

(ii) The Director and Deputy Director, Office of Management, CDER.

(iii) The Director and Deputy Director, Office of Compliance, CDER.

(iv) The Directors and Deputy Directors of the Offices of Drug Evaluation I, II, III, IV, and V, and the Director and Deputy Director of the Office of Biostatistics, Office of Review Management, CDER.

(v) The Directors and Deputy Directors of the Offices of Testing and Research, Generic Drugs, New Drug Chemistry, and Clinical Pharmacology and Biopharmaceutics, Office of Pharmaceutical Science, CDER.

(vi) The Director, Office of Training and Communications (OTCOM), and the Director, Division of Information Disclosure Policy, Office of Regulatory Policy, CDER.

(vii) The Directors of the Divisions of Labeling and Non-prescription Drug Compliance, Prescription Drug Compliance and Surveillance, and Manufacturing and Product Quality, Office of Compliance, CDER.

(15)(i) Regional Food and Drug Directors.

(ii) District Directors.

(iii) The Director, St. Louis Branch.

(iv) The Director, Northeast Regional Laboratory, Northeast Region.

(v) The Director, Southeast Regional Laboratory, Southeast Region.

(vi) The Director, National Forensic Chemistry Center.

(vii) The Director, Arkansas Regional Laboratory.

(viii) The Director, Winchester Engineering Analytical Center.

(b) The following officials are authorized to cause the seal of the Department to be affixed to agreements, awards, citations, diplomas, and similar documents:

(1) Deputy Commissioner; the Senior Associate Commissioner; the Deputy Commissioner for International and Constituent Relations; the Senior Associate Commissioner for Management and Systems; and the Senior Associate Commissioner for Policy, Planning, and Legislation.

(2) The Associate and Deputy Associate Commissioners and the Chief Counsel and Deputies.

(3) The Director and Deputy Directors, CBER; the Director and Deputy Director, CFSAN; the Director and Deputy Directors, CDRH; the Director and Deputy Director, CVM; the Director and Deputy Directors, CDER; and the Director, NCTR, the Deputy Director for Washington Operations, NCTR, and the Deputy Center Directors, Offices of Management and Research, respectively, NCTR.

(4) The Director, Office of Executive Operations, Office of the Senior Associate Commissioner (OSAC), OC; Director, Office of Management, CBER; Director, Office of Management, CDER; Director, Office of Management Systems, CFSAN; Director, Office of Systems and Management, CDRH; Director, Office of Management and Communications, CVM; Associate Director, Office of Management Services, NCTR; and the Director, Office of Resource Management, ORA.

(5) The Director, Office of Human Resources and Management Services (OHRMS), Office of Management and Systems (OMS), OC.

(c) The following officials may further redelegate the authorities under paragraphs (a) and (b) of this section the Deputy Commissioner; the Senior Associate Commissioner; the Deputy Commissioner for International and Constituent Relations; the Senior Associate Commissioner for Management and Systems; the Senior Associate Commissioner for Policy, Planning, and Legislation; the Associate and Deputy Associate Commissioners; the Chief Counsel and Deputy Chief Counsels; the Directors and Deputy Directors for CBER, CFSAN, CDRH, CVM, CDER, and NCTR; the Director, Office of Executive Operations, OSAC, OC; the Directors of the Offices of Management, CBER and CDER; the Director, Office of Management Systems, CFSAN; the Director, Office of Systems and Management, CDRH; the Director, Office of Management and Communications, CVM; the Associate Director, Office of Management Services, NCTR; the Director, Office of Resource Management, ORA; and the Director, OHRMS, OMS, OC. The other officials delegated authority by this section may not further redelegate it.

(d) The Chief, Regulations Editorial Section (RES), Regulations Policy and Management Staff (RPMS), Office of Policy, Planning, and Legislation (OPPL), OC, and his or her alternates are authorized to certify true copies of **Federal Register** documents. The Chief, RES, RPMS, OPPL, OC may designate alternates as required.

§ 5.23 Disclosure of official records and authorization of testimony.

(a) The following officials are authorized to make determinations to disclose official records and information under part 20 of this chapter, except that only the officials, listed in paragraphs (a)(2) through (a)(8) of this section, have the authority under specific sections of part 20 of this chapter.

(1)(i) Deputy Commissioner, the Senior Associate Commissioner, the Deputy Commissioner for International and Constituent Relations, the Senior Associate Commissioner for Management and Systems, the Senior Associate Commissioner for Policy, Planning, and Legislation, and the Associate and Deputy Associate Commissioners.

(ii) The Director, Office of Executive Operations, Office of the Senior Associate Commissioner, Office of the Commissioner (OC).

(iii) The Director, Office of the Executive Secretariat, Office of the Senior Associate Commissioner, OC.

(iv) The Director, Office of Human Resources and Management Services (OHRMS), Office of Management and Systems (OMS), OC; the Director, Division of Management Programs (DMP), OHRMS, OMS, OC; and the Chief, Dockets Management Branch, DMP, OHRMS, OMS, OC.

(v) Program officials at all organizational levels down to and including branch level for all Headquarters organizations.

(vi) Regional Food and Drug Directors and District Directors.

(vii) Director, Winchester Engineering and Analytical Center.

(viii) Chiefs of branches Field/District Offices and Centers.

(ix) Freedom of Information Officers and other employees engaged in Freedom of Information activities.

(x) The Director, Office of Enforcement (OE), Office of Regulatory Affairs (ORA); Deputy Director, OE, ORA; and Director, Division of Compliance Policy, OE, ORA.

(xi) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER); and the Director and Deputy Director, Office of Communication, Training, and Manufacturer's Assistance (OCTMA), CBER.

(xii) The Director and Deputy Director, the Directors, Office of Review Management and Office of Pharmaceutical Science, the Associate Director for Medical Policy, and the Associate Director for Regulatory Policy, Center for Drug Evaluation and Research (CDER).

(xiii) The Director, Center for Devices and Radiological Health (CDRH), the Deputy Director for Regulations and Policy, and the Deputy Director for Science, CDRH.

(xiv) The Director and Deputy Director, Center for Food Safety and Applied Nutrition (CFSAN).

(xv) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(xvi) The Director, National Center for Toxicological Research (NCTR); the Deputy Center Directors, Offices of Research and Management, respectively, NCTR; and the Deputy Director for Washington Operations, NCTR.

(xvii) These officials may not further redelegate this authority.

(2) The Deputy Associate Commissioner for Regulatory Affairs (Deputy ACRA), ORA; the Director and Deputy Director, Office of Enforcement OE, ORA; and the Director, Division of Compliance Policy, OE, ORA are delegated the authority to grant requests for testimony or to authorize the giving of testimony under § 20.1 of this chapter. These officials may not further redelegate this authority.

(3) The Associate and Deputy Associate Commissioners are delegated the authority to disclose official records and information under § 20.82 of this chapter. These officials may not further redelegate this authority.

(4) The Associate and Deputy Associate Commissioners; the Director and Deputy Director, OE, ORA; and the Director, Division of Compliance Policy, OE, ORA are delegated the authority to disclose official records and information under § 20.85 of this chapter. These officials may not further redelegate this authority

(5) The following officials are delegated the authority to disclose confidential commercial information to State government officials under § 20.88(d) of this chapter and the ACRA and the Center Directors may further redelegate this authority.

(i) The ACRA, the Deputy ACRA, ORA and the Director, OE, ORA.

(ii) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER); and the Director and Deputy Director, Office of Communication, Training, and Manufacturer's Assistance (OCTMA), CBER.

(iii) The Director and Deputy Director, CDER; the Directors, Office of Review Management and Office of Pharmaceutical Science, CDER; the Associate Director for Regulatory Policy, CDER.

(iv) The Director, CDRH, the Deputy Director for Regulations and Policy, the Deputy Director for Science, and the Director, Office of Health and Industry Programs, CDRH.

(v) The Director and Deputy Director, CFSAN.

(vi) The Director and Deputy Director, CVM.

(vii) The Director, the Deputy Center Directors, Offices of Research and Management, respectively, NCTR, and the Deputy Director for Washington Operations, NCTR.

(6) The following officials are delegated the authority to disclose nonpublic, predecisional documents to State and foreign government officials under §§ 20.88(e) and 20.89(d) of this chapter and they may not further redelegate this authority.

(i) The Associate Commissioner for Policy, Office of Policy, Planning and Legislation (OPPL); and the Director, Office of International Programs, Office of International and Constituent Relations (OICR).

(ii) For level 2 nonpublic, predecisional guidance documents, any Center Director or Deputy Director, and any Director for an OC office having program responsibilities.

(7) The Associate Commissioner for Policy, OPPL; and the Director, Office of International Programs, OICR are delegated the authority to receive nonpublic, predecisional documents from State and foreign government officials under §§ 20.88(e) and 20.89(d) of this chapter. These officials may not further redelegate this authority.

(8) The following officials are authorized to disclose confidential commercial information to foreign government officials under § 20.89(c) of this chapter; and they may not further redelegate it:

(i) The Deputy ACRA, ORA; and the Director, OE, ORA.

(ii) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER); and the Director and Deputy Director, Office of Communication, Training, and Manufacturer's Assistance (OCTMA), CBER.

(iii) The Director and Deputy Director, CDER; the Directors, Office of Review Management and Office of Pharmaceutical Science, CDER; the Associate Director for Medical Policy, CDER; the Associate Director for Regulatory Policy, CDER, and the Director, Division of Information Disclosure Policy, Office of Regulatory Policy, CDER.

(iv) The Director, CDRH, the Deputy Director for Regulations and Policy and the Deputy Director for Science, CDRH.

(v) The Director and Deputy Director, CFSAN.

(vi) The Director and Deputy Director, CVM.

(vii) The Director, the Deputy Center Directors, Offices of Research and Management, respectively, and the Deputy Director for Washington Operations, NCTR.

(b) The Chief, Information Management Team, Division of Data Management and Services, Office of Information Technology, CDER, is authorized to sign affidavits regarding the presence or absence of records of Registration of Drug Establishments. This official may not further redelegate this authority.

(c) The following officials are authorized to sign affidavits regarding the presence or absence of medical device establishment registration records and these officials may not further redelegate this authority:

(1) The Director, the Deputy Director for Regulations and Policy, and the Deputy Director for Science, CDRH.

(2) The Director and Deputy Director, Office of Compliance, CDRH.

(3) The Director and Deputy Director, Division of Program Operations, Office of Compliance, CDRH.

(4) The Chief, Information Processing and Office Automation Branch, Division of Program Operations, Office of Compliance, CDRH.

(d) The Director, Office of Resource Management, Office of Regulatory Affairs is authorized to sign affidavits regarding the presence or absence of records in the files of that office and this official may not further redelegate this authority

(e) The Director and Deputy Directors, CBER, the Director and Deputy Director, Office of Blood Research and Review (OBRR), and the Director and Deputy Director, Division of Blood Applications, OBRR, CBER, are authorized to sign affidavits regarding the presence or absence of records of registration of blood product establishments. These officials may not further redelegate this authority.

§ 5.24 Authority relating to technology transfer.

(a) The Associate Commissioner for Regulatory Affairs is authorized to perform the functions of the Commissioner of Food and Drugs as requested by the Commissioner regarding the authority to disapprove or require modification of cooperative research and development agreements and licensing agreements and transmit written explanation of such approval or disapproval to the head of the laboratory concerned under section 11(c)(5) (A) and (B) of the Stevenson-Wydler Technology Innovation Act of 1980 (the Act) (15 U.S.C. 3710a(c)(5) (A) and (B)), as amended.

(b) The following officials are authorized to perform the functions of the Commissioner of Food and Drugs (Commissioner) requested by the Commissioner under the Act (15 U.S.C. 3701 *et seq.*), as amended, and Executive Order 12591 of April 10, 1987 (except to the extent that redelegation of those functions is specifically limited in § 5.10(a)(26)), as they pertain to the functions of their respective organizations, including the authority to perform the functions of laboratory directors under the Act as the heads of their respective Federal laboratories, subject to the discretion of the Commissioner to require that agreements entered into under section 11(a) of the Act (15 U.S.C. 3710a(a)) include provisions in accordance with section 11(c)(5)(A) of the Act (15 U.S.C. 3710a(c)(5)(A):

(1) The Director, Center for Biologics Evaluation and Research.

(2) The Director, Center for Devices and Radiological Health.

(3) The Director, Center for Drug Evaluation and Research.

(4) The Director, Center for Food Safety and Applied Nutrition.

(5) The Director, Center for Veterinary Medicine.

(6) The Director, National Center for Toxicological Research.

(7) The Associate Commissioner for Regulatory Affairs.

(c) These officials may not further redelegate these authorities.

§ 5.25 Research, investigation, and testing programs and health information and promotion programs.

(a) The following officials are authorized under sections 301, 307, 311, 1701, 1702, 1703, and 1704 of the Public Health Service Act (the PHS Act) (42 U.S.C. 241, 242l, 243, 300u, 300u–1, 300u–2, 300u–3) to establish research, investigation, and testing programs and health information and health promotion programs, which relate to their assigned functions, and to approve grants for conducting such programs:

(1) The Director, the Deputy Director for Washington Operations, and the Deputy Center Directors, Offices of Research and Management, respectively, National Center for Toxicological Research (NCTR).

(2) The Director and Deputy Directors for Science and for Regulations and Policy, Centers for Devices and Radiological Health (CDRH).

(3) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(4) The Director and Deputy Director, Center for Food Safety and Applied Nutrition (CFSAN).

(5) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(6) The Director and Deputy Director, the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(7) The Director, Office of Orphan Products Development (OPD), Office of the Senior Associate Commissioner (OSAC), Office of the Commissioner (OC).

(b) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH, are authorized to establish an electronic product radiation control program and to approve grants for conducting the program under section 532 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ii).

(c) The Senior Associate Commissioner for Management and Systems, Office of Management and Systems (OMS), OC; the Director and Deputy Director, Office of Facilities, Acquisitions, and Central Services (OFACS), OMS, OC; the Director, Division of Contracts and Procurement Management (DCPM), OFACS, OMS, OC; and the Chief Grants Management Officer and the Grants Management Officer, DCPM, OFACS, OMS, OC are authorized to sign and issue all notices of grant awards and amendments thereto and sign and issue notices of suspension and termination thereof for grants approved under the authority delegated in paragraphs (a) and (b) of this section.

(d) The Director, NCTR, is authorized under section 301 of the PHS Act (42 U.S.C. 241), as amended by Public Law 95–622, to make available to educational institutions, for biomedical and behavioral research, laboratory animals bred for research purposes of the Center that are not required to support Center research programs.

(e) The Senior Associate Commissioner for Management and Systems may further redelegate the authorities in paragraph (c) of this section. With the exception for paragraph (c) of this section, these officials may not further redelegate these authorities.

§ 5.26 Service fellowships.

(a) Under authority of sections 207(g) and 208(f) of the PHS Act (42 U.S.C. 209(g) and 210(f)), and within the limits of an approved service fellowship plan, the following officials are authorized to designate persons to receive service fellowships, appoint service fellows, and determine specific stipend rates for

individual actions within the ranges established under an approved service fellowship plan:

(1) The Deputy Commissioner; the Senior Associate Commissioner; the Deputy Commissioner for International and Constituent Relations; the Senior Associate Commissioner for Management and Systems; the Senior Associate Commissioner for Policy, Planning, and Legislation; the Chief Counsel and Deputy Chief Counsels; and the Associate Commissioners and their Deputies.

(2) The Director, the Deputy Director for Washington Operations, the Deputy Center Directors for Research and Management, respectively, and the Associate Director, Office of Management Services, National Center for Toxicological Research (NCTR).

(3) The Director, the Deputy Directors for Science and for Regulations and Policy, and the Director, Office of Systems and Management, Center for Devices and Radiological Health (CDRH).

(4) The Director, the Deputy Directors, the Associate Director for Research, the Office Directors, and the Director, Office of Management, Center for Biologics Evaluation and Research (CBER).

(5) The Director, the Deputy Director, and Director, Office of Management Systems, Center for Food Safety and Applied Nutrition (CFSAN).

(6) The Director, the Deputy Director, and the Director, Office of Management and Communications, Center for Veterinary Medicine (CVM).

(7) The Director and Deputy Director, the Directors, Office of Review Management and Office of Pharmaceutical Science, and the Director and Deputy Director, Office of Management, Center for Drug Evaluation and Research (CDER).

(8) The Director, Office of Executive Operations, Office of the Senior Associate Commissioner, Office of the Commissioner and the Director, Office of Resource Management, ORA.

(9) Director, Office of Human Resources and Management Services, Office of Management and Systems, Office of the Commissioner.

(b) These officials may further redelegate this authority, with the limitation that the Director, Office of Human Resources and Management Services, OMS, OC, is delegated the authority to approve service fellowship plans and exceptions to the approved plans, and this official may not further redelegate this authority.

§ 5.27 Patent term extensions for human drug products, medical devices, and food and color additives; and authority to perform due diligence determinations and informal hearings.

(a) The Deputy Commissioner is authorized to perform the due diligence determinations and informal hearings functions under section 156(d)(2)(B)(ii) of title 35 U.S.C. (35 U.S.C. 156), as amended, relative to patent term extensions.

(b) The Director, Center for Drug Evaluation and Research (CDER) and the Associate Director for Regulatory Policy, CDER, are authorized to perform the functions delegated to the Commissioner under title 35 U.S.C. 156, as amended, except for making due diligence determinations and holding of informal hearings under title 35 U.S.C. 156(d)(2)(B).

(c) The Chief Mediator and Ombudsman, Office of the Ombudsman, Office of the Senior Associate Commissioner, Office of the Commissioner, is authorized to perform the functions delegated to the Commissioner to make due diligence determinations under title 35 U.S.C. 156 (d)(2)(B), as amended, except for holding of informal hearings under title 35 U.S.C. 156(d)(2)(B)(ii).

(d) These officials may not further redelegate this authority.

§ 5.28 Hearings.

(a) The following officials are authorized to designate officials to hold informal hearings that relate to their assigned functions under sections 305, 404(b), and 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335, 344(b), and 381(a)); section 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1455) (21 U.S.C. 145); section 9(b) of the Federal Caustic Poison Act (44 Stat. 1406; see also Public Law 86–613, section 19 formerly section 18); and section 5 of the Federal Import Milk Act. Officials so designated are delegated authority vested in the Secretary of Agriculture by 7 U.S.C. 2217 (43 Stat. 803) to administer to take from any person an oath, affirmation, affidavit, or deposition for use in any prosecution or proceeding under, or in enforcement of, any law as cited in this part:

(1) The Director and Deputy Director, Center for Food Safety and Applied Nutrition (CFSAN); and the Director of Regulations and Policy, CFSAN.

(2) The Director and Deputy Director, the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); the Associate Director for Regulatory Policy and the Associate Director for Medical Policy, CDER; the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER; and the Director and Deputy Director, Office of Compliance, CDER.

(3) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(4) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(5) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Directors and Deputy Directors, Office of Blood Research and Review, Office of Vaccines Research and Review, Office of Therapeutics Research and Review, and Office of Compliance and Biologics Quality, CBER.

(6) Regional Food and Drug Directors.

(7) District Directors.

(8) The Director, St. Louis Branch.

(b) The Director and Deputy Directors for Science and for Regulations Policy, CDRH, are authorized to hold hearings, and to designate other officials to hold informal hearings, under section 360(a) of the PHS Act.

(c) The following officials are authorized to serve as the presiding officer, and to designate other Food and Drug Administration employees to serve as the presiding officer, at a regulatory hearing and to conduct such a hearing under the provisions of part 16 of this chapter. An official can serve as the presiding officer in a particular hearing only if he or she satisfies the requirements of § 16.42(b) of this chapter with respect to the action that is the subject of the hearing. Such officials are delegated authority vested in the Secretary of Agriculture by 7 U.S.C. 2217 (43 Stat. 803) to administer or to take from any person an oath, affirmation, or deposition for use in any prosecution or proceeding under, or in enforcement of, any law as cited in this part:

(1) The Chief Mediator and Ombudsman, Office of the Ombudsman, Office of the Senior Associate Commissioner, Office of the Commissioner of Food and Drugs (Commissioner).

(2) The Director and Deputy Director, CFSAN.

(3) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER); the Directors, Office of Review Management and Office of Pharmaceutical Science, CDER; the Associate Director for Regulatory Policy and the Associate Director for Medical Policy, CDER, the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management,

CDER; and the Director and Deputy Director, Office of Compliance, CDER.

(4) The Director and Deputy Directors for Science and for Regulations Policy, CDRH.

(5) The Director and Deputy Director, CVM.

(6) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Directors and Deputy Directors, Office of Blood Research and Review, Office of Vaccines Research and Review, Office of Therapeutics Research and Review, and Office of Compliance and Biologics Quality, CBER.

(7) Regional Food and Drug Directors.

(8) District Directors.

(9) The Director, St. Louis Branch.

(10) Such other FDA official as is designated by the Commissioner by memorandum in the proceeding.

(d) These officials may not further redelegate this authority.

§ 5.29 Petitions under part 10.

(a) For drugs assigned to their organizations, the following officials are authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter for a stay of an effective date in § 201.59 of this chapter for compliance with certain labeling requirements for human prescription drugs:

(1)(i) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(ii) The Directors and Deputy Directors, Office of Blood Research and Review (OBRR), Office of Vaccines Research and Review (OVRR), and Office of Therapeutics Research and Review (OTRR), CBER.

(iii) The Directors and Deputy Directors of the Divisions in OBRR, OVRR, and OTRR, CBER.

(2)(i) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(ii) The Directors and Deputy Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(iii) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(b) The following officials are authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter requesting in vitro test modifications under § 331.29 of this chapter:

(1) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, CDER.

(2) The Director, Office of Drug Evaluation V, Office of Review Management, CDER.

(3) The Director and Deputy Director, Division of Over-the-Counter Drug Products, Office of Drug Evaluation V, Office of Review Management, CDER.

(c) The following officials are authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter for a stay of an effective date or for an exemption from the tamper-resistant packaging and labeling requirements set forth in §§ 211.132, 700.25, or 800.12 of this chapter for certain over-the-counter human drug and cosmetic products and medical devices which relate to the assigned functions of the respective organizations:

(1) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, CDER.

(2) The Director and Deputy Director, Center for Food Safety and Applied Nutrition (CFSAN); and the Director of Regulations and Policy, CFSAN.

(3) The Director and the Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(d) The following officials are authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter requesting exemption from the general pregnancy-nursing warning for over-the-counter (OTC) drugs required under § 201.63 of this chapter, requesting exemption from a general overdose warning required under § 330.1(g) of this chapter, and requesting exemption from OTC drug administrative procedures under § 330.10 of this chapter:

(1) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, CDER.

(2) The Director, Office of Drug Evaluation V, Office of Review Management, CDER.

(3) The Director and Deputy Director, Division of Over-the-Counter Drug Products, Office of Drug Evaluation V, Office of Review Management, CDER.

(e)(1) The following officials are authorized to issue 180-day tentative responses to citizen petitions on food and cosmetic matters under § 10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Center:

(i) The Director and Deputy Director, CFSAN.

(ii) The Director of Regulations and Policy, CFSAN.

(iii) The Director, Office of Cosmetics and Colors, CFSAN.

(iv) The Director, Office of Nutritional Products, Labeling and Dietary Supplements, CFSAN.

(v) The Director, Office of Premarket Approval, CFSAN.

(vi) The Director, Office of Plant and Dairy Foods and Beverages, CFSAN.

(vii) The Director, Office of Seafood, CFSAN.

(viii) The Director, Office of Field Programs, CFSAN.

(2) The Director and Deputy Director, Center for Veterinary Medicine (CVM), are authorized to issue 180-day tentative responses to citizen petitions on animal food and drug matters under § 10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Center.

(3) The Director and Deputy Directors, CBER, are authorized to issue 180-day tentative responses to citizen petitions on biological product matters under § 10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Center.

(4) The Director, the Deputy Director, and the Associate Director for Regulatory Policy, CDER, are authorized to issue 180-day tentative responses to citizen petitions on drug product matters under § 10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Center.

(5) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH, are authorized to issue 180-day tentative responses to citizen petitions on medical device matters under § 10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Center.

(f)(1) The Director and Deputy Directors, CBER, are authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter on drug and biological product matters in program areas where they have been delegated final approval authority in the following sections of this chapter:

(i) Section 5.203 *Issuance and revocation of licenses for the propagation or manufacture and preparation of biological products*;

(ii) Section 5.204 *Notification of release for distribution of biological products*;

(iii) Section 5.101 *Termination of exemptions for new drugs for investigational use in human beings or in animals*;

(iv) Section 5.103 *Approval of new drug applications and their supplements.*

(v) Section 5.105 *Issuance of notices relating to proposals to refuse approval*

or to withdraw approval of new drug applications and their supplements.

(vi) Section 5.34 *Issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment.*

(2) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, CDER, are authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter on drug product matters in program areas where they have been delegated final approval authority in the following sections of this chapter:

(i) Section 5.100 *Issuance of notices implementing the provisions of the Drug Amendments of 1962*;

(ii) Section 5.101 *Termination of exemptions for new drugs for investigational use in human beings or in animals*;

(iii) Section 5.103 *Approval of new drug applications and their supplements.*

(iv) Section 5.105 *Issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and their supplements.*

(v) Section 5.34 *Issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment.*

(3) The Director and Deputy Director, Office of Generic Drugs, Office of Pharmaceutical Science, CDER, except for those drug products listed in § 314.440(b) of this chapter, are authorized to issue responses to citizen petitions submitted under § 10.30 of this chapter seeking a determination of the suitability of an abbreviated new drug application for a drug product.

(4) The Directors and Deputy Directors of OBRR, OVRR, and OTRR, CBER, for those drug products listed in § 314.440(b) of this chapter, are authorized to issue responses to citizen petitions submitted under § 10.30 of this chapter seeking a determination of the suitability of an abbreviated new drug application for a drug product.

(5) For drugs assigned to their organization, the following officials are authorized to issue responses to citizen petitions submitted under § 10.30 of this chapter from sponsors of an investigational new drug application who request approval to ship in interstate commerce, in accordance with § 2.125(j) of this chapter, an investigational new drug for human use containing a chlorofluorocarbon.

(i) The Director and Deputy Directors, CBER.

(ii) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, CDER.

(6) The Director and Deputy Director, CVM, are authorized to issue responses to citizen petitions submitted under § 10.30 of this chapter from sponsors of an investigational new animal drug application who request approval to ship in interstate commerce, in accordance with § 21.125(j) of this chapter, an investigational new animal drug for animal use containing a chlorofluorocarbon.

(7) The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM, are authorized to issue responses to citizen petitions submitted under § 10.30 of this chapter, seeking a determination of the suitability of an abbreviated new animal drug application for an animal drug product.

(8) The Director and Deputy Director, CVM, are authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter concerning actions they are authorized to take under § 5.34 *Issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment.*

(g) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH, and the Director, Office of Compliance, CDRH, are authorized to grant or deny citizen petitions submitted under §§ 10.30 and 821.2(b) of this chapter, requesting an exemption or variance from medical device tracking requirements in part 821 of this chapter.

(h) These officials may not further redelegate this authority.

§ 5.30 Authority to select temporary voting members for advisory committees and authority to sign conflict of interest waivers.

(a) Each Center director is authorized to select members of, and consultants to, scientific and technical FDA advisory committees under that Center's management to serve temporarily as voting members on another advisory committee under that Center's management when expertise is required that is not available among current voting standing members of a committee or to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. When additional voting members are added to a committee to provide needed expertise not available among current voting standing members of a committee, a quorum will be based on the total of regular and added members. Authority to select temporary voting members to advisory committees, if such voting members are serving on an advisory committee managed by another Center, has not been redelegated. This authority will continue to be exercised by the Commissioner of Food and Drugs (Commissioner) or the Senior Associate Commissioner, Office of the Commissioner.

(b) Each Center director is authorized, under 18 U.S.C. 208(b)(1), to sign conflict of interest waivers for special Government employees without substantial interest to serve as consultants to advisory committees or in any other capacity within the Centers except as advisory committee members.

(c) These officials may not further redelegate this authority.

§ 5.31 Enforcement activities.

(a) Designated officers and employees of the Food and Drug Administration who have been issued the Food and Drug Administration official credentials consisting of Form FDA–200A, Identification Record, and Form FDA–200B, Specification of General Authority, are authorized:

(1) To conduct examinations, inspections, and investigations; to collect and obtain samples; to have access to and to copy and verify records as authorized by law; to make seizures of items under section 702(e)(5) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 372 (e) (5)); and to supervise compliance operations for the enforcement of the act, the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461), the Federal Caustic Poison Act (44 Stat. 140b; see also Public Law 86–613, section 19, formerly section 18), the Import Milk Act (21 U.S.C. 141–149), the Filled Milk Act (21 U.S.C. 61–64), and sections 351 and 361 of the PHS Act (42 U.S.C. 262 and 264).

(2) To administer oaths and affirmations under section 1 of the act of January 31, 1925 (Ch. 124, 43 Stat. 803); sections 12 to 15 of Reorganization Plan No. IV, effective June 30, 1940; and Reorganization Plan No. 1 of 1953, effective April 11, 1953.

(b) Any officer or employee of the Food and Drug Administration who has been designated by the Commissioner of Food and Drugs (Commissioner) to conduct examinations, investigations, or inspections under the act relating to counterfeit drugs and issued the Food and Drug Administration Official Credential consisting of Form FDA–200D, Special Authority for Criminal Investigators, is authorized to do the following:

(1) As set forth under section 702(e)(1) through (e)(5) of the act (21 U.S.C. 372 (e)(1)–(e)(5)):

(i) Carry firearms;

(ii) Serve and execute search warrants and arrest warrants;

(iii) Execute seizure by process issued under libel under section 304 of the act (21 U.S.C. 334);

(iv) Make arrests without warrant for an offense under the act with respect to counterfeit drugs if the offense is committed in the presence of the criminal investigator or, in the case of a felony, if the investigator has probable cause to believe that the person so arrested has committed, or is committing, such offense; and

(v) Make, prior to the institution of libel proceedings under section 304(a)(2) of the act (21 U.S.C. 334(a)(2)), seizures of drugs or containers or of equipment, punches, dies, plates, stones, labeling, or other things, if they are, or the criminal investigator has reasonable grounds to believe that they are, subject to seizure and condemnation under section 304(a)(2) of the act.

(2) Perform such other functions under the act, or any other law, as the Commissioner may prescribe.

(3) To administer oaths and affirmations under section 1 of the act of January 31, 1925 (Ch. 124, 43 Stat. 803); sections 12 to 15 of Reorganization Plan No. IV, effective June 30, 1940; and Reorganization Plan No. 1 of 1953, effective April 11, 1953.

(c) Any officer or employee of the Food and Drug Administration who has been designated by the Commissioner to provide specialized law enforcement support involving criminal investigations under the act, and other duties as assigned by the Commissioner, and issued the Food and Drug Administration Official Credential consisting of Form FDA–200E, Special Authority for Criminal Investigative Specialists, is authorized to receive information as to all matters relating to such act and regulations issued under the act.

(d) These officials may not further redelegate these authorities.

§ 5.32 Certification following inspections.

Regional Food and Drug Directors and District Directors are authorized to issue certificates of sanitation under § 1240.20 of this chapter. These officials may not further redelegate this authority.

§ 5.33 Issuance of reports of minor violations.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs (Commissioner) under section 309 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 336) (the act) regarding the issuance of written notices or warnings:

(1)(i) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(ii) The Director and Deputy Directors, Office of Compliance and Biologics Quality, CBER.

(2)(i) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(ii) The Director and Deputy Director, Office of Compliance, CDRH.

(iii) For medical devices assigned to their respective divisions, the Division Directors, Office of Compliance, CDRH.

(iv) The Director and Deputy Director, Office of Surveillance and Biometrics (OSB), CDRH, and the Director and Deputy Director, Division of Surveillance Systems (DSS), OSB, CDRH.

(3)(i) The Director and Deputy Director, Center for Food Safety and Applied Nutrition, (CFSAN).

(ii) The Director of Regulations and Policy, CFSAN.

(iii) The Director, Office of Field Programs, CFSAN.

(iv) The Director, Division of Enforcement and Programs, Office of Field Programs, CFSAN.

(4)(i) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(ii) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(iii) The Director, Division of Compliance, Office of Surveillance and Compliance, CVM.

(5)(i) The Director, the Deputy Director, the Associate Director for Regulatory Policy, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(ii) The Director and Deputy Director, Office of Compliance, CDER.

(iii) The Associate Director for Medical Policy, CDER.

(iv) The Director, Division of Drug Marketing, Advertising, and Communications, Office of Medical Policy, CDER.

(6)(i) Regional Food and Drug Directors.

(ii) District Directors.

(iii) Chiefs of District Compliance Branches.

(iv) The Director, St. Louis Branch.

(v) The Director, Northeast Regional Laboratory, Northeast Region.

(vi) The Director, Southeast Regional Laboratory, Southeast Region.

(vii) The Director, Winchester Engineering and Analytical Center.

(viii) The Director, National Forensic Chemistry Center.

(ix) The Director, Arkansas Regional Laboratory.

(b) The following officials are authorized to perform all the functions of the Commissioner under section 539(d) of the act (21 U.S.C. 360pp(d)) regarding the issuance of written notices or warnings:

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Compliance, CDRH.

(3) For medical devices assigned to their respective divisions, the Division Directors, Office of Compliance, CDRH.

(4) The Director and Deputy Director, Office of Surveillance and Biometrics (OSB), CDRH, and the Director and Deputy Director, Division of Surveillance Systems (DSS), OSB, CDRH.

(5) Regional Food and Drug Directors; District Directors; the Director, St. Louis Branch; the Director, Northeast Regional Laboratory, Northeast Region; the Director, Southeast Regional Laboratory, Southeast Region; the Director, Winchester Engineering and Analytical Center; the Director, National Forensic Chemistry Center, and the Director, Arkansas Regional Laboratory when such functions relate to:

(i) Assemblers of diagnostic x-ray systems, as defined in § 1020.30(b) of this chapter; and

(ii) Manufacturers of sunlamp products and ultraviolet lamps intended for use in any sunlamp product as defined in § 1040.20(b) of this chapter.

(c) These officials may not further redelegate these authorities.

§ 5.34 Issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment.

(a) The Director, the Deputy Director, and the Associate Director for Regulatory Policy, Center for Drug Evaluation and Research, the Director and Deputy Director, Center for Veterinary Medicine, and the Director and Deputy Directors, Center for Biologics Evaluation and Research are authorized to issue the following notices and make all findings required in relation to these notices under section 306 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 335a) which relate to the assigned functions of their organizations:

(1) Notices of opportunity for hearing on proposals for mandatory or permissive debarment.

(2) Notices ordering debarment when opportunity for a hearing has been waived.

(3) Notices ordering debarment where the person notifies the agency that the

person consents to debarment under section 306(c)(2)(B) of the act (21 U.S.C. 335a(c)(2)(B)).

(4) Notices of opportunity for hearing on proposals denying an application to terminate debarment under section 306(d)(3) of the act (21 U.S.C. 335u(d)(3)).

(5) Orders denying an application to terminate debarment under section 306(d)(3) of the act (21 U.S.C. 335u(d)(3)) when opportunity for a hearing has been waived.

(b) These officials may not further redelegate these authorities.

§ 5.35 Officials authorized to make certification under 5 U.S.C. 605(b) for any proposed and final rules.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to decisions made under the Regulatory Flexibility Act (5 U.S.C. 605(b)), to certify that a proposed or final rule, if issued, will not have a significant economic impact on a substantial number of small entities:

(1) The Associate Commissioner for Regulatory Affairs.

(2) The Director, Center for Biologics Evaluation and Research.

(3) The Director, Center for Drug Evaluation and Research.

(4) The Director, Center for Devices and Radiological Health.

(5) The Director, Center for Food Safety and Applied Nutrition.

(6) The Director, Center for Veterinary Medicine.

(7) Other Food and Drug Administration Officials authorized to issue **Federal Register** documents.

(b) These officials may not further redelegate this authority.

Subpart C—Human Drugs; Redelegations of Authority

§ 5.100 Issuance of notices implementing the provisions of the Drug Amendments of 1962.

The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research; and the Director, the Deputy Directors for Regulations and Policy and for Science, and the Director and Deputy Directors, Office of Device Evaluation, Center for Devices and Radiological Health, are authorized to issue notices and amendments thereto implementing section 107(c)(3) of the Drug Amendments of 1962 (Pub. L. 87–781) by announcing new or revised efficacy findings on human drugs that are or were subject to the provisions of section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355). These officials may not further redelegate this authority.

§ 5.101 Termination of exemptions for new drugs for investigational use in human beings.

(a) The following officials, for drugs under their jurisdiction, are authorized to perform all the functions of the Commissioner of Food and Drugs on the termination of exemptions for new drugs (including those that are biological products which are subject to the licensing provisions of the Public Health Service Act) for investigational use in human beings under § 312.44 of this chapter and in animals under § 312.160 of this chapter:

(1) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(2) The Director, the Deputy Director, and the Directors, Office of Review Management and Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(3) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(b) The following officials, for drugs under their jurisdiction, are authorized to terminate exemptions for new drugs for investigational use when sponsors fail to submit an annual progress report under § 312.44(b)(1)(viii) of this chapter:

(1) The Directors and Deputy Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(2) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(3) The Directors and Deputy Directors, Office of Blood Research and Review (OBRR), OVRR, and Office of Therapeutics Research and Review (OTRR), CBER.

(4) The Directors and Deputy Directors of the Division of Blood Applications, OBRR, the Division of Vaccines and Related Products Applications, OVRR, and the Division of Application Review and Policy, OTRR, CBER.

(5) The Director and Deputy Directors, Office of Device Evaluation (ODE), CDRH.

(c) The following officials, for drugs under their jurisdiction, are authorized to make the findings set forth in § 312.44(b) of this chapter and to notify sponsors and invite correction before termination action on such exemptions:

(1) The Directors and Deputy Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(2) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(3) The Directors and Deputy Directors, Office of Blood Research and Review (OBRR), Office of Vaccines Research and Review (OVRR), and Office of Therapeutics Research and Review (OTRR), CBER.

(4) The Directors and Deputy Directors of the Division of Blood Applications, OBRR, the Division of Vaccines and Related Products Applications, OVRR, and the Division of Application Review and Policy, OTRR, CBER.

(5) The Director and Deputy Directors, ODE, CDRH.

(d) These officials may not further redelegate these authorities.

§ 5.102 Authority to approve and to withdraw approval of a charge for investigational new drugs.

(a) The following officials, for drugs under their jurisdiction, are authorized to perform all the functions of the Commissioner of Food and Drugs to approve a charge and to withdraw approval to charge for investigational drugs in a clinical trial under an investigational new drug application under § 312.7(d)(1) of this chapter:

(1) The Director, the Deputy Director, and the Directors, Office of Review Management and the Office of Pharmaceutical Science, Center for Drug Evaluation and Research.

(2) The Director and Deputy Directors, Center for Biologics Evaluation and Research.

(b) These officials may not further redelegate this authority.

§ 5.103 Approval of new drug applications and their supplements.

(a)(1) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs (Commissioner) with regard to approval of new drug applications and supplements thereto on drugs for human use, except for those drugs listed in § 314.440(b) of this chapter, that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355):

(i) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(ii) The Directors and Deputy Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER, for drugs under their jurisdiction.

(2) The Director and Deputy Directors, Center for Biologics Evaluation and

Research, for drugs listed in § 314.440(b) of this chapter, are authorized to perform all the functions of the Commissioner with regard to approval of new drug applications and supplements thereto on drugs for human use that have been submitted under section 505 of the act.

(b) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER, for drugs under their jurisdiction, are authorized to perform all functions of the Commissioner with regard to approval of supplemental applications to approved new drug applications for drugs for human use that have been submitted under § 314.70 of this chapter and of new drug applications for drug products other than those that contain new molecular entities (new chemical entities). The applications to which this authorization applies may, in appropriate circumstances, continue to be acted upon by the officials so authorized in § 5.10(a) and paragraph (a) of this section.

(c) The following officials are authorized to perform all the functions of the Commissioner with regard to approval of abbreviated new drug applications and supplements thereto for drugs for human use and new drug applications for drugs with a 5S classification whose clinical safety and efficacy may be supported by appropriate literature citations in lieu of submission of data from original proprietary studies, or section 505(b)(2) of the act (21 U.S.C. 355 (b)(2)) applications under their jurisdiction. The applications to which this authorization applies may, in appropriate circumstances, continue to be acted upon by the officials so authorized in § 5.10(a) and paragraph (a) of this section.

(1) For drugs submitted under §§ 314.50, 314.70, and 314.94 of this chapter, except for those drug products listed in § 314.440(b):

(i) The Director and Deputy Director, Office of Generic Drugs (OGD), Office of Pharmaceutical Science, CDER, except that the Director and Deputy Director, OGD are not authorized to approve new drug applications with a 5S classification if clinical studies are needed.

(ii) The Directors and Deputy Directors of the divisions in Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(2) For drug products listed in § 314.440(b) of this chapter and submitted under §§ 314.50, 314.70, and 314.94 of this chapter: The Directors and Deputy Directors, Office of Blood Research and Review, Office of Vaccines Research and Review, Office of Therapeutics Research and Review, and Office of Compliance and Biologics Quality, CBER.

(d) The following officials are authorized to perform all functions of the Commissioner with respect to approval of supplemental applications to abbreviated new drug applications, 5S applications, or section 505(b)(2) applications for drugs for human use that are described in §§ 314.70(b)(1), (b)(2)(ii) through (b)(2)(x), (c)(1), and (c)(3) of this chapter. (Authority to approve supplements that require in vivo bioavailability studies or that include in vivo bioavailability study waiver requests are not included in this paragraph.)

(1) The Director and Deputy Director, Division of Chemistry I, Office of Generic Drugs, Office of Pharmaceutical Science, CDER.

(2) The Director and Deputy Director, Division of Chemistry II, Office of Generic Drugs, Office of Pharmaceutical Science, CDER.

(3) Associate Director for Chemistry, Office of New Drug Chemistry, Office of Pharmaceutical Science, CDER.

(e) The Director, Division of Labeling and Program Support, Office of Generic Drugs, Office of Pharmaceutical Science, CDER, are authorized to perform all the functions of the Commissioner with respect to approval of supplemental applications to abbreviated new drug applications, 5S applications, or section 505(b)(2) applications for drugs for human use that are described in §§ 314.70(b)(3) and (c)(2)(i) through (c)(2)(iv) of this chapter. Authority to approve supplements that require in vivo bioavailability studies or in vivo study waiver requests is not included in this paragraph.

(f) The supervisory and team leader chemists in the Divisions of New Drug Chemistry I, II, and III, Office of New Drug Chemistry, Office of Pharmaceutical Science, CDER, are authorized to perform all functions of the Commissioner with respect to approval of supplemental applications to new drug applications for drugs for human use that are described in §§ 314(b)(1), (b)(2)(ii) through (b)(2)(x), (c)(1), and (c)(3) of this chapter. Authority to approve supplements that require in vivo bioavailability information or that require a change in the labeling of the drug, except changes that reflect only the use of a different facility or establishment, are not included in this paragraph. The supplemental applications to which this authorization applies may continue to be acted upon by the officials so authorized in § 5.10(a) and paragraphs (a) and (b) of this section.

(g) These officials may not further redelegate these authorities.

§ 5.104 Responses to Drug Enforcement Administration temporary scheduling notices.

The Director, Center for Drug Evaluation and Research (CDER) and the Director, Executive Operations Staff, Office of the Center Director, CDER, are authorized to provide responses to the Drug Enforcement Administration's temporary scheduling notices under section 201(h)(4) of the Controlled Substances Act, as amended (21 U.S.C. 811(h)(4)). The delegation excludes the authority to submit reports to Congress. These officials may not further redelegate this authority.

§ 5.105 Issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and their supplements.

(a) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER), are authorized to issue notices of an opportunity for a hearing on proposals to refuse approval or to withdraw approval of new drug applications and abbreviated new drug applications and supplements thereto on drugs for human use, except for those drugs listed in § 314.440(b) of this chapter, that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) and subpart B of part 314 of this chapter and to issue notices refusing approval or withdrawing approval when opportunity for hearing has been waived.

(b) The Director and Deputy Directors, Center for Biologics Evaluation and Research, for those drugs listed in § 314.440(b) of this chapter, are authorized to issue notices of an opportunity for a hearing on proposals to refuse approval or to withdraw approval of new drug applications and abbreviated new drug applications and supplements thereto on drugs for human use that have been submitted under section 505 of the act and subpart B of part 314 of this chapter and to issue notices refusing approval or withdrawing approval when opportunity for hearing has been waived.

(c) These officials may not further redelegate these authorities.

§ 5.106 Submission of and effective approval dates for abbreviated new drug applications and certain new drug applications.

(a) The following officials are authorized to perform all of the functions of the Commissioner of Food and Drugs with regard to decisions made under section 505 (c)(3)(D), (j)(4)(B)(iv), and (j)(4)(D) and section 505A of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 355(c)(3)(D), (j)(4)(B)(ii) and (j)(4)(D) and 355a) concerning the date of submission or the date of effective approval of abbreviated new drug applications including supplements thereto submitted under section 505(j) of the act (21 U.S.C. 355(j)) and of new drug applications including supplements thereto submitted under section 505(b)(1) (21 U.S.C. 355 (b)(1)) of the act and described under section 505(b)(2) of the act (21 U.S.C. 355(b)(2)):

(1) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(2) The Director and Deputy Director, Office of Generic Drugs, Office of Pharmaceutical Science, CDER.

(b) These officials may not further redelegate this authority.

§ 5.107 Extensions or stays of effective dates for compliance with certain labeling requirements for human prescription drugs.

(a) The following officials are authorized to extend or stay an effective date in § 201.59 of this chapter for compliance with certain labeling requirements for human prescription drugs.

(1) For drugs assigned to their organizations:

(i) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(ii) The Directors and Deputy Directors, Office of Blood Research and Review (OBRR), Office of Vaccines Research and Review (OVRR), and Office of Therapeutics Research and Review (OTRR), CBER.

(iii) The Directors and Deputy Directors of the Divisions in OBRR, OVRR, and OTRR, CBER.

(2) For drugs assigned to their organizations:

(i) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(ii) The Directors and Deputy Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(iii) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(b) These officials may not further redelegate this authority.

§ 5.108 Authority relating to waivers or reductions of prescription drug user fees.

The Director, Center for Drug Evaluation and Research (CDER), and the Associate Director for Regulatory Policy, CDER, are authorized to perform all the functions of the Commissioner of Food and Drugs relating to waivers or reductions of prescription drug user fees under the Prescription Drug User Fee Act of 1992, as originally enacted and as reauthorized by the Food and Drug Administration Modernization Act of 1997, except for the functions under section 736(d)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379h(d)(1)(C)) that pertain to situations where ''the fees will exceed the anticipated present and future costs,'' on behalf of CDER, the Center for Biologics Evaluation and Research, and any other Food and Drug Administration Center. This authority pertains to waivers requested under the public health waiver provision (21 U.S.C. 379h(d)(1)(A)); the barrier to innovation waiver provision (21 U.S.C. 379h(d)(1)(B)); the applications submitted under section 505(b)(1) and (b)(2) of the Federal Food, Drug, and Cosmetic Act waiver provision (21 U.S.C. 379h(d)(1)(D)); the small business waiver provision (21 U.S.C. 379h(d)(1)(E)); and to requests for refunds of fees if an application or supplement is withdrawn after filing (21 U.S.C. 379h(a)(1)(G)); as well as waivers, reductions, or refunds requested on any other basis except fees exceeding the cost. (See § 5.20(h)(1) for the authority to reconsider any user fee decisions made by the Chief Mediator and Ombudsman, the Deputy Chief Mediator and Ombudsman, and/or the former Deputy User Fee Waiver Officer prior to July 1, 1999.) These officials may not further redelegate this authority.

§ 5.109 Issuance of written notices concerning patent information, current good manufacturing practices and false or misleading labeling of new drugs.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under § 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)) regarding the issuance of written notices.

(1) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(2) The Director and Deputy Director, Office of Compliance, CDER.

(3) The Director and Deputy Director, Division of Labeling and Nonprescription Drug Compliance, Office of Compliance, CDER.

(4) The Director and Deputy Director, Division of Manufacturing and Product Quality, Office of Compliance, CDER.

(5) The Director and Deputy Director, Division of Prescription Drug Compliance and Surveillance, Office of Compliance, CDER.

(6) The Associate Director for Medical Policy, and the Director and Deputy Director, Division of Scientific Investigations, Office of Medical Policy, CDER.

(7) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), the Director and Deputy Directors, Office of Compliance and Biologics Quality (OCBQ), CBER, and the Directors, Division of Case Management, Division of Inspections and Surveillance, and Division of Manufacturing and Product Quality, OCBQ, CBER.

(8) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Directors of the Office of Device Evaluation, CDRH.

(9) Regional Food and Drug Directors.

(10) District Directors.

(b) These officials may not further redelegate this authority.

Subpart D—Biologics; Redelegations of Authority

§ 5.200 Functions pertaining to safer vaccines.

(a) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER) are authorized to perform the functions of the Commissioner of Food and Drugs (Commissioner) under part C, subtitle 2 of title XXI of the PHS Act (42 U.S.C. 300aa–25 *et seq.*), as amended, and the National Childhood Vaccine Injury Act of 1986 (42 U.S.C. 300aa–1 note), as amended hereafter, as follows:

(1) Section 2125 of the PHS Act (42 U.S.C. 300aa–25)–Recording and reporting of information.

(2) Section 2127 of the PHS Act (42 U.S.C. 300aa–27)–Mandate for safer childhood vaccines.

(3) Section 2128 of the PHS Act (42 U.S.C. 300aa–28)–Manufacturer recordkeeping and reporting.

(4) Section 312 of the National Childhood Vaccine Injury Act of 1986–Related studies (42 U.S.C. 300aa–1

note), except that the authority to provide for notice and opportunity for public hearing on the review of vaccines and related illnesses and conditions under sections 312(a) and (d) of the National Childhood Vaccine Injury Act of 1986 is not redelegated by the Commissioner.

(5) Section 313 of the National Childhood Vaccine Injury Act of 1986–Study of other vaccine risks (42 U.S.C. 300aa–1 note), except that the authority to provide for notice and opportunity for public hearing on the establishment of guidelines regarding the risks to children of certain vaccines under section 313(a)(1)(B) and (b) of the National Childhood Vaccine Injury Act of 1986 is not redelegated by the Commissioner.

(6) Section 314 of the National Childhood Vaccine Injury Act of 1986–Review of warnings, use instructions, and precautionary information (42 U.S.C. 300aa–1 note).

(b) These officials may not further redelegate these authorities.

§ 5.201 Redelegation of the Center for Biologics Evaluation and Research Director's program authorities.

(a) The following officials are authorized to perform all the functions of the Director, Center for Biologics Evaluation and Research (CBER) with regard to program authorities for their respective areas:

(1) Deputy Directors, CBER.

(2) Associate Directors, CBER.

(3) Office Directors, CBER.

(4) Division Directors, CBER.

(b) These officials may not further redelegate these authorities.

§ 5.202 Issuance of notices of opportunity for a hearing on proposals for denial of approval of applications for licenses, suspension of licenses, or revocation of licenses and certain notices of revocation of licenses.

(a) The Director and Deputy Directors, Center for Biologics Evaluation and Research are authorized to issue:

(1) Notices of opportunity for a hearing on proposals to deny approval or filing of applications for biologics licenses under § 601.4(b) of this chapter.

(2) Notices of opportunity for a hearing on proposals to revoke biologics licenses under § 601.5(b) of this chapter.

(3) Notices of revocation, at the manufacturer's request, of biologics licenses under §§ 601.5(a) and 601.8 of this chapter.

(4) Notices of revocation when the manufacturer has waived the opportunity for hearing under § 601.7(a) of this chapter.

(5) Notice of biologics license suspensions under § 601.6 of this chapter.

(b) These officials may not further redelegate these authorities.

§ 5.203 Issuance and revocation of licenses for the propagation or manufacture and preparation of biological products.

(a) The following officials are authorized to issue licenses under section 351 of the PHS Act (42 U.S.C. 262) for the propagation or manufacture and preparation of biological products as specified in the PHS Act, and to revoke such licenses at the manufacturer's request:

(1) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(2) Directors and Deputy Directors, Office of Blood Research and Review, Office of Vaccines Research and Review, Office of Therapeutics Research and Review, and Office of Compliance and Biologics Quality, CBER.

(b) These officials may not further redelegate this authority.

§ 5.204 Notification of release for distribution of biological products.

(a) The following officials are authorized to issue written notices of release for distribution of licensed biological products under subchapter F (parts 600 through 680.31) of this chapter:

(1) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(2) The Director and Deputy Directors, Office of Compliance and Biologics Quality (OCBQ), CBER.

(3) The Director and Deputy Director, Division of Manufacturing and Product Quality, OCBQ, CBER.

(b) These officials may not further redelegate this authority.

Subpart E—Food and Cosmetics; Redelegations of Authority

§ 5.300 Food standards, food additives, generally recognized as safe (GRAS) substances, color additives, nutrient content claims, and health claims.

(a)(1) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs (Commissioner) under sections 409 and 721 of the act (21 U.S.C. 348 and 379e) regarding the issuance of notices of filing (including notices of extension of, or reopening of, the comment period), and of voluntary withdrawal, of petitions on food additives, generally recognized as safe (GRAS) substances, and color additives that relate to the assigned functions of the respective Center:

(i) The Director and Deputy Director, Center for Food Safety and Applied Nutrition (CFSAN).

(ii) The Director of Regulations and Policy, CFSAN.

(iii) The Director, Office of Premarket Approval, CFSAN.

(iv) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(2) The Director, Deputy Director, and Director of Regulations and Policy, CFSAN are authorized to perform all the functions of the Commissioner under section 401 of the act (21 U.S.C. 341) regarding the issuance of proposed rulemaking (including notices of extension of, or reopening of, the comment period) pertaining to food standards.

(b)(1) The Director, Deputy Director, and Director of Regulations and Policy, CFSAN are authorized to perform all of the functions of the Commissioner under section 409 and 721 of the act (21 U.S.C. 348 and 379e) regarding the approval of the use of food additives under section 409(e) of the act (21 U.S.C. 348(e)) and the listing of color additives under section 721(d)(1) of the act (21 U.S.C. 379e) where the listing does not involve novel or controversial issues and does not involve any questions about the applicability of the Delaney Anti-Cancer Clause.

(2) The following officials are authorized to perform all of the functions of the Commissioner under section 401 of the act (21 U.S.C. 341) regarding the issuance of notices of temporary permits for foods varying from standards of identity under § 130.17 of this chapter:

(i) The Director and Deputy Director, CFSAN.

(ii) The Director of Regulations and Policy, CFSAN.

(iii) The Director, Office of Nutritional Products, Labeling, and Dietary Supplements, CFSAN.

(3) The Director and Deputy Director, CVM, are authorized to perform all the functions of the Commissioner regarding approvals of the use of food additives under section 409(e) of the act (21 U.S.C. 348(e)), where these approvals do not involve novel or controversial issues, including any question about the applicability of the Delaney Anti-Cancer Clause.

(c)(1) The following officials are authorized to issue 90-day letters to food additive petitioners under section 409(c)(2) of the act (21 U.S.C. 348(c)(2)) or to color additive petitions under section 721e(d)(1) (21 U.S.C. 379e(d)(1)) of the act that relate to the assigned functions of the Center:

(i) The Director and Deputy Director, CFSAN.

(ii) The Director of Regulations and Policy, CFSAN.

(iii) The Director, Office of Premarket Approval, CFSAN.

(iv) The Director, Division of Product Policy, Office of Premarket Approval, CFSAN.

(v) The Director, Division of Petition Control, Office of Premarket Approval, CFSAN.

(2) The following officials are authorized to issue 90-day letters to food additive petitioners under section 409(c)(2) of the act (21 U.S.C. 348(c)(2)) that relate to the assigned functions of the Center:

(i) The Director and Deputy Director, CVM.

(ii) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(iii) The Director and Deputy Director, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(d) The following officials are authorized to certify batches of color additives under section 721 of the act (21 U.S.C. 379e):

(1) The Director and Deputy Director, CFSAN.

(2) The Director of Regulations and Policy, CFSAN.

(3) The Director, Office of Cosmetics and Colors, CFSAN.

(e) The following officials are authorized to issue advance notices of proposed rulemaking pertaining to Codex Alimentarius food standards and notices terminating consideration of such standards when comments fail to support the desirability and need for proposing their adoption, under § 130.6 of this chapter:

(1) The Director and Deputy Director, CFSAN.

(2) The Director of Regulations and Policy, CFSAN.

(3) The Director, Office of Nutritional Products, Labeling, and Dietary Supplements, CFSAN.

(f) The following officials are authorized to issue notices of proposed rulemaking and issue or amend regulations affirming GRAS status of food substances under §§ 170.35 or 570.35 of this chapter where the affirmations relate to the assigned functions of the respective Center and do not involve novel or controversial issues:

(1) The Director, Deputy Director, and Director of Regulations and Policy, CFSAN.

(2) The Director and Deputy Director, CVM.

(g)(1) The following officials are authorized to perform all of the functions of the Commissioner under section 403(r)(4) of the act (21 U.S.C. 343(r)(4)) regarding the issuance of decisions to grant or deny petitions for nutrient content claims and health claims that do not present controversial issues and regarding the issuance of any notices of proposed rulemaking that result from such action:

(i) The Director and Deputy Director, CFSAN.

(ii) The Director of Regulations and Policy, CFSAN.

(2) The following officials are authorized to perform all of the functions of the Commissioner under section 403(r)(4) of the act (21 U.S.C. 343(r)(4)) regarding the issuing of letters of filing in response to petitions for nutrient content claims and health claims:

(i) The Director and Deputy Director, CFSAN.

(ii) The Director of Regulations and Policy, CFSAN.

(iii) The Director, Office of Nutritional Products, Labeling, and Dietary Supplements, CFSAN.

(h) The following officials are authorized to issue letters concerning substances determined to be below the ''threshold of regulation'' under § 170.39 of this chapter:

(1) The Director and Deputy Director, CFSAN.

(2) The Director of Regulations and Policy, CFSAN.

(3) The Director, Office of Premarket Approval, CFSAN.

(4) The Directors of the Divisions of Petition Control and Product Policy, Office of Premarket Approval, CFSAN.

(i) The following officials are authorized to perform all of the functions of the Commissioner under section 409(h) of the act (21 U.S.C. 348(h)), excluding the duties to set out in section 409(h)(5) of the act (21 U.S.C. 348(h)(5)), regarding premarket notification of food-contact substances:

(1) The Director and Deputy Director, CFSAN.

(2) The Director of Regulations and Policy, CFSAN.

(3) The Director, Office of Premarket Approval, CFSAN.

(j) These officials may not further redelegate these authorities.

§ 5.301 Issuance of initial emergency permit orders and notices of confirmation of effective date of final regulations on food for human and animal consumption.

(a) The Director and Deputy Director, Center for Food Safety and Applied Nutrition (CFSAN), the Director, Office of Field Programs, CFSAN, and the Director, Division of Enforcement and Programs, Office of Field Programs, CFSAN, are authorized to issue initial emergency permit orders under § 108.5 of this chapter.

(b) The following officials are authorized to issue notices of confirmation of effective date of final regulations on food matters issued under section 701(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(e)):

(1) The Director and Deputy Director, CFSAN.

(2) The Director of Regulations and Policy, CFSAN.

(3) The Director, Office of Nutritional Products, Labeling, and Dietary Supplements, CFSAN.

(4) The Director, Office of Plant and Dairy Foods and Beverages, CFSAN.

(5) The Director, Office of Seafood, CFSAN.

6) The Director, Office of Field Programs, CFSAN.

(7) The Director, Office of Premarket Approval, CFSAN.

(c) These officials may not further redelegate these authorities.

§ 5.302 Detention of meat, poultry, eggs, and related products.

The Regional Food and Drug Directors and District Directors are authorized to perform and to designate other officials to perform all of the functions of the Commissioner of Food and Drugs under:

(a) Section 409(b) of the Federal Meat Inspection Act (21 U.S.C. 679(b)), that relates to the detention of any carcass, part thereof, meat, or meat product of cattle, sheep, swine, goats, or equines.

(b) Section 24(b) of the Poultry Products Inspection Act (21 U.S.C. 467f (b)) that relates to the detention of any poultry carcass, part thereof, or poultry product.

(c) The Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

§ 5.303 Establishing standards and approving accrediting bodies under the National Laboratory Accreditation Program.

The Director, Deputy Director, and Director of Regulations and Policy, Center for Food Safety and Applied Nutrition, are authorized to perform all the functions of the Commissioner of Food and Drugs under sections 1322(b) and (c) of the Food, Agriculture, Conservation, and Trade Act of 1990 (the National Laboratory Accreditation Program) (7 U.S.C. 138a), as amended hereafter, which relate to setting standards for the National Laboratory Accreditation Program and approving State agencies or private, nonprofit entities as accrediting bodies to implement certification and quality assurance programs in accordance with the requirements of these sections. The delegation excludes the authority to submit reports to the Congress. These officials may not further redelegate this authority.

§ 5.304 Approval of schools providing food-processing instruction.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs (Commissioner) under § 113.10 of this chapter regarding the approval of schools giving instruction in retort operations, processing systems operations, aseptic processing and packaging system operations, and container closure inspections:

(1) The Director and Deputy Director, Center for Food Safety and Applied Nutrition (CFSAN).

(2) The Director of Regulations and Policy, CFSAN.

(3) The Director, Office of Plant and Dairy Foods and Beverages, CFSAN.

(b) These officials may not further redelegate this authority.

Subpart F—Medical Devices and Radiological Health; Redelegations of Authority

§ 5.400 Issuance of Federal Register documents to recognize or to withdraw recognition of a standard to meet premarket submission requirements.

(a) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health; and the Director and Deputy Directors, Center for Biologics Evaluation and Research, are authorized to issue **Federal Register** documents under section 514(c) of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 360d(c)) recognizing or withdrawing recognition of a standard for which a person may submit a declaration of conformity in order to meet a premarket submission requirement.

(b) These officials may not further redelegate this authority.

§ 5.401 Issuance of Federal Register documents pertaining to exemptions from premarket notification.

(a) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health; and the Directors and Deputy Directors, Center for Biologics Evaluation and Research, are authorized to make determinations and issue **Federal Register** notices and rules under § 510(m) of the act (21 U.S.C. 360(m)) concerning exemptions from premarket notification.

(b) These officials may not further redelegate this authority.

§ 5.402 Detention of adulterated or misbranded medical devices.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs pertaining to detention, under section 304(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334(g)) and in accordance with § 800.55 of this chapter, of medical devices that may be adulterated or misbranded:

(1) For medical devices assigned to their respective organizations:

(i) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(ii) The Director and Deputy Director, Office of Compliance, CDRH.

(iii) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(iv) The Director and Deputy Directors, Office of Compliance and Biologics Quality, CBER.

(2) Regional Food and Drug Directors.

(3) District Directors.

(4) The Director, St. Louis Branch.

(b) These officials may not further redelegate this authority.

§ 5.403 Authorization to use alternative evidence for determination of the effectiveness of medical devices.

(a) The following officials, for medical devices assigned to their respective organizations, may authorize under section 513(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(a)(3)(B)) the use of valid scientific evidence (other than that prescribed by section 513(a)(3)(A) of the act) for determining the effectiveness of medical devices for the purposes of sections 513, 514, and 515 of the act (21 U.S.C. 360c, 360d, and 360e):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Directors, Office of Device Evaluation, CDRH.

(2) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Directors and Deputy Director, Office of Blood Research and Review (OBRR), Office of Vaccines Research and Review (OVRR), and Office of Therapeutics Research and Review (OTRR), CBER.

(b) These officials may not further redelegate this authority.

§ 5.404 Notification to petitioners of determinations made on petitions for reclassification of medical devices.

(a) The following officials, for medical devices assigned to their respective organizations, are authorized to notify petitioners of determinations made on petitions for reclassification of medical devices that are classified in class III (premarket approval) by sections 513(f) and 520(l) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f) and 360 j(1)) and denials of petitions for reclassification of medical devices that are submitted under section 513(e) of the act (21 U.S.C. 360c(e)) (except for petitions submitted in response to **Federal Register** notices initiating standard-setting under § 514(b) of the act (21 U.S.C. 360d(b)) or premarket approval under section 515(b) of the act (21 U.S.C. 360e(b)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH) and the Director and Deputy Directors, Office of Device Evaluation.

(2) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Directors and Deputy Directors, Office of Blood Research and Review, Office of Vaccines Research and Review, and Office of Therapeutics Research and Review, CBER.

(b) These officials may not further redelegate this authority.

§ 5.405 Determination of classification of devices.

(a) The following officials, for devices assigned to their respective organizations, are authorized to determine the classification of a medical device in commercial distribution prior to May 28, 1976, under section 513(d) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(d)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH) and the Director and Deputy Directors, Office of Device Evaluation (ODE), CDRH.

(2) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Directors of the Office of Blood Research and Review (OBRR), the Office of Vaccines Research and Review (OVRR), and the Office of Therapeutics Research and Review (OTRR), CBER.

(b) The following officials, for devices assigned to their respective organizations, are authorized to determine the classification of a medical device first intended for commercial distribution after May 28, 1976, under section 513 (f)(1)(A) of the act (21 U.S.C. 360c(f)(1)(A)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH, and the Director, Deputy Directors, Division and Deputy Division Directors, Associate Division Directors, Branch Chiefs, and Chief, Premarket Notification Section, ODE, CDRH.

(2) The Director and Deputy Directors, CBER, and the Directors and Deputy

Directors of the OBRR, OVRR, and OTRR, CBER.

(c) The following officials are authorized to make determinations and issue orders classifying devices under section 513(f)(2)(b):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Directors, ODE, CDRH.

(3) The Director and Deputy Directors, CBER, and the Directors and Deputy Directors of the OBRR, OVRR, and OTRR, CBER.

(d) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH, and the Director and Deputy Directors, CBER, and the Directors and Deputy Directors of the OBRR, OVRR, and OTRR, CBER, are authorized to issue **Federal Register** notices under section 513(f)(2)(C) of the act (21 U.S.C. 360c(f)(2)(C)) announcing classification of devices under section 513(f)(2)(B) of the act (21 U.S.C. 360c(f)(2)(B)).

(e) These officials may not further redelegate those authorities.

§ 5.406 Notification to sponsors of deficiencies in petitions for reclassification of medical devices.

(a) The following officials, for medical devices assigned to their respective organizations, are authorized to notify sponsors of deficiencies in petitions for reclassification of medical devices submitted under sections 513(f) and 520(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f) and 360j(l)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Directors, Office of Device Evaluation, CDRH.

(2) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Directors and Deputy Directors of the Office of Blood Research and Review, Office of Vaccines Research and Review, and Office of Therapeutics Research and Review, CBER.

(b) These officials may not further redelegate this authority.

§ 5.407 Approval, disapproval, or withdrawal of approval of product development protocols and applications for premarket approval for medical devices.

(a) The following officials, for medical devices assigned to their respective organizations, are authorized to approve, disapprove, declare as complete or incomplete, or revoke product development protocols for medical devices submitted under section 515(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(f)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), the Director and Deputy Directors, Office of Device Evaluation (ODE), CDRH, and the Division Directors, ODE, CDRH.

(2) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Directors, Office of Blood Research and Review (OBRR), Office of Vaccines Research and Review (OVRR), and Office of Therapeutics Research and Review (OTRR), CBER.

(b)(1) The following officials, for medical devices assigned to their respective organizations, are authorized to approve, disapprove, or withdraw approval of applications for premarket approval for medical devices submitted under sections 515 and 520(l) of the act (21 U.S.C. 360e and 360j(l)):

(i) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH, the Director and Deputy Directors, ODE, CDRH, and the Division Directors, ODE, CDRH.

(ii) The Director and Deputy Directors, CBER, and the Directors and Deputy Directors, OBRR, OVRR, and OTRR, CBER.

(2) For medical devices assigned to their respective division, the Division Directors, Office of Device Evaluation, CDRH, are authorized to approve, disapprove, or withdraw approval of supplemental premarket applications.

(c) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH, for medical devices assigned to their organization, are authorized to issue notices to announce the approval, disapproval, or withdrawal of approval of a device, and to make publicly available a detailed summary of the information on which the decision was based, under sections 515(d), (e), and (g) and 520(h)(1) of the act (21 U.S.C. (d), (e), and (g) and 360j(h)(1)).

(d) These officials may not further redelegate these authorities.

§ 5.408 Determinations concerning the type of valid scientific evidence submitted in a premarket approval application.

(a) The following officials are authorized to make determinations under section 513(a)(3)(D) of the act (21 U.S.C. 360c(a)(3)(D)) concerning the type of valid scientific evidence to be submitted in a premarket approval application that will provide a reasonable assurance that a device is effective under the conditions of use proposed by such person:

(i) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(ii) The Director and Deputy Directors, Office of Device Evaluation (ODE), CDRH.

(iii) The Director, Program Operations Staff, ODE, CDRH.

(iv) For devices assigned to their respective Divisions: the Division Directors and Deputy Division Directors, ODE, CDRH.

(b) These officials may may not further redelegate this authority.

§ 5.409 Determinations that medical devices present unreasonable risk of substantial harm.

(a) The following officials, for medical devices assigned to their respective organizations, are authorized to determine that medical devices present an unreasonable risk of substantial harm to the public health, and to order adequate notification thereof, under section 518(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360h(a)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Compliance, CDRH.

(2) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Compliance and Biologics Quality, CBER.

(3) The Director, the Deputy Director, and the Directors, Office of Review Management and Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); and the Director and Deputy Director, Office of Compliance, CDER.

(b) These officials may not further redelegate this authority.

§ 5.410 Orders to repair or replace, or make refunds for, medical devices.

(a) The following officials, for medical devices assigned to their respective organizations, are authorized to order repair or replacement of, or refund for, medical devices under section 518(b) and (c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360h(b) and (c)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Compliance, CDRH.

(2) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Director and

Deputy Directors, Office of Compliance and Biologics Quality, CBER.

(3) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); and the Director and Deputy Director, Office of Compliance, CDER.

(b) These officials may not further redelegate this authority.

§ 5.411 Medical device recall authority.

(a) The following officials, for medical devices assigned to their respective organizations, are authorized to perform all of the recall functions under section 518(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360h(e)), which have been delegated to the Commissioner of Food and Drugs:

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Compliance, CDRH.

(3) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); and the Director and Deputy Director, Office of Compliance, CDER.

(4) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Directors, Office of Compliance and Biologics Quality, CBER.

(b) These officials may not further redelegate this authority.

§ 5.412 Temporary suspension of a medical device application.

(a) The following officials for medical devices assigned to their respective organizations are authorized under section 515(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(e)), to determine that there is reasonable probability that continuation of the distribution of a device under an approved application would cause serious adverse health consequences or death, and upon making such a determination, to issue an order to temporarily suspend the approval of an application:

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Compliance, CDRH.

(3) The Director and Deputy Directors, Office of Device Evaluation, CDRH.

(4) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER; the Director and Deputy Director, Office of Generic Drugs, Office of Pharmaceutical Science, CDER; and the Director and Deputy Director, Office of Compliance, CDER.

(5) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Directors, Office of Compliance and Biologics Quality, CBER.

(b) These officials may not further redelegate this authority.

§ 5.413 Approval, disapproval, or withdrawal of approval of applications and entering into agreements for investigational device exemptions.

(a) For medical devices assigned to their respective organizations, the following officials are authorized to approve, disapprove, or withdraw approval of applications for investigational device exemptions submitted under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), the Director and Deputy Directors, Office of Device Evaluation, CDRH, and the Director and Deputy Director, Office of Compliance, CDRH.

(2) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Directors and Deputy Directors, Office of Blood Research and Review (OBRR), Office of Vaccines Research and Review (OVRR), and Office of Therapeutics Research and Review (OTRR), CBER.

(b) For medical devices assigned to their respective divisions, the Division Directors, Office of Device Evaluation, CDRH, are authorized to approve, disapprove, or withdraw approval of applications for investigational device exemptions submitted under section 520(g) of the act (21 U.S.C. 360j(y)).

(c) The following officials are authorized to enter into written agreements concerning investigational device exemption protocols under section 520(g)(7) of the act (21 U.S.C. 360j(g)(7)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Directors, Office of Device Evaluation (ODE), CDRH.

(3) The Director, Program Operations Staff, ODE, CDRH.

(4) The Chief, Investigational Device Exemption Section, ODE, CDRH.

(5) For medical devices assigned to their respective Divisions: The Division Directors and Deputy Division Directors, ODE, CDRH.

(6) The Director and Deputy Directors, CBER, and the Director and Deputy Directors of the OBRR, OVRR, and OTRR, CBER.

(d) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH and the Director and Deputy Directors, ODE, CDRH, the Director and Deputy Directors, CBER, and the Director and Deputy Directors of the OBRR, OVRR, and OTRR, CBER, are authorized to make decisions under section 520(g)(7) of the act (21 U.S.C. 360j(g)(7)) with respect to an agreement on an investigational plan, that a substantial scientific issue essential to determining the safety and effectiveness of the device involved has been identified.

(e) These officials may not further redelegate these authorities.

§ 5.414 Postmarket surveillance.

(a) For any class II or class III device (including any device that is or contains a drug or biologic), the failure of which would be reasonably likely to have serious adverse health consequences, or which is intended to be implanted in the human body for more than 1 year, or a life supporting or life sustaining device used outside a user facility, any of the following officials is authorized to require a manufacturer of such device to conduct postmarket surveillance:

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Surveillance and Biometrics, CDRH.

(3) The Director and Deputy Director, Division of Postmarket Surveillance, Office of Surveillance and Biometrics (OSB), and the Director, Issues Management Staff, OSB, CDRH.

(4) The Director and Deputy Directors, Office of Device Evaluation, CDRH.

(5) The Director and Deputy Director, Office of Science and Technology, CDRH.

(6) The Director and Deputy Director, Office of Health and Industry Programs, CDRH.

(7) The Director and Deputy Director, Office of Compliance, CDRH.

(8) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(9) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(10) The Director and Deputy Director, Office of Compliance, CDER.

(11) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(12) The Director and Deputy Director, Office of Compliance and Biologics Quality, CBER.

(13) The Directors and Deputy Directors, Office of Blood Research and Review, Office of Vaccines Research and Review, and Office of Therapeutics Research and Review, CBER.

(b) These officials may not further redelegate these authorities.

§ 5.415 Authority relating to medical device reporting procedures.

(a) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), the Director and Deputy Director, Office of Surveillance and Biometrics (OSB), CDRH, and the Director and Deputy Director, Division of Surveillance Systems (DSS), OSB, CDRH, are authorized to approve electronic reporting under § 803.14 of this chapter.

(b) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH, the Director and Deputy Director, OSB, CDRH, and the Director and Deputy Director, DSS, OSB, CDRH are authorized to request the submission of additional information under § 803.15 of this chapter.

(c) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH, the Director and Deputy Director, OSB, CDRH, and the Director and Deputy Director, DSS, OSB, CDRH are authorized to grant or revoke exemptions and variances from reporting requirements under § 803.19 of this chapter.

(d) These officials may not further redelegate these authorities.

§ 5.416 Medical device tracking.

(a) The following officials are authorized to issue orders under section 519(e) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 360i(e)) requiring manufacturers to adopt methods of tracking devices:

(1) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Compliance, CDRH.

(b) These officials may not further redelegate this authority.

§ 5.417 Authority pertaining to accreditation functions for medical devices.

(a) The following officials are authorized under section 523(a)(1) and (b)(2)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360m(a)(1) and (b)(2)(A)) to respond to a request for accreditation and to accredit persons for the purpose of reviewing reports submitted under section 510(k) of the act (21 U.S.C. 360(k)) and making recommendations regarding the initial classification of devices:

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Health and Industry Programs (OHIP), CDRH.

(3) The Director and Deputy Director, Division of Small Manufacturers Assistance (DSMA), OHIP, CDRH.

(b) The following officials are authorized under section 523(a)(2)(B) and (C) of the act (21 U.S.C. 360m(a)(2)(B) and (C)) to make a determination with respect to the recommendation of an initial classification of a device; and to change the initial classification under section 513(f)(1) of the act (21 U.S.C. 360c(f)(1)) that is recommended by an accredited person to provide to such person, and the person who submitted the report under section 510(k) of the act (21 U.S.C. 360(k)) for the device, a statement explaining in detail the reasons for the change:

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Directors, Office of Device Evaluation (ODE), CDRH.

(3) The Division Directors and Deputy Division Directors, ODE, CDRH.

(c) The following officials are authorized under section 523(b)(2)(B) of the act (21 U.S.C. 360m(b)(2)(B)) to suspend or withdraw accreditation of any person accredited to review reports and to make recommendations under section 523 of the act (21 U.S.C. 360m):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DSMA, OHIP, CDRH.

(d) The following officials are authorized under section 523(b)(2)(C) of the act (21 U.S.C. 360m(b)(2)(c)) to implement the measures described in that section to ensure that persons accredited under section 523 of the act (21 U.S.C. 360m) will continue to meet the standards of accreditation:

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, Office of Compliance, CDRH.

(e) These officials may not further redelegate these authorities.

Subpart G—Animal Drugs; Redelegations of Authority

§ 5.500 Issuance of FEDERAL REGISTER documents pertaining to the determination of safe levels, notice of need for development of an analytical method, notice of availability of a developed analytical method, and prohibition of certain extralabel drug use.

The Director and Deputy Director, Center for Veterinary Medicine (CVM) are authorized to issue **Federal Register** documents pertaining to the determination of safe levels, notice of need for development of an analytical method, notice of availability of a developed analytical method, and prohibition of certain extralabel drug use related to implementation of section 512(a)(4) and (5) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360b(a)(4) and (5)). These officials may further redelegate this authority.

§ 5.501 Approval of new animal drug applications, medicated feed mill license applications and their supplements.

(a) The Director and Deputy Director, Center for Veterinary Medicine (CVM), are authorized to perform all the functions of the Commissioner of Food and Drugs (Commissioner) with regard to the approval of new animal drug applications, and supplements thereto, for new animal drugs submitted under section 512 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b).

(b) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of supplemental applications to approved new animal drugs submitted under section 512 of the act (21 U.S.C. 360b):

(1) The Director, the Deputy Director for Human Food Safety and Consultative Services, and the Deputy Director for Therapeutic and Production Drug Review, Office of New Animal Drug Evaluation, CVM.

(2) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(c) The following officials are authorized to perform all the functions of the Commissioner with regard to the approval of supplemental applications to new animal drug applications that are

described by section 514.8(a)(4)(iii), (iv), and (v), and (d)(3) of this chapter.

(1) The Director, Division of Manufacturing Technologies, Office of New Animal Drug Evaluation, CVM.

(2) The Director, Division of Epidemiology and Surveillance, Office of Surveillance and Compliance, CVM.

(d) The following officials are authorized to perform all the functions of the Commissioner with regard to the approval of medicated feed mill license applications for the manufacture of animal feeds containing new animal drugs under section 512(m) of the act (21 U.S.C. 360b(m), as amended by the Animal Drug Availability Act of 1996 (Public Law 104–250):

(1) The Director and Deputy Director, CVM.

(2) The Director, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(3) The Leader, Medicated Feeds Team, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(4) The Medicated Feeds Specialist, Medicated Feeds Team, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(e) These officials may not further redelegate these authorities.

§ 5.502 Issuance of notices, proposals, and orders relating to new animal drugs and medicated feed mill license applications.

(a) The Director and Deputy Director, Center for Veterinary Medicine (CVM), are authorized to:

(1) Issue notices of opportunity for a hearing on proposals to refuse approval or to withdraw approval of new animal drug applications, and supplements thereto, for drugs for animal use and proposals to refuse approval or to revoke approval of medicated feed mill license applications, and supplements thereto, submitted under section 512(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(m)), as amended by the Animal Drug Availability Act of 1996 (Public Law 104–250);

(2) Issue notices refusing or withdrawing approval when opportunity for hearing has been waived; and

(3) Issue proposals and orders to revoke and amend regulations for new animal drugs for drugs for animal use and medicated feed mill licenses, corresponding to said act on such applications.

(b) The Director and Deputy Director, CVM, are authorized to issue notices of availability of Public Master Files containing data acceptable for use in applications for new animal drugs for drugs for animal use and feeds bearing or containing new animal drugs.

(c) These officials may not further redelegate these authorities.

§ 5.503 Submission of and effective approval dates for abbreviated new animal drug applications and certain new animal drug applications.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs (Commissioner) with regard to decisions made under section 512(c)(2)(D)(iv) and (c)(2)(F) of the Federal, Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(D)(iv) and (c)(2)(F) concerning the date of submission and the date of effective approval of abbreviated new animal drug applications including supplements thereto, submitted under section 512(b)(2) of the act (21 U.S.C. 360b(b)(2)), and of new animal drug applications including supplements thereto, submitted under section 512(b)(1) of the act (21 U.S.C. 360b(b)(1)):

(1) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(2) The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM.

(b) These officials may not further redelegate this authority.

§ 5.504 Issuance of written notices concerning patent information, current good manufacturing practices and false or misleading labeling of new animal drugs and feeds bearing or containing new animal drugs.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs (Commissioner) under sections 512(e) and 512 (m)(4)(B)(ii) and (m)(4)(B)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(e), (m)(4)(B)(ii), and (m)(4)(B)(iii)) regarding the issuance of written notices:

(1) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(2) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(3) The Director, Division of Compliance, Office of Surveillance and Compliance, CVM.

(4) Regional Food and Drug Directors.

(5) District Directors.

(b) These officials may not further redelegate this authority.

§ 5.505 Termination of exemptions for new drugs for investigational use in animals.

(a) The following officials are authorized to perform all functions of the Commissioner of Food and Drugs with regard to the termination of new animal drugs for investigational use in animals under § 511.1 of this chapter:

(1) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(2) The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM.

(b) These officials may not further redelegate this authority.

Subpart H—Radiation Control; Redelegations of Authority

§ 5.600 Variances from performance standards for electronic products.

(a) The following officials are authorized to grant and withdraw variances and issue notices of availability of any approved variance or any amendment or extension thereof, from the provisions of performance standards for electronic products established in subchapter J of this chapter:

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Compliance, CDRH.

(b) These officials may not further redelegate this authority.

§ 5.601 Exemption of electronic products from performance standards and prohibited acts.

(a) The following officials are authorized to exempt from performance standards any electronic product intended for use by departments or agencies of the United States under section 534 (a)(5) of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 360kk(a)(5)) and to exempt an electronic product or class of products from all or part of the provisions of section 538(a) of the act (21 U.S.C. 360oo(a)) under section 538(b) of the act (21 U.S.C. 360oo(b)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Compliance, CDRH.

(b) These officials may not further redelegate this authority.

§ 5.602 Testing programs and methods of certification and identification for electronic products.

(a) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Compliance, CDRH, are authorized to review and evaluate industry testing programs under section 534(g) of the Federal Food, Drug and Cosmetic Act the act (21 U.S.C. 360kk(g)) and to approve or disapprove alternate

methods of certification and identification and to disapprove testing programs upon which certification is based under section 534(h) of the act (21 U.S.C. 360kk(h)).

(b) These officials may not further redelegate this authority.

§ 5.603 Notification of defects in, and repair or replacement of, electronic products.

(a) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Compliance, CDRH, are authorized to perform all functions of the Commissioner of Food and Drugs (Commissioner), relating to notification of defects in, noncompliance of, and repair or replacement of or refund for, electronic products under section 534 of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 360kk) and under §§ 1003.11, 1003.22, 1003.31, 1004.2, 1004.3, 1004.4, and 1004.6 of this chapter; and Regional Food and Drug Directors, District Directors, and the Director, St. Louis Branch, are authorized to perform all such functions relating to:

(1) Assemblers of diagnostic x-ray systems, as defined in § 1020.30(b) of this chapter.

(2) Manufacturers of sunlamp products and ultraviolet lamps intended for use in any sunlamp product, as defined in § 1040.20(b) of this chapter.

(b) The Director and Deputy Director, Office of Compliance, CDRH, and the Division Directors, Office of Compliance, CDRH, are authorized to notify manufacturers of defects in, and noncompliance of, electronic products under section 535(e) of the act (21 U.S.C. 360ll(e)) and under § 1003.11(a) of this chapter; and the chiefs of District Compliance Branches are authorized to perform all such functions relating to:

(1) Assemblers of diagnostic x-ray systems, as defined in § 1020.30(b) of this chapter.

(2) Manufacturers of sunlamp products and ultraviolet lamps intended for use in any sunlamp products, as defined in § 1040.20(b) of this chapter.

(c) These officials may not further redelegate these authorities.

§ 5.604 Manufacturers requirement to provide data to ultimate purchasers of electronic products.

(a) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health, are authorized to require manufacturers to provide performance and technical data to the ultimate purchaser of electronic products under section 537(c) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360nn(c)).

(b) These officials may not further redelegate these authorities.

§ 5.605 Dealer and distributor direction to provide data to manufacturers of electronic products.

(a) The Director and Deputy Director for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), the Director and Deputy Director, Office of Compliance, CDRH, and the Division Directors, Office of Compliance, CDRH, are authorized to direct dealers and distributors of electronic products to furnish information on first purchasers of such products to the manufacturer of the product under section 537(f) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360nn(f)).

(b) These officials may not further redelegate these authorities.

§ 5.606 Acceptance of assistance from State and Local authorities for enforcement of radiation control legislation and regulations.

(a) The Director and Deputy Directors, Center for Devices and Radiological Health, are authorized to accept assistance from State and Local authorities engaged in activities related to health or safety or consumer protection on a reimbursable basis or otherwise, under section 541 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360rr).

(b) These officials may not further redelegate these authorities.

Subpart I—Product Designation; Redelegations of Authority

§ 5.700 Authority relating to determination of product primary jurisdiction.

The Chief Mediator and Ombudsman, Office of the Ombudsman, Office of the Senior Associate Commissioner, Office of the Commissioner, as product jurisdiction officer is authorized to make a determination under section 563 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360bbb–2) respecting the classification of a product as a drug, biological product, device, or a combination product subject to section 503(g) of the act (21 U.S.C. 353(g)), and to assign primary responsibility respecting the organizational component of the Food and Drug Administration that will regulate the product. This official may not further redelegate this authority.

§ 5.701 Premarket approval of a product that is or contains a biologic, a device, or a drug.

(a) For a product that is or contains a biologic, a device, or a drug, the following officials in the Center for Biologics Evaluation and Research, Center for Devices and Radiological Health, or Center for Drug Evaluation and Research who currently hold delegated premarket approval authority for biologics, devices, or drugs, respectively, are hereby delegated all the authorities necessary for premarket approval of any product that is a biologic, a device, or a drug, or any combination of two or more of these products:

(1) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER) and the Directors of the Office of Blood Research and Review, Office of Vaccines Research and Review, Office of Therapeutics Research and Review, and Office of Compliance and Biologics Quality, CBER.

(2) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), and the Director, Office of Device Evaluation, CDRH.

(3) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); and the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(b) These officials may not further redelegate this authority.

Subpart J—Imports and Exports; Redelegations of Authority

§ 5.800 Imports and exports.

(a) The Regional Food and Drug Directors, District Directors, and the Director, St. Louis Branch, are authorized, under section 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381), to perform the following functions or to designate officials to:

(1) Request from the Secretary of the Treasury samples of food, drugs (including biological products), devices, or cosmetics imported or offered for import.

(2) Determine whether such articles are in compliance with the act.

(3) Authorize relabeling or other compliance actions to bring articles into compliance under the Act.

(4) Supervise such compliance actions.

(b) The Director and Deputy Directors for Science and for Regulations and

Policy, Center for Devices and Radiological Health (CDRH); the Director and Deputy Director, Office of Compliance, CDRH; Regional Food and Drug Directors; District Directors; and the Director, St. Louis Branch, are authorized, under section 536 of the act (21 U.S.C. 360mm), to perform the following functions or to designate officials to:

(1) Request from the Secretary of the Treasury samples of electronic products imported or offered for import to determine whether such products are in compliance with section 534 of the act (21 U.S.C. 360kk).

(2) Refuse admission of noncomplying products and notify the Secretary of the Treasury of such refusal.

(3) Supervise operations to bring noncomplying products into compliance under section 534 of the act (21 U.S.C. 360kk).

(4) Refuse or grant permission and time extensions to bring noncomplying products into compliance with section 534 of the act (21 U.S.C. 360kk) in accordance with a corrective action plan approved by the Directors, Offices of Compliance Surveillance and Biometrics, CDRH.

(c) The following officials are authorized, under section 538(b) of the act (21 U.S.C. 360oo(b)), to exempt persons from issuing a certification, as required by section 534(h) of the act (21 U.S.C. 360kk(h)) for electronic products imported into the United States for testing, evaluation, demonstrations, or training, which will not be introduced into commerce and upon completion of their function will be destroyed or exported in accord with U.S. Customs Service's regulations:

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, Office of Compliance, CDRH.

(3) Regional Food and Drug Directors.

(4) District Directors.

(5) The Director, St. Louis Branch.

(d) The Regional Food and Drug Directors, District Directors, and the Director, St. Louis Branch, are authorized to exercise all of the functions of the Commissioner of Food and Drugs (Commissioner) under section 362 of the Public Health Service Act (42 U.S.C. 265) that relate to the prohibition of the introduction of foods, drugs, devices, cosmetics, and electronic products, and other items or products regulated by the Food and Drug Administration into the United States when it is determined that it is required in the interest of public health, and such functions relate to the law enforcement functions of the Food and Drug Administration.

(e) The following officials are authorized to perform all the functions of the Commissioner pertaining to exportation of medical devices under section 801(e) of the act (21 U.S.C. 381(e)):

(1) For medical devices assigned to their respective organization:

(i) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(ii) The Director and Deputy Director, Office of Compliance, CDRH.

(iii) The Director and Deputy Director, Division of Program Operations, Office of Compliance, CDRH.

(iv) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(v) The Director and Deputy Directors, Office of Compliance and Biologics Quality, CBER.

(2) Regional Food and Drug Directors.

(3) District Directors.

(4) The Director, St. Louis Branch.

(f) The following officials are authorized to perform the functions of the Commissioner for drugs under their jurisdiction, pertaining to authorizing the reimportation of prescription drugs under section 801(d)(2) of the act (21 U.S.C. 381(d)(2)) for emergency medical care:

(1) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER) and the Director, Office of Compliance and Biologics Quality, CBER.

(2) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER) and the Director and Deputy Director, Office of Compliance, CDER.

(g) These officials may not further redelegate these authorities.

§ 5.801 Export of unapproved drugs.

(a) The following officials are authorized, under section 802(b)(2) and (b)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382(b)(2) and (b)(3)), to grant or deny petitions to export unapproved new drugs and biological products and to issue notices of receipt of such petitions for human drugs assigned to their respective organizations:

(1) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(2) The Director and Deputy Directors, Office of Compliance and Biologics Quality, CBER.

(3) The Director, the Deputy Director, and the Directors, Office Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(4) The Director and Deputy Director, Office of Compliance, CDER.

(b) The following officials are authorized, under section 802(e) of the act (21 U.S.C. 382(e)), to approve or disapprove an application to export a drug (including a biological product) to be used in the prevention or treatment of a tropical disease or another disease as described in section 802(e) for human drugs assigned to their respective organizations:

(1) The Director and Deputy Directors, CBER.

(2) The Director and Deputy Directors, Office of Compliance and Biologics Quality, CBER.

(3) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, CDER.

(4) The Director and Deputy Director, Office of Compliance, CDER.

(c) The following officials are authorized, under section 351(h) of the Public Health Service Act (42 U.S.C. 262(h)), to approve or disapprove an application to export a partially processed biological product:

(1) The Director and Deputy Directors, CBER.

(2) The Director and Deputy Directors, Office of Compliance and Biologics Quality, CBER.

(d) These officials may not further redelegate these authorities.

§ 5.802 Manufacturer's resident import agents.

The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH) and the Director and Deputy Director, Office of Compliance, CDRH, are authorized to reject manufacturer's designation of import agents under § 1005.25(b) of this chapter. These officials may not further redelegate this authority.

Subpart K—Orphan Products; Redelegations of Authority

§ 5.900 Orphan products.

(a) The Director, Office of Orphan Products Development (OPD), Office of the Senior Associate Commissioner (OSAC), Office of the Commissioner (OC), is authorized to issue notices, and amendments thereto, inviting sponsorship for orphan products (human and animal drugs, biological products, and medical devices) and submission of:

(1) Notices of claimed investigational exemption for a new drug or new drug applications;

(2) Notices of claimed investigational exemption for a new animal drug or new animal drug applications;

(3) Applications for biologics licenses for biological products; or

(4) Applications for an investigational device exemption or premarket approval applications for medical devices, as appropriate.

(b) The Director, OPD, OSAC, OC, is authorized:

(1) To determine whether there is reason to believe that a drug is a drug for a disease or condition that is rare in the United States under section 525(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360aa(a)) and to designate such drug as a drug for a rare disease or condition under section 526(a) of the act (21 U.S.C. 360bb(a)).

(2) To issue holders of approved applications or licenses notice and opportunity for the submission of views under section 527(b)(1) of the act (921 U.S.C. 360cc(b)(1)).

(3) To encourage sponsors of an investigational new drug for a rare disease or condition to design protocols for clinical investigations to permit the addition to the investigation of persons with the disease or condition under section 528 of the act (21 U.S.C. 360dd).

(c) The following officials are authorized to provide sponsors, under section 525(a) of the act (21 U.S.C. 360aa(a)), with recommendations for nonclinical or clinical investigations believed to be necessary for a drug for a rare disease or condition to be approved or licensed:

(1) For drugs under their jurisdiction:

(i) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(ii) The Directors and Deputy Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(iii) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(2) For biological products under their jurisdiction:

(i) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(ii) The Directors and Deputy Directors, Office of Blood Research and Review (OBRR), Office of Vaccines Research and Review (OVRR), Office of Therapeutics Research and Review (OTRR), CBER.

(iii) The Directors and Deputy Directors of the Divisions in OBRR, OVRR, and OTRR, CBER.

(d) These officials may not further redelegate these authorities.

Subpart L—Mammography Facilities; Redelegations of Authority

§ 5.1000 Authority to ensure that mammography facilities meet quality standards.

(a) The following officials are authorized to ensure mammography facilities obtain certificates under section 354(b) of the Public Health Service Act (the PHS Act) (42 U.S.C. 263b(b)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Health and Industry Programs (OHIP), CDRH.

(3) The Director and Deputy Director, Division of Mammography Quality and Radiation Programs (DMQRP), OHIP, CDRH.

(b) The following officials are authorized to issue, renew and extend certificates to mammography facilities under section 354(c) of the PHS Act (42 U.S.C. 263b(c)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(c) The following officials are authorized to accept an application for a certificate under section 354(d)(1) of the PHS Act (42 U.S.C. 263b(d)(1)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(d) The following officials are authorized to approve accreditation bodies to accredit mammography facilities under section 354(e)(1)(A) of the PHS Act (42 U.S.C. 263b(e)(1)(A)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(e) The following officials are authorized to ensure accreditation bodies provide satisfactory assurances of compliance under section 354(e)(1)(C) of the PHS Act (42 U.S.C. 263b(e)(1)(c)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(f) The Director, CDRH is authorized to issue regulations under which the Director may withdraw approval of accreditation bodies under section 354(e)(2)(A) of the PHS Act (42 U.S.C. 263b(e)(2)(A)).

(g) The following officials are authorized to determine the expiration date of a certificate of a facility accredited by an accreditation body after the body's approval is withdrawn, or a State's certification authority has been withdrawn, or a facility's accreditation has been revoked by an accreditation body under sections 354(e)(2)(B) and 354(e)(5) of the PHS Act (42 U.S.C. 263b(e)(2)(B) and (e)(5)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(h) The following officials are authorized to determine the applicable standards for a facility for accreditation under section 354(e)(3) of the PHS Act (42 U.S.C. 263b(e)(3)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(i) The following officials are authorized to ensure accreditation bodies make on site visits and to determine whether other measures are appropriate under section 354(e)(4) of the PHS Act (42 U.S.C. 263b(e)(4)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(j) The following officials are authorized to evaluate annually the performance of each approved accreditation body as provided by section 354(e)(6)(A) of the PHS Act (41 U.S.C. 263b(e)(6)(A)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(k) The following officials are authorized to determine the compliance of certified facilities with established standards through annual facility inspections as provided by section 354(g) of the PHS Act (42 U.S.C. 263b(g)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(l) The following officials are authorized to promote voluntary compliance with established standards instead of taking actions under section 354(i) of the PHS Act (42 U.S.C. 263b(i)) by imposing directed plans of correction and/or payment of the cost of onsite monitoring under section 354(h)(1) of the PHS Act (42 U.S.C. 263b(h)(l)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(m) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH are authorized to impose sanctions under section 354(h)(2) of the PHS Act (42 U.S.C. 263b(h)(2)).

(n) The following officials are authorized to develop and implement the procedures for determining when and how to impose sanctions as provided by section 354(h)(3) of the PHS Act (42 U.S.C. 263b(h)(3)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(o) The following officials are authorized to suspend or revoke individual facility certificates under section 354(i)(1) and (i)(2) of the PHS Act (42 U.S.C. 263b(i)(1) and (i)(2)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(p) The following officials are authorized under section 354(i)(3) of the PHS Act (42 U.S.C. 263b(i)(3)) to ensure that no person who owned or operated a facility at the time the cause of revocation occurred may, within 2 years of the revocation of the certificate, own or operate a mammography facility:

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(q) The following officials are authorized to compile and make available to physicians and the general public information determined to be useful in evaluating the performance of mammography facilities as provided by section 354(l) of the PHS Act (42 U.S.C. 263b(l):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(r) The following officials are authorized to ensure that appropriate Federal agencies are consulted in the development of standards, regulations, evaluations, procedures for compliance and oversight as provided by section 354(o) of the PHS Act (42 U.S.C. 263b(o)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(s) The following officials may authorize a State to carry out certification program requirements and implement quality standards under sections 354(q)(1) and (q)(2) of the PHS Act (42 U.S.C. 263b(g)(1) and (g)(2)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(t) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH are authorized, after providing notice and opportunity for corrective action, to withdraw the approval of a State's authority to carry out certification requirements and implement quality standards under section 354(q)(4) of the PHS Act (42 U.S.C. 263b(g)(4)).

(u) These officials may not further redelegate these authorities.

Subpart M—Organization

§ 5.1100 Headquarters.

The central organization of the Food and Drug Administration consists of the following:

Office of the Commissioner.[1]

Office of the Chief Counsel.

Office of Equal Opportunity.

Office of the Administrative Law Judge.

Office of the Senior Associate Commissioner.

Office of Executive Secretariat.

Office of Public Affairs.

Office of the Ombudsman.

Office of Orphan Products Development.

Office of Internal Affairs.

Office of Executive Operations.

Office of Science Coordination and Communication.

Office of Human Research Trials.

Office of International and Constituent Relations.

Office of International Programs.

Office of Consumer Affairs.

Office of Women's Health.

Office of Special Health Issues.

Office of Policy, Planning, and Legislation.

Office of Policy.

Office of Planning.

Office of Legislation.

Office of Management and Systems.

Office of Human Resources and Management Services.

Office of Information Resources Management.

Office of Financial Management.

Office of Facilities, Acquisitions, and Central Services.[2]

Center for Biologics Evaluation and Research.[3]

Office of the Center Director.

Scientific Advisors and Consultants Staff.

Equal Employment Opportunity and Workforce Diversity Staff.

Quality Assurance Staff.

Regulations and Policy Staff.

Veterinary Services Staff.

Office of Management.

Regulatory Information Management Staff.

Division of Planning, Evaluation, and Budget.

Division of Management Services.

Office of Information Technology Management.

Division of Information Technology Operations.

Division of Information Technology Development.

Division of Information Technology Infrastructure.

Office of Compliance and Biologics Quality.

Division of Case Management.

Division of Manufacturing and Product Quality.

Division of Inspections and Surveillance.

Office of Blood Research and Review.

Human Tissue Staff.

[1] Mailing address: 5600 Fishers Lane, Rockville, MD 20857.

[2] Mailing address: 5630 Fishers Lane, Rockville, MD 20857.

[3] Mailing address: 1401 Rockville Pike, Rockville, MD 20852–1448.

Policy and Publications Staff.
Division of Emerging and Transfusion Transmitted Diseases.
Division of Hematology.
Division of Blood Applications.
Office of Therapeutics Research and Review.
Division of Cellular and Gene Therapies.
Division of Therapeutic Proteins.
Division of Monoclonal Antibodies.
Division of Clinical Trial Design and Analysis.
Division of Application Review and Policy.
Office of Vaccines Research and Review.
Division of Bacterial, Parasitic, and Allergenic Products.
Division of Viral Products.
Division of Vaccines and Related Products Applications.
Office of Communication, Training, and Manufacturers Assistance.
Division of Disclosure and Oversight Management.
Division of Manufacturers Assistance and Training.
Division of Communication and Consumer Affairs.
Office of Biostatistics and Epidemiology.
Division of Biostatistics.
Division of Epidemiology.

Center for Food Safety and Applied Nutrition.[4]

Office of the Center Director.
Food Safety Initiatives Staff.
Office of Science
Quality Assurance Staff.
CFSAN Staff College.
Microbial Research and Risk Assessment Staff.
JIFSAN Liaison Staff.
CFSAN Food Advisory Committee Staff.
Office of Applied Research and Safety Assessment.
Muirkirk Technical Operations Staff.
Division of Molecular Biology.
Division of Virulence Assessment.
Division of Toxicology and Nutritional Product Studies.
Division of In Vitro and Biochemical Toxicology.
Office of Regulations and Policy.
Regulations Coordination Staff.
Office of Constituent Operations.
Consumer Education Staff.
Industry Activities Staff.
International Activities Staff.
Office of Management Systems.
Safety Management Systems.
Division of Information Resources Management.
Division of Planning and Financial Resources Management.
Division of Management Operations.
Division of Administrative Services Management.
Office of Operations.
Equal Employment Opportunity Staff.
Executive Operations Staff.
Office of Cosmetics and Colors.
Division of Programs and Enforcement Policy.
Division of Science and Applied Technology.
Office of Nutritional Products, Labeling and Dietary Supplements.
Division of Compliance and Enforcement.
Division of Standards and Labeling Regulations.
Division of Nutrition Science Policy.
Office of Premarket Approval.
Division of Product Policy.
Division of Petition Control.
Division of Health Effects Evaluation.
Division of Product Manufacture and Use.
Office of Plant and Dairy Foods and Beverages.
Division of Pesticides and Industrial Chemicals.
Division of Natural Products.
Division of Food Processing and Packaging.
Division of Plant Product Safety.
Division of Dairy and Egg Safety.
Division of Risk Assessment.
Division of Microbiological Studies.
Office of Seafood.
Division of Special Programs.
Division of Programs and Enforcement Policy.
Division of Science and Applied Technology.
Office of Field Programs.
Division of Enforcement and Programs.
Division of HACCP Programs.
Division of Cooperative Programs.
Office of Scientific Analysis and Support.
Division of General Scientific Support.
Division of Mathematics.
Division of Market Studies.

Center for Drug Evaluation and Research.[1]

Office of the Center Director.
Equal Employment Opportunity Staff.
Executive Operations Staff.
Office of Regulatory Policy.
Division of Regulatory Policy I.
Division of Regulatory Policy II.
Division of Information Disclosure Policy.
Office of Management.[1]
Strategic Planning Staff.[1]
Division of Management and Budget.[5]
Division of Management Services.[1]
Office of Training and Communication.[1]
Medwatch Staff.
Division of Library and Information Services.
Division of Training and Development.
Division of Public Affairs.
Division of Drug Information.
Office of Compliance.[6]
Division of Manufacturing and Product Quality.
Division of Prescription Drug Compliance and Surveillance.
Division of Labeling and Non-Prescription Drug Compliance.
Office of Information Technology.[1]
Quality Assurance Staff.
Technology Support Services Staff.
Division of Data Management and Services.
Division of Applications Development and Services.
Division of Infrastructure Management and Services.
Office of Medical Policy.[1]
Division of Drug Marketing, Advertising and Communication.[1]
Division of Scientific Investigations.[5]
Office of Review Management.[1]
Advisors and Consultants Staff.[2]
Office of Drug Evaluation I.[1]
Division of Cardio-Renal Drug Products.
Division of Neuropharmacological Drug Products.
Division of Oncology Drug Products.
Office of Drug Evaluation II.[1]
Division of Metabolic and Endocrine Drug Products.
Division of Pulmonary and Allergy Drug Products.
Division of Anesthetic, Critical Care and Addiction Drug Products.
Office of Drug Evaluation III.[1]
Division of Gastrointestinal and Coagulation Drug Products.
Division of Medical Imaging and Radiopharmaceutical Drug Products.

[4] Mailing address: 200 C St. SW., Washington, DC 20204.

[5] Mailing address: 7500 Standish Pl., Rockville, MD 20855.

[6] Mailing address: 7520 Standish Pl., Rockville, MD 20855.

Division of Reproductive and Urologic Drug Products.
Office of Drug Evaluation IV.[1]
Division of Anti-Infective Drug Products.
Division of Anti-Viral Drug Products.
Division of Special Pathogen and Immunologic Drug Products.
Office of Drug Evaluation V.[1]
Division of Anti-Inflammatory, Analgesic and Opthalmologic Drug Products.
Division of Dermatologic and Dental Drug Products.
Division of Over-The-Counter Drug Products.
Office of Biostatistics.[1]
Quantitative Methods Research Staff.
Division of Biometrics I.
Division of Biometrics II.
Division of Biometrics III.
Office of Post-Marketing Drug Risk Assessment.[1]
Extramural Programs Staff.
Information Technology Staff.
Division of Drug Risk Evaluation I.
Division of Drug Risk Evaluation II.
Office of Pharmaceutical Science.[1]
Quality Implementation Staff.[1]
Operations Staff.[1]
Office of Clinical Pharmacology and Biopharmaceutics.
Pharmacometrics Staff.
Division of Pharmaceutical Evaluation I.[1]
Division of Pharmaceutical Evaluation II.[1]
Division of Pharmaceutical Evaluation III.[1]
Office of Generic Drugs.[6]
Division of Bioequivalence.
Division of Chemistry I.
Division of Chemistry II.
Division of Labeling and Program Support.
Office of New Drug Chemistry.[1]
Division of New Drug Chemistry I.[1]
Division of New Drug Chemistry II.[1]
Division of New Drug Chemistry III.[1]
Office of Testing and Research.[1]
Informatics and Computational Safety Analysis Staff.
Laboratory of Clinical Pharmacology.[1]
Division of Applied Pharmacology Research.[7]
Division of Pharmaceutical Analysis.[8]
Division of Product Quality Research.[1]

Office of Regulatory Affairs.[1]
Equal Employment Opportunity Staff.
Office of Resource Management.
Strategic Initiatives Staff.
Division of Planning, Evaluation, and Management.
Division of Information Systems.
Division of Human Resource Development.
Division of Management Operations.
Division of Personnel Operations.
Office of Enforcement.
Division of Compliance Management and Operations.
Division of Compliance Policy.
Division of Compliance Information and Quality Assurance.
Office of Regional Operations.
Division of Federal-State Relations.
Division of Field Science.
Division of Emergency and Investigational Operations.
Division of Import Operations and Policy.
Office of Criminal Investigations.
Mid-Atlantic Area Office.[9]
Midwest Area Office. [10]
Northeast Area Office.[11]
Pacific Area Office.[12]
Southeast Area Office.[13]
Southwest Area Office.[14]

Center for Veterinary Medicine.[15]
Office of the Center Director.
Office of Management and Communications.
Administrative Staff.
Communications Staff.
Information Resources Management Staff.
Office of New Animal Drug Evaluation.
Division of Therapeutic Drugs for Food Animals.
Division of Biometics and Production Drugs
Division of Therapeutic Drugs for Nonfood Animals.
Division of Manufacturing Technologies.
Division of Human Food Safety.
Office of Surveillance and Compliance.
Division of Surveillance.
Division of Animal Feeds.
Division of Compliance.
Division of Epidemiology.
Office of Research.
Administrative Staff.
Division of Residue Chemistry.
Division of Animal Research.
Division of Animal and Food Microbiology.

Center for Devices and Radiological Health.[16]
Office of the Center Director.
Equal Employment Opportunity Staff.
Office of Systems and Management.
Integrity Committee and Conference Management Staff.
Division of Management Operations.
Division of Information Dissemination.
Division of Information Technology Management.
Division of Planning, Analysis and Finance.
Office of Compliance.
Promotion and Advertising Policy Staff.
Division of Bioresearch Monitoring.
Division of Program Operations.
Division of Enforcement I.
Division of Enforcement II.
Division of Enforcement III.
Office of Device Evaluation.
Program Management Staff.
Program Operations Staff.
Division of Cardiovascular and Respiratory Devices.
Division of Reproductive, Abdominal and Radiological Devices.
Division of General, Restorative and Neurological Devices.
Division of Clinical Laboratory Devices.
Division of Ophthalmic, Ear, Nose, and Throat Devices.
Division of Dental, Infection Control, and General Hospital Devices.
Office of Science and Technology.
Division of Mechanics and Materials Science.
Division of Life Sciences.
Division of Physical Sciences.
Division of Electronics and Computer Sciences.
Division of Management Information and Support Services.
Office of Health and Industry Programs.
Program Operations Staff.

[7] Mailing address: 8301 Muirkirk Rd., Laurel, MD 20708.
[8] Mailing address: 1114 Market St., St. Louis, MO 63101.
[9] Mailing address: 900 U.S. Customhouse, Second Chestnut St., Philadelphia, PA 19106.
[10] Mailing address: 901 Warrenville Rd., suite 360, Lisle, IL 60532.
[11] Mailing address: 158–15 Liberty Ave., Jamaica, NY 11433.
[12] Mailing address: 13301 Clay St., Oakland CA 94512.
[13] Mailing address: 60 Eighth St. NE, Atlanta, GA 30309.
[14] Mailing address: 7920 Elmbrook Rd., Dallas, TX 75247.
[15] Mailing address: 7500 Standish Pl., MPN–2, Rockville, MD 20855.
[16] Mailing address: 9200 Corporate Blvd., Rockville, MD 20850.

Regulations Staff.
Staff College.
Division of Device User Programs and Systems Analysis.
Division of Small Manufacturers Assistance.
Division of Mammography Quality and Radiation Programs.
Division of Communication Media.
Office of Surveillance and Biometrics.
Issues Management Staff.
Division of Biostatistics.
Division of Postmarket Surveillance.
Division of Surveillance Systems.

National Center for Toxicological Research.[17]

Office of the Center Director.
Environmental Health and Program Assurance Staff.
Office of Research.
Technology Advancement Staff.
Division of Biochemical Toxicology.
Division of Genetic and Reproductive Toxicology.
Division of Biometry and Risk Assessment.
Division of Microbiology.
Division of Chemistry.
Division of Neurotoxicology.
Division of Veterinary Services.
Division of Molecular Epidemiology.
Office of Management.
Office of Management Services.
Division of Facilities, Engineering and Maintenance.
Division of Administrative Services.
Division of Contracts and Acquisitions.
Office of Planning, Finance and Information Technology.
Division of Planning.
Division of Financial Management.
Division of Information Technology.

§ 5.1105 Chief Counsel, Food and Drug Administration.

The Office of the Chief Counsel's mailing address is 5600 Fishers Lane, rm. 6–57, Rockville, MD 20857.

§ 5.1110 Food and Drug Administration Public Information Offices.

(a) *Dockets Management Branch (HFA–305).* The Dockets Management Branch Public Room is located in rm. 1061, 5630 Fishers Lane, Rockville, MD 20852. Telephone: 301–827–6860.

(b) *Freedom of Information Staff (HFI–35).* The Freedom of Information Public Room is located in rm. 12A–30, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301–827–6567.

(c) *Press Relations Staff (HFI–40).* Press Offices are located in rm. 15–05, Parklawn Bldg, 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301–827–6242; and in rm. 3807, FB–8, 200 C St. SW., Washington, DC 20204. Telephone 202–205–4144.

§ 5.1115 Field structure.

NORTHEAST REGION

Regional Field Office: 158–15 Liberty Ave., Jamaica, NY 11433.

Northeast Regional Laboratory: 158–15 Liberty Ave., Jamaica, NY 11433.

New York District Office: 158–15 Liberty Ave., Jamaica, NY 11433.

New England District Office: One Montvale Ave., Stoneham, MA 02180.

Winchester Engineering and Analytical Center: 109 Holton St., Winchester, MA 01890

CENTRAL REGION

Regional Field Office: U.S. Customhouse, Second and Chestnut Sts., rm. 900, Philadelphia, PA 19106.

Philadelphia District Office: U.S. Customhouse, Second and Chestnut Sts., rm. 900, Philadelphia, PA 19106.

Baltimore District Office: 900 Madison Ave., Baltimore, MD 21201–2199.

Cincinnati District Office: 6751 Steger Dr., Cincinnati, OH 45237–3097.

Forensic Chemistry Center: 6751 Steger Dr., Cincinnati, OH 45237–3097.

New Jersey District Office: Waterview Corporate Center, 10 Waterview Blvd., 3d Floor, Parsippany, NJ 07054.

Chicago District Office: 300 South Riverside Plaza, suite 550, South Chicago, IL 60606.

Detroit District Office: 1560 East Jefferson Ave., Detroit, MI 48207–3179.

Minneapolis District Office: 240 Hennepin Ave., Minneapolis, MN 55401–1912.

SOUTHEAST REGION

Regional Field Office: 60 Eighth St. NE., Atlanta, GA 30309.

Southeast Regional Laboratory: 60 Eighth St. NE., Atlanta, GA 30309.

Atlanta District Office: 60 Eighth St. NE., Atlanta, GA 30309.

New Orleans District Office: Textron Bldg., 6600 Plaza Dr., suite 400, New Orleans, LA 70127.

Nashville Branch of NOL-DO: 297 Plus Park Blvd., Nashville, TN 37217.

Florida District Office: 555 Winderley, suite 200, Maitland, FL 32751.

San Juan District Office: 466 Fernandez Juncos Ave., San Juan, PR 00901–3223.

SOUTHWEST REGION

Regional Field Office: 7920 Elmwood Rd., suite 102, Dallas, TX 75247–4982.

Dallas District Office: 3310 Live Oak St., Dallas, TX 75204.

Denver District Office: Bldg. 20, Denver Federal Center, Sixth and Kipling Sts., P.O. Box 25087, Denver, CO 80225–0087.

Kansas City District Office: 11630 West 80th St., Lenexa, KS 66214–3338.

St. Louis Branch: 12 Sunnen Dr., suite 122, St. Louis, MO 63143–3800.

Arkansas Regional Laboratory: 3900 NCTR Rd., Bldg. 14–T, rm. 104, Jefferson, AR 72079–9502.

PACIFIC REGION

Regional Field Office: 1301 Clay St., suite 1180–N, Oakland, CA 94612–5217.

San Francisco District Office: 1431 Harbor Bay Pkwy., Alameda, CA 94502–7070.

Los Angeles District Office: 19900 Mac Arthur Blvd., suite 300, Irvine, CA 92715.

Seattle District Office: P.O. Box 3012, Bothell, WA 98021–3012.

Pacific Regional Laboratory, SW: 1521 West Pico Blvd., Los Angeles, CA 90015–2488.

Pacific Regional Laboratory, NW: 22201 23rd Dr. SE., Bothell, WA 98021–4421.

Dated: May 30, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

Note: This appendix will not appear in the Code of Federal Regulations.

[17] Mailing address: 3900 NCTR Dr., Jefferson, AR 72079.

APPENDIX A—PART 5; CORRESPONDING FORMER AND NEW SUBPARTS, SECTION NUMBERS, AND SUBJECTS

Former CFR Subpart, Section No., and Subject	New CFR Subpart, Section No., and Subject
Subpart A, § 5.10–Delegations from the Secretary, the Assistant Secretary for Health, and Public Health Service Officials.	Subpart A, § 5.10–Delegations from the Secretary for Health and Human Services to the Commissioner of Food and Drugs
Subpart A, § 5.11–Reservation of Authority	Subpart A, § 5.11–(same subject)
Subpart B, § 5.20–General Redelegations of Authority from the Commissioner to other officers of FDA..	Subpart B, § 5.20–(same subject)
Subpart B, § 5.21–Emergency functions	Subpart B, § 5.21–(same subject)
Subpart B, § 5.22–Certification of true copies and use of Department seal.	Subpart B, § 5.22–(same subject)
Subpart B, § 5.23–Disclosure of official records	Subpart B, § 5.23–Disclosure of official records and authorization of testimony
Subpart B, § 5.24–Authority relating to technology transfer	Subpart B, § 5.24–(same subject)
Subpart B, § 5.25–Research, investigation, and testing programs and health information and health promotion programs.	Subpart B, § 5.25–Research, investigation, and testing programs and health information and promotion programs
Subpart B, § 5.26–Service fellowships	Subpart B, § 5.26–(same subject)
Subpart B, § 5.27–Patent term extensions for human drug products, medical devices, and food and color additives.	Subpart B, § 5.27–Patent term extensions for human drug products, medical devices, and food and color additives; and authority to perform due diligence determinations and informal hearings
Subpart B, § 5.28–Cardiac pacemaker devices and pacemaker leads	Deleted because the Social Security Act was repealed.
Subpart B, § 5.29–Functions pertaining to safer vaccines	Subpart D, § 5.200–(same subject)
Subpart B, § 5.30–Hearings	Subpart B, § 5.28–(same subject)
Subpart B, § 5.31–Petitions under part 10	Subpart B, § 5.29–(same subject)
Subpart B, § 5.32–Authority relating to determination of product primary jurisdiction.	Subpart I, § 5.700–(same subject)
Subpart B, § 5.33–Premarket approval of a product that is or contains a biologic, a device, or a drug.	Subpart I, § 5.701–(same subject)
Subpart B, § 5.34–Authority to select temporary voting members for advisory committees and authority to sign conflict of interest waivers.	Subpart B, § 5.30–(same subject)
Subpart B, § 5.35–Enforcement activities	Subpart B, § 5.31–(same subject)
Subpart B, § 5.36–Certification following inspections	Subpart B, § 5.32–(same subject)
Subpart B, § 5.37–Issuance of reports of minor violations	Subpart B, § 5.33–(same subject)
Subpart B, § 5.38–Issuance of written notices concerning patent information, current good manufacturing practices and false or misleading labeling of new drugs, new animal drugs, and feeds bearing or containing new animal drugs.	Subpart C, § 5.109–Issuance of written notices concerning patent information, current good manufacturing practices and false or misleading labeling of new drugs.
	Subpart G, § 5.504–Issuance of written notices concerning patent information, current good manufacturing practices and false or misleading labeling of new animal drugs and feeds bearing or containing new animal drugs.
Subpart B, § 5.39–Redelegation of the Center for Biologics Evaluation and Research Director's program authorities.	Subpart D, § 5.201–(same subject)
Subpart B, § 5.40–Issuance of FEDERAL REGISTER documents pertaining to the determination of safe levels, notice of need for development of an analytical method, notice of availability of a developed analytical method, and prohibition of certain extralabel drug use.	Subpart G, § 5.500–(same subject)
Subpart B, § 5.44–Export of unapproved drugs	Subpart J, § 5.801–(same subject)
Subpart B, § 5.45–Imports and exports	Subpart J, § 5.800–(same subject)
Subpart B, § 5.46–Manufacturer's resident import agents	Subpart J, § 5.802–(same subject)
Subpart B, § 5.47–Detention of adulterated or misbranded medical devices.	Subpart F, § 5.402–(same subject)
Subpart B, § 5.49–Authorization to use alternative evidence for determination of the effectiveness of medical devices.	Subpart F, § 5.403–(same subject)
Subpart B, § 5.50–Notification to petitioners of determinations made on petitions for reclassification of medical devices.	Subpart F, § 5.404–(same subject)
Subpart B, § 5.51–Determination of classification of devices	Subpart F, § 5.405–(same subject)
Subpart B, § 5.52–Notification to sponsors of deficiencies in petitions for reclassification of medical devices.	Subpart F, § 5.406–(same subject)
Subpart B, § 5.53–Approval, disapproval, or withdrawal of approval of product development protocols and applications for premarket approval for medical devices.	Subpart F, § 5.407–(same subject)
Subpart B, § 5.54–Determinations that medical devices present unreasonable risk of substantial harm.	Subpart F, § 5.409–(same subject)
Subpart B, § 5.55–Orders to repair or replace, or make refunds for, medical devices.	Subpart F, § 5.410–(same subject)
Subpart B, § 5.56–Recall authority	Subpart F, § 5.411–Medical device recall authority
Subpart B, § 5.57–Temporary suspension of a medical device application.	Subpart F, § 5.412–(same subject)
Subpart B, § 5.58–Orphan products	Subpart K, § 5.900–(same subject)
Subpart B, § 5.59–Approval, disapproval, or withdrawal of approval of applications for investigational device exemptions.	Subpart F, § 5.413–Approval, disapproval, or withdrawal of approval of applications and entering into agreements for investigational device exemptions
Subpart B, § 5.60–Required and discretionary postmarket surveillance	Subpart F, § 5.414–Postmarket surveillance (proposed subject)

APPENDIX A—PART 5; CORRESPONDING FORMER AND NEW SUBPARTS, SECTION NUMBERS, AND SUBJECTS—Continued

Former CFR Subpart, Section No., and Subject	New CFR Subpart, Section No., and Subject
Subpart B, § 5.61–Food standards, food additives, generally recognized as safe (GRAS) substances, color additives, nutrient content claims, and health claims.	Subpart E, § 5.300–(same subject)
Subpart B, § 5.62–Issuance of initial emergency permit orders and notices of confirmation of effective date of final regulations on food for human and animal consumption.	Subpart E, § 5.301–(same subject)
Subpart B, § 5.63–Detention of meat, poultry, eggs, and related products.	Subpart E, § 5.302–(same subject)
Subpart B, § 5.64–Establishing standards and approving accrediting bodies under the National Laboratory Accreditation Program.	Subpart E, § 5.303–(same subject)
Subpart B, § 5.66–Approval of schools providing food-processing instruction.	Subpart E, § 5.304–(same subject)
Subpart B, § 5.67–Issuance of notices of opportunity for a hearing on proposals for denial of approval of applications for licenses, suspension of licenses, or revocation of licenses and certain notices of revocation of licenses.	Subpart D, § 5.202–(same subject)
Subpart B, § 5.68–Issuance and revocation of licenses for the propagation or manufacture and preparation of biological products.	Subpart D, § 5.203–(same subject)
Subpart B, § 5.69–Notification of release for distribution of biological products.	Subpart D, § 5.204–(same subject)
Subpart B, § 5.70–Issuance of notices implementing the provisions of the Drug Amendments of 1962.	Subpart C, § 5.100–(same subject)
Subpart B, § 5.71–Termination of exemptions for new drugs for investigational use in human beings and in animals (Note: § 5.71(d) is under animal drugs).	Subpart C, § 5.101–(same subject)
.....	Subpart G, § 5.505–(same subject)
Subpart B, § 5.72–Authority to approve and to withdraw approval of a charge for investigational new drugs.	Subpart C, § 5.102–(same subject)
Subpart B, § 5.75–Removed, effective 5/20/99	None
Subpart B, 5.76–Removed, effective 5/20/99	None
Subpart B, § 5.78–Removed, effective 5/20/99	None
Subpart B, § 5.80–Approval of new drug applications and their supplements.	Subpart C, § 5.103–(same subject)
Subpart B, § 5.81–Responses to Drug Enforcement Administration temporary scheduling notices.	Subpart C, § 5.104–(same subject)
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Subpart B, § 5.89–Notification of defects in, and repair or replacement of, electronic products.	Subpart H, § 5.603–(same subject)
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Subpart B, § 5.91–Dealer and distributor direction to provide data to manufacturers of electronic products.	Subpart H, § 5.605–(same subject)
Subpart B, § 5.92–Acceptance of assistance from State and Local authorities for enforcement of radiation control legislation and regulations.	Subpart H, § 5.606–(same subject)
Subpart B, § 5.93–Submission of and effective approval dates for abbreviated new drug applications and certain new drug applications.	Subpart C, § 5.106–(same subject)
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Subpart B, § 5.100–Officials authorized to make certification under 5 U.S.C. 605(b) for any proposed and final rules.	Subpart B, § 5.35–(same subject)

APPENDIX A—PART 5; CORRESPONDING FORMER AND NEW SUBPARTS, SECTION NUMBERS, AND SUBJECTS—Continued

Former CFR Subpart, Section No., and Subject	New CFR Subpart, Section No., and Subject
Subpart B, § 5.101–Authority relating to waivers or reductions of prescription drug user fees.	Subpart C, § 5.108–(same subject)
Subpart C, § 5.200 through § 5.215–Organization	Subpart M, § 5.1100–(same subject)
New–Not previously codified	Subpart F, § 5.416–Medical device tracking
New–Not previously codified	Subpart F, § 5.400–Issuance of FEDERAL REGISTER documents to recognize or to withdraw recognition of a standard to meet premarket submission requirements
New–Not previously codified	Subpart F, § 5.401–Issuance of FEDERAL REGISTER documents pertaining to exemptions from premarket notification.
New–Not previously codified	Subpart F, § 5.408–Determinations concerning the type of valid scientific evidence submitted in a premarket approval application.
New–Not previously codified	Subpart F, § 5.417–Authority pertaining to accreditation functions for medical devices.

[FR Doc. 01–14294 Filed 6–7–01; 8:45 am]

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Federal Register

Friday,
June 8, 2001

Part III

Department of Health and Human Services

Health Care Financing Administration

Medicare Program; Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule; Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1170–PN]

RIN 0938–AK56

Medicare Program; Five-Year Review of Work Relative Value Units Under the Physician Fee Schedule

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Proposed notice.

SUMMARY: This proposed notice discusses changes to work relative value units (RVUs) affecting payment for physicians' services. Section 1848(c)(2)(B)(i) of the Social Security Act requires that we review RVUs no less often than every 5 years. This is the second review of work RVUs since we implemented the physician fee schedule on January 1, 1992. These work RVUs are proposed to be effective for services furnished beginning January 1, 2002.

DATES: To be assured of consideration, we must receive comments at the appropriate address, as provided below, no later than 5 p.m. on August 7, 2001.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address only: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–1170–PN, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be timely received in the event of delivery delays. If you prefer, you may deliver your written comments by courier (1 original and 3 copies) to one of the following addresses:

Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201,
or
Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–8013

Comments mailed to the above addresses may be delayed and received too late to be considered.

Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–1170–PN. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document at the headquarters of the Health Care Financing Administration, 7500 Security Boulevard, Baltimore, Maryland, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. Please call (410) 786–7197 to make an appointment to view the public comments.

FOR FURTHER INFORMATION CONTACT:
Jim Menas, (410) 786–4507.
Rick Ensor, (410) 786–5617.
Diane Milstead, (410) 786–3355.
Marc Hartstein (Regulatory Impact Analysis), (410) 786–4539.

SUPPLEMENTARY INFORMATION

Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 or by faxing to (202) 512–2250. The cost for each copy is $9. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

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Because of the many organizations and terms to which we refer by acronym in this proposed notice, we are listing these acronyms and their corresponding terms in alphabetical order below:

AANA Arthroscopy Association of North America
AAO American Academy of Opthalmology
AAP American Academy of Pediatrics
ABA American Burn Association
ACG American College of Gastroenterology
ACOG American College of Obstetrics and Gynecology
ACR American College of Radiology
ACS American College of Surgeons
AGA American Gastrointestinal Association
AMA American Medical Association
APMA American Podiatric Medical Association
APSA American Pediatric Surgical Association
APTA American Physical Therapy Association
ASA American Society of Anesthesiologists
ASCRS American Society of Colon and Rectal Surgeons
ASGE American Society for Gastrointestinal Endoscopy
ASPS American Society of Plastic Surgery
ASTS American Society for Transplant Surgeons
AUA American Urological Association
BBA Balanced Budget Act
CPT Current procedural terminology
CY Calendar year
ERCP Endoscopic retrograde cholangio-pancreatography
FDA Food and Drug Administration
FR **Federal Register**
GAF Geographic adjustment factor
GCPI Geographic practice cost index
GPO Government Printing Office

HCFA Health Care Financing Administration
HCPAC Health Care Professionals Advisory Committee
HCPCS HCFA Common Procedure Coding System
HHS Health and Human Services
IWPUT Intra-service work per unit of time
MEI Medicare economic index
MQSA Mammography Quality Standards Act of 1992
MSA Metropolitan statistical area
PE Practice expense
PEAC Practice Expense Advisory Committee
RFA Regulatory Flexibility Act
RIA Regulatory impact analysis
RUC [AMA's Specialty Society] Relative [Value] Update Committee
RVU Relative value unit
STS Society of Thoracic Surgeons
SVS Society for Vascular Surgery

I. Background

A. Legislative History

Since January 1, 1992, Medicare has paid for physician services under section 1848 of the Social Security Act (the Act), ''Payment for Physicians'' Services.'' This section contains three major elements, (1) a fee schedule for the payment of physicians' services; (2) a sustainable growth rate for the rates of increase in Medicare expenditures for physicians' services; and (3) limits on the amounts that nonparticipating physicians can charge beneficiaries. The Act requires that payments under the fee schedule be based on national uniform relative value units (RVUs) based on the resources used in furnishing a service. Section 1848(c) of the Act requires that national RVUs be established for physician work, practice expense, and malpractice expense.

Section 1848(c)(2)(B)(ii)(II) of the Act provides that adjustments in RVUs may not cause total physician fee schedule payments to differ by more than $20 million from what they would have been had the adjustments not been made. If this tolerance is exceeded, we must make adjustments to the conversion factors (CFs) to preserve budget neutrality.

B. Published Changes to the Physician Fee Schedule

In the July 2000 proposed rule (65 FR 44177), we listed all of the final rules published through November 1999, relating to updates to the RVUs and revisions to the payment policies under the physician fee schedule. In the November 2000 final rule (65 FR 65376), we finalized the calendar year (CY) 2000 interim physician work RVUs and issued new interim work RVUs for new and revised codes for CY 2001. The final rule also discussed the activities underway with respect to the second 5-year refinement of work RVUs.

C. Current Proposed Notice

This proposed notice discusses changes to work RVUs affecting payment for physicians' services. Section 1848(c)(2)(B)(i) of the Act requires that we review RVUs no less often than every 5 years. We implemented the physician fee schedule effective for services furnished beginning January 1, 1992: the first 5-year review of work was initiated in December 1994 and was effective for services furnished beginning January 1, 1997. The revisions proposed in this notice are subject to a 60-day public comment period. We will review public comments, make adjustments as appropriate, and include revised values in our physician fee schedule final rule, to be published by November 1, 2001, effective for services furnished beginning January 1, 2002.

D. The 5-Year Review Process

We initiated the second 5-year review by soliciting public comments on potentially misvalued work RVUs for all services in the 2000 physician fee schedule in our November 2, 1999 final rule (64 FR 59427). To allow sufficient time for recommendations, we provided a 120-day comment period. We included a discussion of the activities underway with respect to the second 5-year refinement of work RVUs in the July 17, 2000 proposed rule (65 FR 44201).

We received comments from approximately 30 specialty groups, organizations, and individuals involving over 900 CPT and HCPCS codes. We also received comments on the proposed process for the 5-year review. As we indicated in the November 2, 1999 final rule and in the July 17, 2000 proposed rule, we shared these comments with the AMA Specialty Society Relative Value Update Committee (RUC). The RUC was formed in November 1991 and grew out of a series of discussions between the AMA and major national medical specialty societies. The work of the RUC is supported by the RUC Advisory Committee, which is made up of representatives of 100 specialty societies in the AMA's House of Delegates.

The RUC currently makes recommendations to us on RVUs for new and revised CPT codes (hereafter referred to as codes). This process was used during the first 5-year review, and we believe that it was beneficial. We indicated that we believe the perspective of the RUC is helpful because of its experience in recommending RVUs for the codes that have been added to, or revised by, the CPT panel since we implemented the physician fee schedule in 1992. By virtue of its multispecialty membership and consultation with specialty societies, the RUC involves the medical community in formulating its recommendations. For codes used only by non-physician practitioners, the Health Care Professionals Advisory Committee (HCPAC), a companion to the RUC, has made recommendations to us.

As we stated in the first 5-year review, we retain the responsibility for analyzing the comments and recommendations, developing the proposed rule, evaluating comments on the proposed rule, and deciding whether to revise RVUs.

After we sent the RUC the comments we received on potentially misvalued services, the RUC identified specialty societies interested in making presentations concerning those misvalued services. In making presentations to the RUC, specialty societies compiled data using a standard survey instrument whereby respondents compared the surveyed service with similar ''reference'' services that have established, agreed upon work values. Respondents were asked to estimate the work for the survey code, the time to perform pre-, intra-, and postservice activities, and the technical skill, risk, and judgement involved with performing the service. Postservice activities were broken down into hospital and office visits and were assigned an appropriate evaluation and management code by the respondent. Each specialty society selected the physician sample that was surveyed. A minimum of 30 responses was required by the RUC for the survey to be considered valid.

For this 5-year review, the RUC permitted a specialty society to use a ''minisurvey'' for some codes if the number of codes a specialty was reviewing was extremely high. These minisurveys required less information from the respondent but were similar in design.

Some specialty societies used a ''building-block'' approach to validate the survey results for surgical services. In constructing the building blocks, a service is divided into ''pre-'', ''intra-'', and ''post-'' service components. The preservice component consists of all services furnished before the physician makes the skin incision (for example, preoperative evaluation and scrubbing)

the intraservice component consists of the ''skin-to-skin'' time, and the postservice component includes immediate postsurgery services and subsequent hospital and office visits. Each component (or building block) is then assigned work RVUs. Preservice and intraservice work RVUs are based on time and intensity, and postservice work is based on the specified evaluation and management service for each postoperative visit. These three values are then summed to compute ''building-block'' work RVUs.

The results of the surveys were reviewed and organized by the specialty society and then presented to the RUC. Based on the survey results and a discussion, the RUC developed a recommendation. The RUC used six workgroups to evaluate the codes. Each workgroup evaluated a series of related codes and submitted its report to the full RUC. The RUC then evaluated those reports and sent recommendations to us. Both the workgroups and the RUC evaluated the relative work (time and intensity) for each service compared to other services on the fee schedule.

We received recommendations on work RVUs from the RUC for all of the codes we forwarded, with the exception of the anesthesia codes and conscious sedation codes.

II. Discussion of Comments and Decisions

A. Review of Comments

During the comment period for our November 2, 1999 final rule, we received approximately 35 public comments on approximately 900 codes. After review by our medical staff, we forwarded all of the comments we received concerning misvalued services to the RUC. The RUC submitted work RVU recommendations for all of the codes we forwarded with the exception of the anesthesia codes and conscious sedation codes. The RUC used six workgroups to evaluate the codes. Each workgroup evaluated a series of related codes and submitted its report to the full RUC. The RUC then evaluated those reports and sent its recommendations to us. Both the workgroups and the RUC evaluated the relative work (time and intensity) for each service compared to other services on the fee schedule.

As discussed below, we further analyzed all of the RUC recommendations; we evaluated both the recommended work RVUs and the rationale for the recommendations. If we had concerns about the application of a particular methodology, we verified that the recommended work RVUs were appropriate by using alternative methodologies.

Table 1, Five-Year Review of Work Relative Value Units, lists the codes reviewed during the 5-year review. This table includes the following information:

- *CPT/HCPCS Code.* This is the CPT or alphanumeric HCPCS code for a service.
- *Modifier.* A modifier-26 is shown if the work RVUs represent the professional component of the service.
- *Description.* This is an abbreviated version of the narrative description of the code.
- *2000 Work RVUs.* The work RVUs that appeared in the November 2, 1999 final rule are shown for each reviewed code.
- *Requested Work RVUs.* This column identifies the work RVUs requested by the commenting specialty or individual commenter. If we received more than one comment on a code, the code is listed more than once with the recommended RVUs. If the commenters did not recommend specific RVUs, we indicate this by ''N/A''. A ''WD'' (withdrawal) indicates the commenter withdrew the request for review of a code and chose not to pursue review of the code under the 5-year review.
- *RUC Recommendation.* This column identifies the work RVUs recommended by the RUC. ''CPT'' indicates that that the RUC referred this code to the AMA CPT Editorial Panel for review and clarification and recommended maintaining the current work RVUs. An ''(e)'' indicates the commenting specialty withdrew the proposal; therefore, the RUC recommends maintaining the current work RVUs.
- *HCPAC Recommendation.* This column identifies the work RVUs recommended by the HCPAC. An ''(a)'' in this column indicates there was no HCPAC recommendation.
- *HCFA Decision.* This column indicates whether we agreed with the RUC recommendation (''agree''); we are proposing work RVUs higher than the RUC recommendation (''increase''); or we are proposing work RVUs that are less than the RUC recommendation (''decrease''). Codes for which we did not accept the RUC recommendation are discussed in greater detail following Table 1. An ''(a)'' in this column indicates that in the absence of a RUC recommendation we are proposing to maintain the present work RVUs. A ''(b)'' in this column indicates that these services were reviewed as part of the July 2000 Multispecialty Refinement Panels for new and/or revised services. (Meetings of Multispecialty Refinement Panels are conducted as needed to allow specialty representatives the opportunity to discuss the comments they submitted on our decisions on new or revised services published in the final rule. The goal of multispecialty refinement panels is to consider the interests of those who commented on the work RVUs against the redistributive effects that would occur in other specialties. Following each discussion of a specific service, panel members were instructed to individually rate the service under discussion. We then used a statistical analysis of these ratings to create final work RVUs for the services under discussion.) A ''(d)'' indicates there was no HCPAC recommendation. We propose maintaining current work RVUs.
- *Proposed work RVUs:* This column contains the 2002 proposed work RVUs.

The following is a categorization of our proposals as related to the RUC recommended work RVUs from the 5-year review of work RVUs. The RUC supplied us with recommendations on 857 services. We accepted RUC's recommended work RVUs for 792 of the services reviewed and disagreed with RUC's recommended work RVUs for 65 of the services reviewed. This is an acceptance percentage of 92 percent. Of the 65 services for which we did not accept the RUC's recommended work RVUs we increased the work RVUs for 37 services, decreased the work RVUs for 22 services, and rejected the RUC recommendation of an increase for 6 services that had already been reviewed at the Multispecialty Refinement Panel for CY 2000.

Additionally, the HCPAC reviewed a total of 12 services as part of the 5-year review. For 5 of the services reviewed, the HCPAC did not offer a recommendation. Of the remaining 7 services reviewed by the HCPAC, we have accepted the HCPAC recommendations.

TABLE 1.—FIVE-YEAR REVIEW OF WORK RELATIVE VALUE UNITS

CPT/ HCPCS code [1]	Mod	Descriptor	2000 work RVU	Requested work RVU	RUC REC	HCPAC REC	HCFA decision	Proposed work RVU
11055		Trim skin lesion	0.27	0.43		(a)	(a)	0.27
11056		Trim skin lesion, 2 to 4	0.39	0.61		(a)	(a)	0.39
11057		Trim skin lesions, over 4	0.50	0.79		(a)	(a)	0.50
11100		Biopsy of skin lesion	0.81	WD	(e)		(a)	0.81
11402		Removal of skin lesion	1.61	2.20	1.61		agree	1.61
11642		Removal of skin lesion	2.93	3.05	2.93		agree	2.93
11642		Removal of skin lesion	2.93	3.87	2.93		agree	2.93
11719		Trim nail(s)	0.11	0.17		(a)	(a)	0.11
11730		Removal of nail plate	1.13	WD	(e)		(a)	1.13
12001		Repair superficial wound(s)	1.70	N/A	CPT		CPT	1.70
12002		Repair superficial wound(s)	1.86	N/A	CPT		CPT	1.86
12011		Repair superficial wound(s)	1.76	2.37	1.76		agree	1.76
13101		Repair of wound or lesion	3.92	5.43	3.92		agree	3.92
13131		Repair of wound or lesion	3.79	4.79	3.79		agree	3.79
13132		Repair of wound or lesion	5.95	6.95	5.95		agree	5.95
15000		Skin graft	4.00	5.95	CPT		CPT	4.00
15001		Skin graft add-on	1.00	2.50	CPT		CPT	1.00
15100		Skin split graft	9.05	9.05	CPT		CPT	9.05
15101		Skin split graft add-on	1.72	1.72	CPT		CPT	1.72
15120		Skin split graft	9.83	9.83	CPT		CPT	9.83
15121		Skin split graft add-on	2.67	2.67	CPT		CPT	2.67
15350		Skin homograft	4.00	4.00	CPT		CPT	4.00
15351		Skin homograft add-on	1.00	1.00	CPT		CPT	1.00
15400		Skin heterograft	4.00	4.00	CPT		CPT	4.00
15401		Skin heterograft add-on	1.00	1.00	CPT		CPT	1.00
17000		Destroy benign/premal lesion	0.60	WD	(e)		(a)	0.60
17003		Destroy lesions, 2-14	0.15	WD	(e)		(a)	0.15
17004		Destroy lesions, 15 or more	2.79	WD	(e)		(a)	2.79
19000		Drainage of breast lesion	0.84	1.27	0.84		agree	0.84
19100		Biopsy of breast	1.27	3.88	1.27		agree	1.27
19125		Excision, breast lesion	6.06	9.00	6.06		agree	6.06
19160		Removal of breast tissue	5.99	8.38	5.99		agree	5.99
19162		Remove breast tissue, nodes	13.53	15.68	13.53		agree	13.53
19240		Removal of breast	16.00	18.87	16.00		agree	16.00
20205		Deep muscle biopsy	2.35	3.42	CPT		CPT	2.35
20245		Bone biopsy, excisional	3.95	7.97	8.50		decrease	7.78
20600		Drain/inject, joint/bursa	0.66	WD	(e)		(a)	0.66
20605		Drain/inject, joint/bursa	0.68	WD	(e)		(a)	0.68
21740		Reconstruction of sternum	16.50	21.00	CPT		CPT	16.50
21800		Treatment of rib fracture	0.96	1.77	0.96		agree	0.96
23076		Removal of shoulder lesion	7.63	13.40	CPT		CPT	7.63
23472		Reconstruct shoulder joint	16.92	21.27	21.10		agree	21.10
23485		Revision of collar bone	13.43	18.73	13.43		agree	13.43
23585		Treat scapula fracture	8.96	11.46	8.96		agree	8.96
23615		Treat humerus fracture	9.35	15.85	9.35		agree	9.35
23630		Treat humerus fracture	7.35	12.45	7.35		agree	7.35
23680		Treat dislocation/fracture	10.06	13.10	10.06		agree	10.06
24076		Remove arm/elbow lesion	6.30	10.20	CPT		CPT	6.30
24435		Repair humerus with graft	13.17	20.36	13.17		agree	13.17
24545		Treat humerus fracture	10.46	12.26	10.46		agree	10.46
25076		Removal of forearm lesion	4.92	12.96	CPT		CPT	4.92
26562		Repair of web finger	9.68	12.56	15.00		agree	15.00
27048		Remove hip/pelvis lesion	6.25	13.01	CPT		CPT	6.25
27075		Extensive hip surgery	17.23	28.52	35.00		agree	35.00
27077		Extensive hip surgery	23.13	30.00	40.00		agree	40.00
27216		Treat pelvic ring fracture	15.19	25.00	15.19		agree	15.19
27217		Treat pelvic ring fracture	14.11	17.11	14.11		agree	14.11
27218		Treat pelvic ring fracture	20.15	22.15	20.15		agree	20.15
27226		Treat hip wall fracture	14.91	19.91	14.91		agree	14.91
27236		Treat thigh fracture	15.60	17.60	15.60		agree	15.60
27280		Fusion of sacroiliac joint	13.39	21.00	13.39		agree	13.39
27282		Fusion of pubic bones	11.34	21.66	11.34		agree	11.34
27284		Fusion of hip joint	16.76	20.12	23.45		agree	23.45
27328		Removal of thigh lesion	5.57	8.70	CPT		CPT	5.57

[1] All CPT codes and descriptors copyright 2000 American Medical Association

TABLE 1.—FIVE-YEAR REVIEW OF WORK RELATIVE VALUE UNITS—Continued

CPT/ HCPCS code [1]	Mod	Descriptor	2000 work RVU	Requested work RVU	RUC REC	HCPAC REC	HCFA decision	Proposed work RVU
27472		Repair/graft of thigh	17.72	23.62	17.72		agree	17.72
27513		Treatment of thigh fracture	17.92	20.92	17.92		agree	17.92
27536		Treat knee fracture	15.65	19.00	15.65		agree	15.65
27590		Amputate leg at thigh	12.03	15.52	12.03		agree	12.03
27619		Remove lower leg lesion	8.40	10.02	CPT		CPT	8.40
27724		Repair/graft of tibia	14.99	19.34	18.20		agree	18.20
27822		Treatment of ankle fracture	9.20	10.68	11.00		agree	11.00
27823		Treatment of ankle fracture	11.80	13.27	13.00		agree	13.00
27828		Treat lower leg fracture	16.23	19.00	16.23		agree	16.23
28299		Correction of bunion	8.88	11.90	9.18		agree	9.18
28322		Repair of metatarsals	8.34	13.26	8.34		agree	8.34
28420		Treat/graft heel fracture	16.64	23.52	16.64		agree	16.64
28445		Treat ankle fracture	9.33	15.97	15.62		agree	15.62
28705		Fusion of foot bones	15.21	20.46	18.80		agree	18.80
29450		Application of leg cast	1.02	3.00	2.08		agree	2.08
29450		Application of leg cast	1.02	N/A	2.08		agree	2.08
29881		Knee arthroscopy/surgery	7.76	WD	(e)		(a)	7.76
29883		Knee arthroscopy/surgery	9.46	12.00	11.05		agree	11.05
29889		Knee arthroscopy/surgery	15.13	16.68	16.00		agree	16.00
29889		Knee arthroscopy/surgery	15.13	18.47	16.00		agree	16.00
31600		Incision of windpipe	3.62	6.42	7.18		agree	7.18
31622		Dx bronchoscope/wash	2.78	4.17	2.78		agree	2.78
31622		Dx bronchoscope/wash	2.78	N/A	2.78		agree	2.78
31625		Bronchoscopy with biopsy	3.37	N/A	3.37		agree	3.37
31645		Bronchoscopy, clear airways	3.16	N/A	3.16		agree	3.16
32000		Drainage of chest	1.54	2.88	1.54		agree	1.54
32000		Drainage of chest	1.54	N/A	1.54		agree	1.54
32005		Treat lung lining chemically	2.19	N/A	2.19		agree	2.19
32020		Insertion of chest tube	3.98	N/A	3.98		agree	3.98
32035		Exploration of chest	8.67	N/A	8.67		agree	8.67
32095		Biopsy through chest wall	8.36	N/A	8.36		agree	8.36
32100		Exploration/biopsy of chest	11.84	N/A	15.24		agree	15.24
32110		Explore/repair chest	13.62	N/A	23.00		agree	23.00
32220		Release of lung	19.27	N/A	24.00		agree	24.00
32225		Partial release of lung	13.96	N/A	13.96		agree	13.96
32320		Free/remove chest lining	20.54	N/A	24.00		agree	24.00
32440		Removal of lung	21.02	35.08	25.00		agree	25.00
32440		Removal of lung	21.02	N/A	25.00		agree	25.00
32480		Partial removal of lung	18.32	27.17	23.75		agree	23.75
32480		Partial removal of lung	18.32	N/A	23.75		agree	23.75
32482		Bilobectomy	19.71	N/A	25.00		agree	25.00
32491		Lung volume reduction	21.25	N/A	21.25		agree	21.25
32500		Partial removal of lung	14.30	N/A	22.00		agree	22.00
32520		Remove lung & revise chest	21.68	N/A	21.68		agree	21.68
32602		Thoracoscopy, diagnostic	5.96	N/A	5.96		agree	5.96
32651		Thoracoscopy, surgical	12.91	N/A	12.91		agree	12.91
32652		Thoracoscopy, surgical	18.66	N/A	18.66		agree	18.66
32655		Thoracoscopy, surgical	13.10	N/A	13.10		agree	13.10
32657		Thoracoscopy, surgical	13.65	N/A	13.65		agree	13.65
33207		Insertion of heart pacemaker	8.04	WD	(e)		(a)	8.04
33234		Removal of pacemaker system	7.82	N/A	7.82		agree	7.82
33235		Removal of pacemaker electrode	9.40	N/A	9.40		agree	9.40
33400		Repair of aortic valve	25.34	N/A	28.50		agree	28.50
33405		Replacement of aortic valve	30.61	N/A	35.00		agree	35.00
33406		Replacement of aortic valve	32.30	N/A	37.50		agree	37.50
33410		Replacement of aortic valve	32.46	N/A	32.46		agree	32.46
33411		Replacement of aortic valve	32.47	N/A	36.25		agree	36.25
33412		Replacement of aortic valve	34.79	N/A	42.00		agree	42.00
33413		Replacement of aortic valve	35.24	N/A	43.50		agree	43.50
33415		Revision, subvalvular tissue	27.15	N/A	27.15		agree	27.15
33425		Repair of mitral valve	27.00	N/A	27.00		agree	27.00
33426		Repair of mitral valve	31.03	N/A	33.00		agree	33.00
33427		Repair of mitral valve	33.72	N/A	40.00		agree	40.00
33430		Replacement of mitral valve	31.43	N/A	33.50		agree	33.50
33468		Revision of tricuspid valve	30.12	N/A	30.12		agree	30.12
33475		Replacement, pulmonary valve	28.41	N/A	33.00		agree	33.00

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TABLE 1.—FIVE-YEAR REVIEW OF WORK RELATIVE VALUE UNITS—Continued

CPT/ HCPCS code [1]	Mod	Descriptor	2000 work RVU	Requested work RVU	RUC REC	HCPAC REC	HCFA decision	Proposed work RVU
33506		Repair artery, translocation	26.71	N/A	35.50		agree	35.50
33510		CABG, vein, single	25.12	N/A	29.00		agree	29.00
33511		CABG, vein, two	27.40	N/A	30.00		agree	30.00
33512		CABG, vein, three	29.67	N/A	31.80		agree	31.80
33513		CABG, vein, four	31.95	N/A	32.00		agree	32.00
33514		CABG, vein, five	35.00	N/A	32.75		agree	32.75
33516		Cabg, vein, six or more	37.40	N/A	35.00		agree	35.00
33517		CABG, artery-vein, single	2.57	N/A	2.57		agree	2.57
33518		CABG, artery-vein, two	4.85	N/A	4.85		agree	4.85
33519		CABG, artery-vein, three	7.12	N/A	7.12		agree	7.12
33521		CABG, artery-vein, four	9.40	N/A	9.40		agree	9.40
33522		CABG, artery-vein, five	11.67	N/A	11.67		agree	11.67
33523		Cabg, art-vein, six or more	13.95	N/A	13.95		agree	13.95
33530		Coronary artery, bypass/reop	5.86	N/A	5.86		agree	5.86
33533		CABG, arterial, single	25.83	N/A	30.00		agree	30.00
33534		CABG, arterial, two	28.82	N/A	32.20		agree	32.20
33535		CABG, arterial, three	31.81	N/A	34.50		agree	34.50
33536		Cabg, arterial, four or more	34.79	N/A	37.50		agree	37.50
33611		Repair double ventricle	32.30	N/A	34.00		agree	34.00
33612		Repair double ventricle	33.26	N/A	35.00		agree	35.00
33615		Repair, simple fontan	32.06	N/A	34.00		agree	34.00
33617		Repair, modified fontan	34.03	N/A	37.00		agree	37.00
33619		Repair single ventricle	37.57	N/A	45.00		agree	45.00
33641		Repair heart septum defect	21.39	N/A	21.39		agree	21.39
33660		Repair of heart defects	25.54	N/A	30.00		agree	30.00
33670		Repair of heart chambers	32.73	N/A	35.00		agree	35.00
33681		Repair heart septum defect	27.67	N/A	30.61		agree	30.61
33694		Repair of heart defects	31.73	N/A	34.00		agree	34.00
33697		Repair of heart defects	33.71	N/A	36.00		agree	36.00
33730		Repair heart-vein defect(s)	31.67	N/A	34.25		agree	34.25
33750		Major vessel shunt	21.41	N/A	21.41		agree	21.41
33767		Major vessel shunt	24.50	N/A	24.50		agree	24.50
33770		Repair great vessels defect	33.29	N/A	37.00		agree	37.00
33778		Repair great vessels defect	35.82	N/A	40.00		agree	40.00
33780		Repair great vessels defect	36.94	N/A	41.75		agree	41.75
33786		Repair arterial trunk	34.84	N/A	39.00		agree	39.00
33820		Revise major vessel	16.29	N/A	16.29		agree	16.29
33840		Remove aorta constriction	20.63	N/A	20.63		agree	20.63
33860		Ascending aortic graft	33.96	N/A	38.00		agree	38.00
33861		Ascending aortic graft	34.52	N/A	42.00		agree	42.00
33863		Ascending aortic graft	36.47	N/A	45.00		agree	45.00
33870		Transverse aortic arch graft	40.31	N/A	44.00		agree	44.00
33875		Thoracic aortic graft	33.06	N/A	CPT		CPT	33.06
33877		Thoracoabdominal graft	42.60	N/A	CPT		CPT	42.60
33917		Repair pulmonary artery	24.50	N/A	24.50		agree	24.50
33919		Repair pulmonary atresia	32.67	N/A	40.00		agree	40.00
33945		Transplantation of heart	42.10	N/A	42.10		agree	42.10
34001		Removal of artery clot	12.91	WD	(e)		(a)	12.91
34101		Removal of artery clot	9.97	N/A	10.00		agree	10.00
34111		Removal of arm artery clot	8.07	N/A	10.00		agree	10.00
34151		Removal of artery clot	16.86	27.51	25.00		agree	25.00
34151		Removal of artery clot	16.86	28.00	25.00		agree	25.00
34201		Removal of artery clot	9.13	10.40	10.03		agree	10.03
34201		Removal of artery clot	9.13	10.58	10.03		agree	10.03
34203		Removal of leg artery clot	12.21	14.99	16.50		agree	16.50
34203		Removal of leg artery clot	12.21	16.50	16.50		agree	16.50
34401		Removal of vein clot	12.86	26.63	25.00		agree	25.00
34401		Removal of vein clot	12.86	28.00	25.00		agree	25.00
34421		Removal of vein clot	9.93	15.75	12.00		agree	12.00
34421		Removal of vein clot	9.93	15.94	12.00		agree	12.00
34451		Removal of vein clot	14.44	29.05	27.00		agree	27.00
34451		Removal of vein clot	14.44	30.00	27.00		agree	27.00
34490		Removal of vein clot	7.60	N/A	9.86		agree	9.86
34501		Repair valve, femoral vein	10.93	N/A	16.00		agree	16.00
34510		Transposition of vein valve	13.25	N/A	18.95		agree	18.95
34520		Cross-over vein graft	13.74	N/A	17.95		agree	17.95

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TABLE 1.—FIVE-YEAR REVIEW OF WORK RELATIVE VALUE UNITS—Continued

CPT/ HCPCS code [1]	Mod	Descriptor	2000 work RVU	Requested work RVU	RUC REC	HCPAC REC	HCFA decision	Proposed work RVU
34530		Leg vein fusion	17.61	N/A	16.64		agree	16.64
35011		Repair defect of artery	11.65	14.10	18.00		agree	18.00
35011		Repair defect of artery	11.65	18.00	18.00		agree	18.00
35013		Repair artery rupture, arm	17.40	15.38	22.00		agree	22.00
35013		Repair artery rupture, arm	17.40	20.00	22.00		agree	22.00
35045		Repair defect of arm artery	11.26	11.05	17.57		agree	17.57
35045		Repair defect of arm artery	11.26	16.50	17.57		agree	17.57
35081		Repair defect of artery	28.01	33.13	28.01		agree	28.01
35082		Repair artery rupture, aorta	36.35	37.00	38.50		agree	38.50
35082		Repair artery rupture, aorta	36.35	41.80	38.50		agree	38.50
35092		Repair artery rupture, aorta	38.39	50.00	45.00		agree	45.00
35092		Repair artery rupture, aorta	38.39	58.61	45.00		agree	45.00
35103		Repair artery rupture, groin	33.57	41.00	40.50		agree	40.50
35103		Repair artery rupture, groin	33.57	44.12	40.50		agree	40.50
35111		Repair defect of artery	16.43	23.24	25.00		agree	25.00
35111		Repair defect of artery	16.43	28.00	25.00		agree	25.00
35112		Repair artery rupture,spleen	18.69	29.20	30.00		agree	30.00
35112		Repair artery rupture,spleen	18.69	30.00	30.00		agree	30.00
35121		Repair defect of artery	25.99	30.29	30.00		agree	30.00
35121		Repair defect of artery	25.99	32.00	30.00		agree	30.00
35122		Repair artery rupture, belly	33.45	36.83	35.00		agree	35.00
35122		Repair artery rupture, belly	33.45	37.00	35.00		agree	35.00
35131		Repair defect of artery	18.55	23.15	25.00		agree	25.00
35131		Repair defect of artery	18.55	28.00	25.00		agree	25.00
35132		Repair artery rupture, groin	21.95	30.00	30.00		agree	30.00
35132		Repair artery rupture, groin	21.95	30.54	30.00		agree	30.00
35141		Repair defect of artery	14.46	19.38	20.00		agree	20.00
35141		Repair defect of artery	14.46	20.00	20.00		agree	20.00
35142		Repair artery rupture, thigh	15.86	23.36	23.30		agree	23.30
35142		Repair artery rupture, thigh	15.86	25.00	23.30		agree	23.30
35151		Repair defect of artery	17.00	20.26	22.64		agree	22.64
35151		Repair defect of artery	17.00	22.00	22.64		agree	22.64
35152		Repair artery rupture, knee	16.70	24.98	25.62		agree	25.62
35152		Repair artery rupture, knee	16.70	27.50	25.62		agree	25.62
35182		Repair blood vessel lesion	17.74	N/A	30.00		agree	30.00
35184		Repair blood vessel lesion	12.25	N/A	18.00		agree	18.00
35189		Repair blood vessel lesion	18.43	N/A	28.00		agree	28.00
35190		Repair blood vessel lesion	12.75	N/A	12.75		agree	12.75
35201		Repair blood vessel lesion	9.99	12.74	16.14		agree	16.14
35201		Repair blood vessel lesion	9.99	18.35	16.14		agree	16.14
35206		Repair blood vessel lesion	9.25	N/A	13.25		agree	13.25
35221		Repair blood vessel lesion	16.42	26.00	24.39		agree	24.39
35221		Repair blood vessel lesion	16.42	28.95	24.39		agree	24.39
35226		Repair blood vessel lesion	9.06	14.00	14.50		agree	14.50
35226		Repair blood vessel lesion	9.06	15.82	14.50		agree	14.50
35231		Repair blood vessel lesion	12.00	15.64	20.00		agree	20.00
35231		Repair blood vessel lesion	12.00	18.90	20.00		agree	20.00
35236		Repair blood vessel lesion	10.54	12.85	17.11		agree	17.11
35236		Repair blood vessel lesion	10.54	18.00	17.11		agree	17.11
35246		Repair blood vessel lesion	19.84	26.00	26.45		agree	26.45
35246		Repair blood vessel lesion	19.84	N/A	26.45		agree	26.45
35251		Repair blood vessel lesion	17.49	31.00	30.20		agree	30.20
35251		Repair blood vessel lesion	17.49	34.04	30.20		agree	30.20
35256		Repair blood vessel lesion	11.38	N/A	18.36		agree	18.36
35261		Repair blood vessel lesion	11.63	15.51	17.80		agree	17.80
35261		Repair blood vessel lesion	11.63	18.90	17.80		agree	17.80
35266		Repair blood vessel lesion	10.30	15.79	14.91		agree	14.91
35266		Repair blood vessel lesion	10.30	17.00	14.91		agree	14.91
35276		Repair blood vessel lesion	18.75	22.00	24.25		agree	24.25
35276		Repair blood vessel lesion	18.75	N/A	24.25		agree	24.25
35281		Repair blood vessel lesion	16.48	29.00	28.00		agree	28.00
35281		Repair blood vessel lesion	16.48	32.01	28.00		agree	28.00
35286		Repair blood vessel lesion	11.87	N/A	16.16		agree	16.16
35311		Rechanneling of artery	23.85	30.00	27.00		agree	27.00
35311		Rechanneling of artery	23.85	N/A	27.00		agree	27.00
35321		Rechanneling of artery	11.97	16.47	16.00		agree	16.00

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TABLE 1.—FIVE-YEAR REVIEW OF WORK RELATIVE VALUE UNITS—Continued

CPT/ HCPCS code [1]	Mod	Descriptor	2000 work RVU	Requested work RVU	RUC REC	HCPAC REC	HCFA decision	Proposed work RVU
35321		Rechanneling of artery	11.97	18.35	16.00		agree	16.00
35331		Rechanneling of artery	23.52	24.81	26.20		agree	26.20
35331		Rechanneling of artery	23.52	28.01	26.20		agree	26.20
35351		Rechanneling of artery	20.11	24.09	23.00		agree	23.00
35351		Rechanneling of artery	20.11	25.50	23.00		agree	23.00
35355		Rechanneling of artery	16.09	20.01	18.50		agree	18.50
35355		Rechanneling of artery	16.09	20.75	18.50		agree	18.50
35361		Rechanneling of artery	23.59	29.08	28.20		agree	28.20
35361		Rechanneling of artery	23.59	30.00	28.20		agree	28.20
35363		Rechanneling of artery	24.66	32.00	30.20		agree	30.20
35363		Rechanneling of artery	24.66	35.67	30.20		agree	30.20
35371		Rechanneling of artery	11.64	12.97	14.72		agree	14.72
35371		Rechanneling of artery	11.64	17.75	14.72		agree	14.72
35372		Rechanneling of artery	13.56	18.04	18.00		agree	18.00
35372		Rechanneling of artery	13.56	19.53	18.00		agree	18.00
35381		Rechanneling of artery	15.81	N/A	CPT		CPT	15.81
35511		Artery bypass graft	16.83	19.75	21.20		agree	21.20
35511		Artery bypass graft	16.83	21.50	21.20		agree	21.20
35518		Artery bypass graft	15.42	18.59	21.20		agree	21.20
35518		Artery bypass graft	15.42	23.00	21.20		agree	21.20
35521		Artery bypass graft	16.17	20.46	22.20		agree	22.20
35521		Artery bypass graft	16.17	25.25	22.20		agree	22.20
35526		Artery bypass graft	20.00	30.00	29.95		agree	29.95
35526		Artery bypass graft	20.00	N/A	29.95		agree	29.95
35531		Artery bypass graft	25.61	33.62	36.20		agree	36.20
35531		Artery bypass graft	25.61	38.00	36.20		agree	36.20
35533		Artery bypass graft	20.52	28.00	28.00		agree	28.00
35533		Artery bypass graft	20.52	29.99	28.00		agree	28.00
35536		Artery bypass graft	23.11	25.33	31.70		agree	31.70
35536		Artery bypass graft	23.11	33.00	31.70		agree	31.70
35541		Artery bypass graft	25.80	N/A	CPT		CPT	25.80
35546		Artery bypass graft	25.54	N/A	CPT		CPT	25.54
35551		Artery bypass graft	26.67	N/A	CPT		CPT	26.67
35556		Artery bypass graft	21.76	24.50	21.76		agree	21.76
35556		Artery bypass graft	21.76	24.50	21.76		agree	21.76
35558		Artery bypass graft	14.04	22.00	21.20		agree	21.20
35558		Artery bypass graft	14.04	22.08	21.20		agree	21.20
35560		Artery bypass graft	23.56	28.19	32.00		agree	32.00
35560		Artery bypass graft	23.56	35.50	32.00		agree	32.00
35563		Artery bypass graft	15.14	24.00	24.20		agree	24.20
35563		Artery bypass graft	15.14	25.00	24.20		agree	24.20
35565		Artery bypass graft	15.14	23.65	23.20		agree	23.20
35565		Artery bypass graft	15.14	24.00	23.20		agree	23.20
35571		Artery bypass graft	18.58	23.65	24.06		agree	24.06
35571		Artery bypass graft	18.58	26.92	24.06		agree	24.06
35582		Vein bypass graft	27.13	N/A	CPT		CPT	27.13
35587		Vein bypass graft	19.05	24.47	24.75		agree	24.75
35587		Vein bypass graft	19.05	27.00	24.75		agree	24.75
35621		Artery bypass graft	14.54	16.53	20.00		agree	20.00
35621		Artery bypass graft	14.54	21.50	20.00		agree	20.00
35623		Bypass graft, not vein	16.62	17.62	24.00		agree	24.00
35623		Bypass graft, not vein	16.62	25.75	24.00		agree	24.00
35626		Artery bypass graft	23.63	27.58	27.75		agree	27.75
35626		Artery bypass graft	23.63	30.00	27.75		agree	27.75
35631		Artery bypass graft	24.60	32.51	34.00		agree	34.00
35631		Artery bypass graft	24.60	36.00	34.00		agree	34.00
35636		Artery bypass graft	22.46	27.32	29.50		agree	29.50
35636		Artery bypass graft	22.46	36.00	29.50		agree	29.50
35641		Artery bypass graft	24.57	N/A	CPT		CPT	24.57
35646		Artery bypass graft	25.81	N/A	CPT		CPT	25.81
35650		Artery bypass graft	14.36	15.74	19.00		agree	19.00
35650		Artery bypass graft	14.36	19.80	19.00		agree	19.00
35654		Artery bypass graft	18.61	23.54	25.00		agree	25.00
35654		Artery bypass graft	18.61	26.00	25.00		agree	25.00
35661		Artery bypass graft	13.18	17.89	19.00		agree	19.00
35661		Artery bypass graft	13.18	19.53	19.00		agree	19.00

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TABLE 1.—FIVE-YEAR REVIEW OF WORK RELATIVE VALUE UNITS—Continued

CPT/ HCPCS code [1]	Mod	Descriptor	2000 work RVU	Requested work RVU	RUC REC	HCPAC REC	HCFA decision	Proposed work RVU
35663		Artery bypass graft	14.17	20.90	22.00		agree	22.00
35663		Artery bypass graft	14.17	23.00	22.00		agree	22.00
35665		Artery bypass graft	15.40	19.84	21.00		agree	21.00
35665		Artery bypass graft	15.40	22.00	21.00		agree	21.00
35666		Artery bypass graft	19.19	20.00	22.19		agree	22.19
35666		Artery bypass graft	19.19	22.00	22.19		agree	22.19
35671		Artery bypass graft	14.80	17.80	19.33		agree	19.33
35671		Artery bypass graft	14.80	24.00	19.33		agree	19.33
35701		Exploration, carotid artery	5.55	9.38	8.50		agree	8.50
35701		Exploration, carotid artery	5.55	15.00	8.50		agree	8.50
35721		Exploration, femoral artery	5.28	N/A	7.18		agree	7.18
35741		Exploration popliteal artery	5.37	N/A	8.00		agree	8.00
35840		Explore abdominal vessels	9.77	N/A	CPT		CPT	9.77
35860		Explore limb vessels	5.55	N/A	CPT		CPT	5.55
35905		Excision, graft, thorax	18.19	32.00	31.25		agree	31.25
35905		Excision, graft, thorax	18.19	N/A	31.25		agree	31.25
35907		Excision, graft, abdomen	19.24	37.33	35.00		agree	35.00
35907		Excision, graft, abdomen	19.24	40.00	35.00		agree	35.00
36400		Drawing blood	0.18	N/A	0.38		decrease	0.18
36405		Drawing blood	0.18	N/A	0.32		decrease	0.18
36406		Drawing blood	0.18	N/A	CPT		CPT	0.18
36489		Insertion of catheter, vein	1.22	2.75	2.50		agree	2.50
36489		Insertion of catheter, vein	1.22	3.41	2.50		agree	2.50
36520		Plasma and/or cell exchange	1.74	N/A	CPT		CPT	1.74
36533		Insertion of access device	5.32	5.28	CPT		CPT	5.32
36534		Revision of access device	2.80	5.15	CPT		CPT	2.80
36535		Removal of access device	2.27	3.89	CPT		CPT	2.27
36600		Withdrawal of arterial blood	0.32	WD	(e)		(a)	0.32
36620		Insertion catheter, artery	1.15	2.25	CPT		CPT	1.15
36625		Insertion catheter, artery	2.11	2.65	2.11		agree	2.11
36822		Insertion of cannula(s)	5.42	19.00	5.42		agree	5.42
37565		Ligation of neck vein	4.44	9.01	10.88		agree	10.88
37565		Ligation of neck vein	4.44	14.50	10.88		agree	10.88
37600		Ligation of neck artery	4.57	9.19	11.25		agree	11.25
37600		Ligation of neck artery	4.57	14.00	11.25		agree	11.25
37605		Ligation of neck artery	6.19	11.85	13.11		agree	13.11
37605		Ligation of neck artery	6.19	17.50	13.11		agree	13.11
37609		Temporal artery procedure	2.30	3.38	3.00		agree	3.00
37609		Temporal artery procedure	2.30	N/A	3.00		agree	3.00
37615		Ligation of neck artery	5.73	12.31	CPT		CPT	5.73
37615		Ligation of neck artery	5.73	18.00	CPT		CPT	5.73
37617		Ligation of abdomen artery	15.95	N/A	22.06		agree	22.06
37618		Ligation of extremity artery	4.84	N/A	CPT		CPT	4.84
37650		Revision of major vein	5.13	N/A	7.80		agree	7.80
37660		Revision of major vein	10.61	N/A	21.00		agree	21.00
37700		Revise leg vein	3.73	N/A	CPT		CPT	3.73
37720		Removal of leg vein	5.66	10.71	CPT		CPT	5.66
37730		Removal of leg veins	7.33	N/A	CPT		CPT	7.33
37735		Removal of leg veins/lesion	10.53	N/A	CPT		CPT	10.53
37760		Revision of leg veins	10.47	N/A	CPT		CPT	10.47
37785		Revision secondary varicosity	3.84	N/A	CPT		CPT	3.84
38100		Removal of spleen, total	13.01	14.70	14.50		agree	14.50
38100		Removal of spleen, total	13.01	16.21	14.50		agree	14.50
38101		Removal of spleen, partial	13.74	14.79	15.31		agree	15.31
38115		Repair of ruptured spleen	14.19	15.55	15.82		agree	15.82
38300		Drainage, lymph node lesion	1.53	1.01	1.99		agree	1.99
38305		Drainage, lymph node lesion	4.61	6.59	6.00		agree	6.00
38308		Incision of lymph channels	4.95	7.35	6.45		agree	6.45
38500		Biopsy/removal, lymph nodes	2.88	3.29	3.75		agree	3.75
38500		Biopsy/removal, lymph nodes	2.88	4.58	3.75		agree	3.75
38510		Biopsy/removal, lymph nodes	4.14	6.28	6.43		agree	6.43
38520		Biopsy/removal, lymph nodes	5.12	6.93	6.67		agree	6.67
38525		Biopsy/removal, lymph nodes	4.66	5.30	6.07		agree	6.07
38530		Biopsy/removal, lymph nodes	6.13	9.58	7.98		agree	7.98
38571		Laparoscopy, lymphadenectomy	12.38	19.84	12.38		agree	12.38
38572		Laparoscopy, lymphadenectomy	14.32	23.17	16.59		agree	16.59

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TABLE 1.—FIVE-YEAR REVIEW OF WORK RELATIVE VALUE UNITS—Continued

CPT/ HCPCS code [1]	Mod	Descriptor	2000 work RVU	Requested work RVU	RUC REC	HCPAC REC	HCFA decision	Proposed work RVU
38740		Remove armpit lymph nodes	6.77	10.68	8.42		increase	10.02
38745		Remove armpit lymph nodes	8.84	12.78	11.00		increase	13.00
38746		Remove thoracic lymph nodes	4.39	N/A	4.89		agree	4.89
38760		Remove groin lymph nodes	8.74	11.35	10.88		increase	12.94
38765		Remove groin lymph nodes	16.06	18.77	19.98		agree	19.98
38780		Remove abdomen lymph nodes	16.59	N/A	16.59		agree	16.59
39010		Exploration of chest	11.79	N/A	11.79		agree	11.79
39220		Removal chest lesion	17.42	N/A	17.42		agree	17.42
39400		Visualization of chest	5.61	N/A	5.61		agree	5.61
39503		Repair of diaphragm hernia	34.85	122.75	95.00		decrease	34.85
42205		Reconstruct cleft palate	9.59	12.00	13.29		agree	13.29
43107		Removal of esophagus	28.79	N/A	40.00		agree	40.00
43112		Removal of esophagus	31.22	N/A	43.50		agree	43.50
43117		Partial removal of esophagus	30.02	N/A	40.00		agree	40.00
43122		Parital removal of esophagus	29.11	N/A	40.00		agree	40.00
43215		Esophagus endoscopy	2.60	4.91	CPT		CPT	2.60
43217		Esophagus endoscopy	2.90	3.63	2.90		agree	2.90
43219		Esophagus endoscopy	2.80	3.50	3.18		decrease	2.80
43228		Esoph endoscopy, ablation	3.77	4.72	3.77		agree	3.77
43239		Upper GI endoscopy, biopsy	2.69	2.96	2.87		decrease	2.69
43239		Upper GI endoscopy, biopsy	2.69	3.79	2.87		decrease	2.69
43244		Upper GI endoscopy/ligation	4.59	5.05	5.05		decrease	4.59
43246		Place gastrostomy tube	4.33	4.76	4.33		agree	4.33
43246		Place gastrostomy tube	4.33	5.04	4.33		agree	4.33
43247		Operative upper GI endoscopy	3.39	4.51	3.59		decrease	3.39
43249		Esoph endoscopy, dilation	2.90	5.01	3.35		decrease	2.90
43251		Operative upper GI endoscopy	3.70	4.44	3.70		agree	3.70
43255		Operative upper GI endoscopy	4.40	5.40	4.82		decrease	4.40
43258		Operative upper GI endoscopy	4.55	5.01	4.55		agree	4.55
43259		Endoscopic ultrasound exam	4.89	N/A	8.59		decrease	4.89
43263		Endo cholangiopancreatograph	6.19	7.12	7.29		decrease	6.19
43265		Endo cholangiopancreatograph	8.90	N/A	10.02		decrease	8.90
43269		Endo cholangiopancreatograph	6.04	7.50	8.21		decrease	6.04
43305		Repair esophagus and fistula	17.15	WD	(e)		(a)	17.15
43310		Repair of esophagus	25.39	50.50	CPT		CPT	25.39
43312		Repair esophagus and fistula	28.42	56.75	CPT		CPT	28.42
43320		Fuse esophagus & stomach	16.07	26.45	19.93		agree	19.93
43324		Revise esophagus & stomach	16.58	17.75	20.57		agree	20.57
43325		Revise esophagus & stomach	16.17	21.65	20.06		agree	20.06
43326		Revise esophagus & stomach	15.91	20.53	19.74		agree	19.74
43330		Repair of esophagus	15.94	15.44	19.77		agree	19.77
43331		Repair of esophagus	16.23	17.60	20.13		agree	20.13
43340		Fuse esophagus & intestine	15.81	26.72	19.61		agree	19.61
43341		Fuse esophagus & intestine	16.81	29.07	20.85		agree	20.85
43350		Surgical opening, esophagus	12.72	32.97	15.78		agree	15.78
43351		Surgical opening, esophagus	14.79	31.92	18.35		agree	18.35
43352		Surgical opening, esophagus	12.30	25.47	15.26		agree	15.26
43360		Gastrointestinal repair	28.78	61.17	35.70		agree	35.70
43361		Gastrointestinal repair	32.65	65.83	40.50		agree	40.50
43400		Ligate esophagus veins	17.09	29.96	21.20		agree	21.20
43401		Esophagus surgery for veins	17.81	34.94	22.09		agree	22.09
43405		Ligate/staple esophagus	16.13	36.67	20.01		agree	20.01
43410		Repair esophagus wound	10.86	13.65	13.47		agree	13.47
43415		Repair esophagus wound	17.06	30.45	25.00		agree	25.00
43420		Repair esophagus opening	11.57	14.10	14.35		agree	14.35
43425		Repair esophagus opening	16.95	26.93	21.03		agree	21.03
43500		Surgical opening of stomach	8.44	11.81	11.05		agree	11.05
43501		Surgical repair of stomach	15.31	20.44	20.04		agree	20.04
43502		Surgical repair of stomach	17.67	21.20	23.13		agree	23.13
43510		Surgical opening of stomach	9.99	18.81	13.08		agree	13.08
43520		Incision of pyloric muscle	7.63	8.88	9.99		agree	9.99
43605		Biopsy of stomach	9.15	10.41	11.98		agree	11.98
43610		Excision of stomach lesion	11.15	17.37	14.60		agree	14.60
43611		Excision of stomach lesion	13.63	23.82	17.84		agree	17.84
43620		Removal of stomach	22.54	33.61	30.04		agree	30.04
43621		Removal of stomach	23.06	35.55	30.73		agree	30.73

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TABLE 1.—FIVE-YEAR REVIEW OF WORK RELATIVE VALUE UNITS—Continued

CPT/ HCPCS code [1]	Mod	Descriptor	2000 work RVU	Requested work RVU	RUC REC	HCPAC REC	HCFA decision	Proposed work RVU
43622		Removal of stomach	24.41	35.56	32.53		agree	32.53
43631		Removal of stomach, partial	19.66	23.28	22.59		agree	22.59
43632		Removal of stomach, partial	19.66	25.92	22.59		agree	22.59
43633		Removal of stomach, partial	20.10	27.68	23.10		agree	23.10
43634		Removal of stomach, partial	21.86	34.19	25.12		agree	25.12
43638		Removal of stomach, partial	21.76	29.96	29.00		agree	29.00
43638		Removal of stomach, partial	21.76	39.80	29.00		agree	29.00
43639		Removal of stomach, partial	22.25	39.80	29.65		agree	29.65
43640		Vagotomy & pylorus repair	14.81	17.32	17.02		agree	17.02
43641		Vagotomy & pylorus repair	15.03	21.34	17.27		agree	17.27
43651		Laparoscopy, vagus nerve	10.15	15.17	10.15		agree	10.15
43652		Laparoscopy, vagus nerve	12.15	19.21	12.15		agree	12.15
43800		Reconstruction of pylorus	10.46	11.86	13.69		agree	13.69
43810		Fusion of stomach and bowel	11.19	13.81	14.65		agree	14.65
43820		Fusion of stomach and bowel	11.74	15.78	15.37		agree	15.37
43825		Fusion of stomach and bowel	14.68	18.16	19.22		agree	19.22
43830		Place gastrostomy tube	7.28	7.28	9.53		agree	9.53
43832		Place gastrostomy tube	11.92	11.92	15.60		agree	15.60
43840		Repair of stomach lesion	11.89	11.89	15.56		agree	15.56
43842		Gastroplasty for obesity	14.71	17.14	18.47		agree	18.47
43843		Gastroplasty for obesity	14.85	20.62	18.65		agree	18.65
43846		Gastric bypass for obesity	19.15	23.43	24.05		agree	24.05
43847		Gastric bypass for obesity	21.44	29.95	26.92		agree	26.92
43848		Revision gastroplasty	23.41	27.07	29.39		agree	29.39
43850		Revise stomach-bowel fusion	19.69	23.27	24.72		agree	24.72
43855		Revise stomach-bowel fusion	20.83	24.15	26.16		agree	26.16
43860		Revise stomach-bowel fusion	19.91	26.08	25.00		agree	25.00
43865		Revise stomach-bowel fusion	21.12	27.30	26.52		agree	26.52
43870		Repair stomach opening	7.40	9.65	9.69		agree	9.69
43880		Repair stomach-bowel fistula	19.63	23.60	24.65		agree	24.65
44005		Freeing of bowel adhesion	13.84	15.43	16.23		agree	16.23
44010		Incision of small bowel	10.68	15.90	12.52		agree	12.52
44020		Exploration of small bowel	11.93	15.04	13.99		agree	13.99
44021		Decompress small bowel	12.01	15.18	14.08		agree	14.08
44025		Incision of large bowel	12.18	14.08	14.28		agree	14.28
44050		Reduce bowel obstruction	11.40	13.75	14.03		agree	14.03
44050		Reduce bowel obstruction	11.40	14.58	14.03		agree	14.03
44055		Correct malrotation of bowel	13.14	22.00	22.00		agree	22.00
44110		Excision of bowel lesion(s)	10.07	14.39	11.81		agree	11.81
44111		Excision of bowel lesion(s)	12.19	16.32	14.29		agree	14.29
44120		Removal of small intestine	14.50	15.82	17.00		agree	17.00
44125		Removal of small intestine	14.96	17.54	17.54		agree	17.54
44130		Bowel to bowel fusion	12.36	17.87	14.49		agree	14.49
44130		Bowel to bowel fusion	12.36	N/A	14.49		agree	14.49
44140		Partial removal of colon	18.35	20.94	18.35		increase	21.00
44140		Partial removal of colon	18.35	24.58	18.35		increase	21.00
44143		Partial removal of colon	20.17	30.36	20.17		increase	22.99
44144		Partial removal of colon	18.89	29.46	18.89		increase	21.53
44144		Partial removal of colon	18.89	N/A	18.89		increase	21.53
44145		Partial removal of colon	23.18	27.91	23.18		increase	26.42
44146		Partial removal of colon	24.16	30.97	24.16		increase	27.54
44147		Partial removal of colon	18.17	N/A	18.17		increase	20.71
44150		Removal of colon	21.01	27.41	21.01		increase	23.95
44151		Removal of colon/ileostomy	20.04	32.89	20.04		increase	26.88
44151		Removal of colon/ileostomy	20.04	N/A	20.04		increase	26.88
44152		Removal of colon/ileostomy	24.41	33.61	24.41		increase	27.83
44153		Removal of colon/ileostomy	26.83	33.11	26.83		increase	30.59
44155		Removal of colon/ileostomy	24.44	33.61	24.44		increase	27.86
44156		Removal of colon/ileostomy	23.01	36.27	23.01		increase	30.79
44156		Removal of colon/ileostomy	23.01	N/A	23.01		increase	30.79
44160		Removal of colon	15.88	17.45	18.62		agree	18.62
44200		Laparoscopy, enterolysis	14.44	16.11	14.44		agree	14.44
44300		Open bowel to skin	8.88	13.09	12.11		agree	12.11
44310		Ileostomy/jejunostomy	11.70	18.14	15.95		agree	15.95
44312		Revision of ileostomy	5.88	6.79	8.02		agree	8.02
44314		Revision of ileostomy	11.04	14.45	15.05		agree	15.05

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TABLE 1.—FIVE-YEAR REVIEW OF WORK RELATIVE VALUE UNITS—Continued

CPT/ HCPCS code [1]	Mod	Descriptor	2000 work RVU	Requested work RVU	RUC REC	HCPAC REC	HCFA decision	Proposed work RVU
44316		Devise bowel pouch	15.47	26.57	21.09		agree	21.09
44320		Colostomy	12.94	18.84	17.64		agree	17.64
44340		Revision of colostomy	5.66	6.79	7.72		agree	7.72
44345		Revision of colostomy	11.32	14.45	15.43		agree	15.43
44346		Revision of colostomy	12.46	17.19	16.99		agree	16.99
44388		Colon endoscopy	2.82	3.10	3.70		decrease	2.82
44389		Colonoscopy with biopsy	3.13	3.44	4.26		decrease	3.13
44390		Colonoscopy for foreign body	3.83	4.21	4.81		decrease	3.83
44391		Colonoscopy for bleeding	4.32	4.75	5.18		decrease	4.32
44392		Colonoscopy and polypectomy	3.82	4.20	4.81		decrease	3.82
44393		Colonoscopy, lesion removal	4.84	5.32	5.00		decrease	4.84
44394		Colonoscopy w/snare	4.43	4.87	4.43		agree	4.43
44394		Colonoscopy w/snare	4.43	N/A	4.43		agree	4.43
44602		Suture, small intestine	10.61	15.26	11.91		increase	16.03
44603		Suture, small intestine	14.00	19.50	15.72		increase	18.66
44604		Suture, large intestine	14.28	16.59	16.03		agree	16.03
44605		Repair of bowel lesion	15.37	25.03	17.25		increase	19.53
44615		Intestinal stricturoplasty	14.19	18.97	15.93		agree	15.93
44620		Repair bowel opening	10.87	14.99	12.20		agree	12.20
44625		Repair bowel opening	13.41	16.79	15.05		agree	15.05
44626		Repair bowel opening	22.59	24.43	25.36		agree	25.36
44640		Repair bowel-skin fistula	14.83	22.29	16.65		increase	21.65
44650		Repair bowel fistula	15.25	22.29	17.12		increase	22.27
44660		Repair bowel-bladder fistula	14.63	24.70	16.42		increase	21.36
44661		Repair bowel-bladder fistula	16.99	25.63	19.07		increase	24.81
44680		Surgical revision, intestine	13.72	21.32	15.40		agree	15.40
44700		Suspend bowel w/prosthesis	14.35	19.35	16.11		agree	16.11
44800		Excision of bowel pouch	11.23	10.85	11.23		agree	11.23
44820		Excision of mesentery lesion	10.31	11.23	12.09		agree	12.09
44850		Repair of mesentery	9.57	12.00	10.74		agree	10.74
44900		Drain app abscess, open	8.82	11.79	10.14		agree	10.14
44950		Appendectomy	8.70	8.37	10.00		agree	10.00
44960		Appendectomy	10.74	13.67	12.34		agree	12.34
44970		Laparoscopy, appendectomy	8.70	10.26	8.70		agree	8.70
45000		Drainage of pelvic abscess	4.52	10.29	3.88		increase	4.52
45020		Drainage of rectal abscess	4.72	7.71	4.05		increase	4.72
45100		Biopsy of rectum	3.68	4.34	3.16		increase	3.68
45108		Removal of anorectal lesion	4.76	5.25	4.09		increase	4.76
45110		Removal of rectum	23.80	29.53	28.00		agree	28.00
45111		Partial removal of rectum	16.48	N/A	16.48		agree	16.48
45112		Removal of rectum	25.96	32.46	30.54		agree	30.54
45113		Partial proctectomy	25.99	33.11	30.58		agree	30.58
45114		Partial removal of rectum	23.22	29.46	27.32		agree	27.32
45116		Partial removal of rectum	20.89	21.98	24.58		agree	24.58
45119		Remove rectum w/reservoir	26.21	31.60	30.84		agree	30.84
45120		Removal of rectum	24.60	31.09	24.60		agree	24.60
45121		Removal of rectum and colon	27.04	32.14	27.04		agree	27.04
45123		Partial proctectomy	14.20	22.51	16.71		agree	16.71
45126		Pelvic exenteration	38.39	47.99	45.16		agree	45.16
45130		Excision of rectal prolapse	13.97	14.26	16.44		agree	16.44
45135		Excision of rectal prolapse	16.39	30.14	19.28		agree	19.28
45160		Excision of rectal lesion	13.02	19.86	15.32		agree	15.32
45170		Excision of rectal lesion	9.77	12.81	11.49		agree	11.49
45190		Destruction, rectal tumor	8.28	9.09	9.74		agree	9.74
45305		Proctosigmoidoscopy & biopsy	1.01	1.22	1.01		agree	1.01
45309		Proctosigmoidoscopy	2.01	2.45	2.01		agree	2.01
45330		Diagnostic sigmoidoscopy	0.96	1.39	0.96		agree	0.96
45337		Sigmoidoscopy & decompress	2.36	N/A	2.36		agree	2.36
45339		Sigmoidoscopy	3.14	N/A	3.14		agree	3.14
45378		Diagnostic colonoscopy	3.70	4.66	3.70		agree	3.70
45380		Colonoscopy and biopsy	4.01	5.01	4.44		decrease	4.01
45383		Lesion removal colonoscopy	5.87	7.34	5.87		agree	5.87
45384		Colonoscopy	4.70	5.88	4.70		agree	4.70
45385		Lesion removal colonoscopy	5.31	6.64	5.31		agree	5.31
45505		Repair of rectum	6.02	7.57	7.58		agree	7.58
45540		Correct rectal prolapse	12.92	17.79	16.27		agree	16.27

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TABLE 1.—FIVE-YEAR REVIEW OF WORK RELATIVE VALUE UNITS—Continued

CPT/ HCPCS code [1]	Mod	Descriptor	2000 work RVU	Requested work RVU	RUC REC	HCPAC REC	HCFA decision	Proposed work RVU
45541		Correct rectal prolapse	10.64	13.23	13.40		agree	13.40
45550		Repair rectum/remove sigmoid	18.26	27.91	23.00		agree	23.00
45560		Repair of rectocele	8.40	7.70	10.58		agree	10.58
45562		Exploration/repair of rectum	12.21	12.09	15.38		agree	15.38
45563		Exploration/repair of rectum	18.63	21.50	23.47		agree	23.47
45800		Repair rect/bladder fistula	14.11	14.36	17.77		agree	17.77
45805		Repair fistula w/colostomy	16.50	20.94	20.78		agree	20.78
45820		Repair rectourethral fistula	14.67	13.81	18.48		agree	18.48
45825		Repair fistula w/colostomy	16.87	20.38	21.25		agree	21.25
45900		Reduction of rectal prolapse	1.83	3.27	2.61		agree	2.61
45905		Dilation of anal sphincter	1.61	3.15	2.30		agree	2.30
45910		Dilation of rectal narrowing	1.96	3.23	2.80		agree	2.80
45910		Dilation of rectal narrowing	1.96	N/A	2.80		agree	2.80
45915		Remove rectal obstruction	2.20	3.58	3.14		agree	3.14
46040		Incision of rectal abscess	4.96	5.53	4.26		increase	4.96
46045		Incision of rectal abscess	4.32	5.38	3.71		increase	4.32
46060		Incision of rectal abscess	5.69	8.55	4.89		increase	5.69
46083		Incise external hemorrhoid	1.40	1.52	1.40		agree	1.40
46083		Incise external hemorrhoid	1.40	2.34	1.40		agree	1.40
46221		Ligation of hemorrhoid(s)	1.43	1.94	2.04		agree	2.04
46230		Removal of anal tabs	2.57	1.94	2.57		agree	2.57
46250		Hemorrhoidectomy	4.53	4.13	3.89		agree	3.89
46255		Hemorrhoidectomy	5.36	4.98	4.60		agree	4.60
46257		Remove hemorrhoids & fissure	6.28	5.43	5.40		agree	5.40
46258		Remove hemorrhoids & fistula	6.67	5.86	5.73		agree	5.73
46258		Remove hemorrhoids & fistula	6.67	N/A	5.73		agree	5.73
46260		Hemorrhoidectomy	7.42	6.18	6.37		agree	6.37
46261		Remove hemorrhoids & fissure	8.24	7.11	7.08		agree	7.08
46262		Remove hemorrhoids & fistula	8.73	7.11	7.50		agree	7.50
46270		Removal of anal fistula	3.72	4.28	3.20		increase	3.72
46275		Removal of anal fistula	4.56	5.18	3.92		increase	4.56
46280		Removal of anal fistula	5.98	5.95	5.14		increase	5.98
46288		Repair anal fistula	7.13	8.08	6.13		increase	7.13
46320		Removal of hemorrhoid clot	1.61	1.52	1.61		agree	1.61
46320		Removal of hemorrhoid clot	1.61	2.63	1.61		agree	1.61
46700		Repair of anal stricture	7.25	10.22	9.13		agree	9.13
46705		Repair of anal stricture	7.17	6.90	6.90		agree	6.90
46715		Repair of anovaginal fistula	7.46	7.20	7.20		agree	7.20
46716		Repair of anovaginal fistula	12.15	15.15	15.07		agree	15.07
46730		Construction of absent anus	21.57	25.50	26.75		agree	26.75
46735		Construction of absent anus	25.94	36.00	32.17		agree	32.17
46740		Construction of absent anus	23.11	35.00	30.00		agree	30.00
46742		Repair of imperforated anus	29.67	38.00	35.80		agree	35.80
46744		Repair of cloacal anomaly	33.21	52.00	52.63		agree	52.63
46746		Repair of cloacal anomaly	36.74	53.50	58.22		agree	58.22
46748		Repair of cloacal anomaly	40.52	55.00	64.21		agree	64.21
46750		Repair of anal sphincter	8.14	10.99	10.25		agree	10.25
46753		Reconstruction of anus	6.58	5.45	8.29		agree	8.29
46754		Removal of suture from anus	1.54	2.93	2.20		agree	2.20
46760		Repair of anal sphincter	11.46	21.77	14.43		agree	14.43
46761		Repair of anal sphincter	10.99	12.15	13.84		agree	13.84
46762		Implant artificial sphincter	10.09	15.01	12.71		agree	12.71
46900		Destruction, anal lesion(s)	1.91	1.32	1.91		agree	1.91
46910		Destruction, anal lesion(s)	1.86	1.72	1.86		agree	1.86
46916		Cryosurgery, anal lesion(s)	1.86	1.72	1.86		agree	1.86
46917		Laser surgery, anal lesions	1.86	3.32	1.86		agree	1.86
46922		Excision of anal lesion(s)	1.86	3.12	1.86		agree	1.86
46924		Destruction, anal lesion(s)	2.76	3.93	2.76		agree	2.76
46924		Destruction, anal lesion(s)	2.76	4.24	2.76		agree	2.76
46934		Destruction of hemorrhoids	4.08	4.63	3.51		agree	3.51
46935		Destruction of hemorrhoids	2.43	4.17	2.43		agree	2.43
46936		Destruction of hemorrhoids	4.30	5.12	3.69		agree	3.69
46940		Treatment of anal fissure	2.32	1.71	2.32		agree	2.32
46942		Treatment of anal fissure	2.04	1.71	2.04		agree	2.04
46945		Ligation of hemorrhoids	2.14	2.37	1.84		agree	1.84
46946		Ligation of hemorrhoids	3.00	2.57	2.58		agree	2.58

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TABLE 1.—FIVE-YEAR REVIEW OF WORK RELATIVE VALUE UNITS—Continued

CPT/ HCPCS code [1]	Mod	Descriptor	2000 work RVU	Requested work RVU	RUC REC	HCPAC REC	HCFA decision	Proposed work RVU
47010		Open drainage, liver lesion	10.28	16.25	16.01		agree	16.01
47015		Inject/aspirate liver cyst	9.70	19.15	15.11		agree	15.11
47100		Wedge biopsy of liver	7.49	9.24	11.67		agree	11.67
47120		Partial removal of liver	22.79	39.57	35.50		agree	35.50
47122		Extensive removal of liver	35.39	53.02	55.13		agree	55.13
47125		Partial removal of liver	31.58	44.50	49.19		agree	49.19
47130		Partial removal of liver	34.25	46.45	53.35		agree	53.35
47134		Partial removal, donor liver	39.15	49.00	CPT		CPT	39.15
47300		Surgery for liver lesion	9.68	12.45	15.08		agree	15.08
47350		Repair liver wound	12.56	19.16	19.56		agree	19.56
47360		Repair liver wound	17.28	28.64	26.92		agree	26.92
47361		Repair liver wound	30.25	40.14	47.12		agree	47.12
47362		Repair liver wound	11.88	24.94	18.51		agree	18.51
47400		Incision of liver duct	20.86	35.12	32.49		agree	32.49
47420		Incision of bile duct	16.72	27.63	19.88		agree	19.88
47425		Incision of bile duct	16.68	32.49	19.83		agree	19.83
47460		Incise bile duct sphincter	15.17	25.74	18.04		agree	18.04
47480		Incision of gallbladder	9.10	15.26	10.82		agree	10.82
47562		Laparoscopic cholecystectomy	11.09	9.59	11.09		agree	11.09
47563		Laparoscopic cholecystectomy	11.94	12.40	11.94		agree	11.94
47564		Laparo cholecystectomy/explr	14.23	17.67	14.23		agree	14.23
47570		Laparo cholecystoenterostomy	12.58	18.62	12.58		agree	12.58
47600		Removal of gallbladder	11.42	11.67	13.58		agree	13.58
47605		Removal of gallbladder	12.36	13.26	14.69		agree	14.69
47610		Removal of gallbladder	15.83	17.97	18.82		agree	18.82
47612		Removal of gallbladder	15.80	22.68	18.78		agree	18.78
47620		Removal of gallbladder	17.36	24.70	20.64		agree	20.64
47701		Bile duct revision	27.81	36.50	27.81		agree	27.81
47711		Excision of bile duct tumor	19.37	31.38	23.03		agree	23.03
47712		Excision of bile duct tumor	25.44	38.58	30.24		agree	30.24
47715		Excision of bile duct cyst	15.81	32.81	18.80		agree	18.80
47716		Fusion of bile duct cyst	13.83	19.34	16.44		agree	16.44
47720		Fuse gallbladder & bowel	13.38	18.16	15.91		agree	15.91
47721		Fuse upper gi structures	16.08	21.91	19.12		agree	19.12
47740		Fuse gallbladder & bowel	15.54	20.63	18.48		agree	18.48
47741		Fuse gallbladder & bowel	17.95	24.39	21.34		agree	21.34
47760		Fuse bile ducts and bowel	21.74	21.91	25.85		agree	25.85
47765		Fuse liver ducts & bowel	20.93	30.62	24.88		agree	24.88
47780		Fuse bile ducts and bowel	22.29	26.86	26.50		agree	26.50
47785		Fuse bile ducts and bowel	26.23	36.32	31.18		agree	31.18
47800		Reconstruction of bile ducts	19.60	26.89	23.30		agree	23.30
47801		Placement, bile duct support	12.76	23.47	15.17		agree	15.17
47802		Fuse liver duct & intestine	18.13	34.11	21.55		agree	21.55
47900		Suture bile duct injury	16.74	20.50	19.90		agree	19.90
48000		Drainage of abdomen	14.91	40.79	28.07		agree	28.07
48001		Placement of drain, pancreas	18.83	55.20	35.45		agree	35.45
48005		Resect/debride pancreas	22.40	57.70	42.17		agree	42.17
48020		Removal of pancreatic stone	14.22	23.50	15.70		agree	15.70
48100		Biopsy of pancreas	11.08	14.57	12.23		agree	12.23
48120		Removal of pancreas lesion	14.36	26.05	15.85		agree	15.85
48140		Partial removal of pancreas	20.78	28.60	22.94		agree	22.94
48145		Partial removal of pancreas	21.76	34.32	24.02		agree	24.02
48146		Pancreatectomy	23.91	45.57	26.40		agree	26.40
48148		Removal of pancreatic duct	15.71	25.00	17.34		agree	17.34
48150		Partial removal of pancreas	43.48	54.73	48.00		agree	48.00
48150		Partial removal of pancreas	43.48	54.75	48.00		agree	48.00
48152		Pancreatectomy	39.63	39.63	43.75		agree	43.75
48153		Pancreatectomy	43.38	54.73	47.89		agree	47.89
48154		Pancreatectomy	39.95	51.80	44.10		agree	44.10
48155		Removal of pancreas	22.32	44.70	24.64		agree	24.64
48180		Fuse pancreas and bowel	22.39	32.52	24.72		agree	24.72
48500		Surgery of pancreas cyst	13.84	18.99	15.28		agree	15.28
48510		Drain pancreatic pseudocyst	12.96	16.08	14.31		agree	14.31
48520		Fuse pancreas cyst and bowel	14.12	19.68	15.59		agree	15.59
48540		Fuse pancreas cyst and bowel	17.86	21.28	19.72		agree	19.72
48545		Pancreatorrhaphy	16.47	33.39	18.18		agree	18.18

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TABLE 1.—FIVE-YEAR REVIEW OF WORK RELATIVE VALUE UNITS—Continued

CPT/ HCPCS code [1]	Mod	Descriptor	2000 work RVU	Requested work RVU	RUC REC	HCPAC REC	HCFA decision	Proposed work RVU
48547		Duodenal exclusion	23.40	41.76	25.83		agree	25.83
49000		Exploration of abdomen	11.68	13.42	11.68		agree	11.68
49002		Reopening of abdomen	10.49	12.67	10.49		agree	10.49
49010		Exploration behind abdomen	12.28	15.06	12.28		agree	12.28
49020		Drain abdominal abscess	16.79	28.33	20.73		increase	22.84
49040		Drain, open, abdom abscess	9.94	23.60	12.27		increase	13.52
49060		Drain, open, retrop abscess	11.66	19.52	14.40		increase	15.86
49085		Remove abdomen foreign body	8.93	14.23	11.03		increase	12.14
49200		Removal of abdominal lesion	10.25	12.19	10.25		agree	10.25
49201		Removal of abdominal lesion	14.84	16.27	14.84		agree	14.84
49215		Excise sacral spine tumor	22.36	24.96	33.50		agree	33.50
49215		Excise sacral spine tumor	22.36	30.00	33.50		agree	33.50
49220		Multiple surgery, abdomen	14.88	17.39	14.88		agree	14.88
49255		Removal of omentum	11.14	13.42	11.14		agree	11.14
49320		Diag laparo separate proc	5.10	5.95	5.10		agree	5.10
49321		Laparoscopy; biopsy	5.40	N/A	5.40		agree	5.40
49322		Laparoscopy; aspiration	5.70	N/A	5.70		agree	5.70
49421		Insert abdominal drain	5.54	6.99	5.54		agree	5.54
49422		Remove perm cannula/catheter	6.25	6.35	6.25		agree	6.25
49425		Insert abdomen-venous drain	11.37	13.82	11.37		agree	11.37
49426		Revise abdomen-venous shunt	9.63	11.10	9.63		agree	9.63
49428		Ligation of shunt	2.38	5.38	6.06		agree	6.06
49429		Removal of shunt	7.40	9.57	7.40		agree	7.40
49495		Repair inguinal hernia, init	5.89	6.96	CPT		CPT	5.89
49495		Repair inguinal hernia, init	5.89	12.50	CPT		CPT	5.89
49496		Repair inguinal hernia, init	8.79	10.56	CPT		CPT	8.79
49496		Repair inguinal hernia, init	8.79	14.00	CPT		CPT	8.79
49500		Repair inguinal hernia	4.68	7.61	5.48		agree	5.48
49501		Repair inguinal hernia, init	7.58	9.26	8.88		agree	8.88
49505		Repair inguinal hernia	6.49	8.31	7.60		agree	7.60
49505		Repair inguinal hernia	6.49	11.50	7.60		agree	7.60
49507		Repair inguinal hernia	8.17	11.38	9.57		agree	9.57
49520		Rerepair inguinal hernia	8.22	11.02	9.63		agree	9.63
49521		Repair inguinal hernia, rec	10.22	13.97	11.97		agree	11.97
49525		Repair inguinal hernia	7.32	8.36	8.57		agree	8.57
49540		Repair lumbar hernia	8.87	8.52	10.39		agree	10.39
49550		Repair femoral hernia	7.37	8.36	8.63		agree	8.63
49553		Repair femoral hernia, init	8.06	10.31	9.44		agree	9.44
49555		Repair femoral hernia	7.71	8.50	9.03		agree	9.03
49557		Repair femoral hernia, recur	9.52	11.82	11.15		agree	11.15
49560		Repair abdominal hernia	9.88	11.69	11.57		agree	11.57
49561		Repair incisional hernia	12.17	15.67	14.25		agree	14.25
49565		Rerepair abdominal hernia	9.88	14.03	11.57		agree	11.57
49566		Repair incisional hernia	12.30	16.43	14.40		agree	14.40
49570		Repair epigastric hernia	4.86	7.00	5.69		agree	5.69
49572		Repair epigastric hernia	5.75	9.77	6.73		agree	6.73
49580		Repair umbilical hernia	3.51	5.71	4.11		agree	4.11
49582		Repair umbilical hernia	5.68	9.99	6.65		agree	6.65
49585		Repair umbilical hernia	5.32	5.71	6.23		agree	6.23
49587		Repair umbilical hernia	6.46	9.34	7.56		agree	7.56
49590		Repair abdominal hernia	7.29	9.54	8.54		agree	8.54
49605		Repair umbilical lesion	22.66	97.62	76.00		decrease	22.66
49606		Repair umbilical lesion	18.60	21.31	18.60		agree	18.60
49650		Laparo hernia repair initial	6.27	7.66	6.27		agree	6.27
49651		Laparo hernia repair recur	8.24	7.88	8.24		agree	8.24
49900		Repair of abdominal wall	12.28	16.92	12.28		agree	12.28
49905		Omental flap	6.55	17.79	CPT		CPT	6.55
50200		Biopsy of kidney	2.63	N/A	CPT		CPT	2.63
50230		Removal of kidney	22.07	N/A	CPT		CPT	22.07
51595		Remove bladder/revise tract	37.14	N/A	37.14		agree	37.14
51596		Remove bladder/create pouch	39.52	N/A	39.52		agree	39.52
52300		Cystoscopy and treatment	5.31	WD	(e)		(a)	5.31
52327		Cystoscopy, inject material	5.19	WD	(e)		(a)	5.19
52340		Cystoscopy and treatment	9.68	WD	(e)		(a)	9.68
56515		Destruction, vulva lesion(s)	1.88	3.09	2.76		agree	2.76
56740		Remove vagina gland lesion	3.76	5.74	4.57		agree	4.57

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TABLE 1.—FIVE-YEAR REVIEW OF WORK RELATIVE VALUE UNITS—Continued

CPT/ HCPCS code [1]	Mod	Descriptor	2000 work RVU	Requested work RVU	RUC REC	HCPAC REC	HCFA decision	Proposed work RVU
57100		Biopsy of vagina	0.97	1.90	1.20		agree	1.20
57130		Remove vagina lesion	2.43	5.67	2.43		agree	2.43
57292		Construct vagina with graft	13.09	N/A	13.09		agree	13.09
57307		Fistula repair & colostomy	15.93	20.24	15.93		agree	15.93
57410		Pelvic examination	1.75	4.08	1.75		agree	1.75
57505		Endocervical curettage	1.14	0.97	1.14		agree	1.14
57555		Remove cervix/repair vagina	8.95	WD	(e)		(a)	8.95
58150		Total hysterectomy	15.24	17.75	15.24		agree	15.24
58152		Total hysterectomy	15.09	20.60	20.60		agree	20.60
58260		Vaginal hysterectomy	12.20	12.98	12.98		agree	12.98
58262		Vaginal hysterectomy	13.99	17.88	14.77		agree	14.77
58263		Vaginal hysterectomy	15.28	21.26	16.06		agree	16.06
58267		Hysterectomy & vagina repair	15.00	17.55	17.04		agree	17.04
58270		Hysterectomy & vagina repair	13.48	15.58	14.26		agree	14.26
58275		Hysterectomy/revise vagina	14.98	N/A	15.76		agree	15.76
58280		Hysterectomy/revise vagina	15.41	N/A	17.01		agree	17.01
58285		Extensive hysterectomy	18.57	N/A	22.26		agree	22.26
58323		Sperm washing	0.23	0.55	0.23		agree	0.23
58400		Suspension of uterus	6.36	11.68	6.36		agree	6.36
58600		Division of fallopian tube	3.84	4.60	5.60		agree	5.60
58605		Division of fallopian tube	3.34	4.60	5.00		agree	5.00
58611		Ligate oviduct(s) add-on	0.63	N/A	1.45		agree	1.45
58700		Removal of fallopian tube	6.49	11.68	12.05		agree	12.05
58740		Revise fallopian tube(s)	5.83	11.29	14.00		agree	14.00
58805		Drainage of ovarian cyst(s)	5.88	11.68	5.88		agree	5.88
58820		Drain ovary abscess, open	4.22	6.03	4.22		agree	4.22
58825		Transposition, ovary(s)	6.13	11.68	10.98		agree	10.98
58920		Partial removal of ovary(s)	6.78	11.68	11.36		agree	11.36
58950		Resect ovarian malignancy	15.27	16.93	16.93		agree	16.93
58951		Resect ovarian malignancy	21.81	28.99	22.38		agree	22.38
59150		Treat ectopic pregnancy	6.89	11.67	11.67		agree	11.67
59151		Treat ectopic pregnancy	7.86	11.49	11.49		agree	11.49
59812		Treatment of miscarriage	3.25	4.01	4.01		agree	4.01
59870		Evacuate mole of uterus	4.28	5.00	6.01		agree	6.01
60100		Biopsy of thyroid	0.97	1.88	1.56		agree	1.56
60220		Partial removal of thyroid	10.53	11.82	11.90		agree	11.90
60220		Partial removal of thyroid	10.53	14.24	11.90		agree	11.90
60252		Removal of thyroid	18.20	22.32	20.57		agree	20.57
60254		Extensive thyroid surgery	23.88	27.43	26.99		agree	26.99
60260		Repeat thyroid surgery	15.46	18.83	17.47		agree	17.47
60270		Removal of thyroid	17.94	23.05	20.27		agree	20.27
60271		Removal of thyroid	14.89	18.68	16.83		agree	16.83
60280		Remove thyroid duct lesion	6.08	WD	(e)		(a)	6.08
60540		Explore adrenal gland	17.03	20.53	17.03		agree	17.03
60545		Explore adrenal gland	19.88	25.66	19.88		agree	19.88
62263		Lysis epidural adhesions	6.14	7.20	7.20		(b)	6.14
62310		Inject spine c/t	1.91	1.95	2.20		(b)	1.91
62311		Inject spine l/s (cd)	1.54	1.57	1.78		(b)	1.54
62318		Inject spine w/cath, c/t	2.04	2.26	2.35		(b)	2.04
62319		Inject spine w/cath l/s (cd)	1.87	1.88	2.15		(b)	1.87
65855		Laser surgery of eye	4.30	N/A	3.85		agree	3.85
66170		Glaucoma surgery	12.16	WD	(e)		(a)	12.16
66172		Incision of eye	15.04	WD	(e)		(a)	15.04
66180		Implant eye shunt	14.55	N/A	14.55		agree	14.55
66986		Exchange lens prosthesis	12.28	N/A	12.28		agree	12.28
67028		Injection eye drug	2.52	N/A	2.52		agree	2.52
67108		Repair detached retina	20.82	WD	(e)		(a)	20.82
67218		Treatment of retinal lesion	13.52	N/A	18.53		agree	18.53
67904		Repair eyelid defect	6.26	N/A	6.26		agree	6.26
69000		Drain external ear lesion	1.45	WD	(e)		(a)	1.45
69005		Drain external ear lesion	2.11	WD	(e)		(a)	2.11
69020		Drain outer ear canal lesion	1.48	WD	(e)		(a)	1.48
69100		Biopsy of external ear	0.81	WD	(e)		(a)	0.81
69105		Biopsy of external ear canal	0.85	WD	(e)		(a)	0.85
69110		Remove external ear, partial	3.44	WD	(e)		(a)	3.44
69120		Removal of external ear	4.05	WD	(e)		(a)	4.05

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TABLE 1.—FIVE-YEAR REVIEW OF WORK RELATIVE VALUE UNITS—Continued

CPT/ HCPCS code [1]	Mod	Descriptor	2000 work RVU	Requested work RVU	RUC REC	HCPAC REC	HCFA decision	Proposed work RVU
69140		Remove ear canal lesion(s)	7.97	WD	(e)		(a)	7.97
69145		Remove ear canal lesion(s)	2.62	WD	(e)		(a)	2.62
69150		Extensive ear canal surgery	13.43	WD	(e)		(a)	13.43
69155		Extensive ear/neck surgery	20.80	WD	(e)		(a)	20.80
69200		Clear outer ear canal	0.77	WD	(e)		(a)	0.77
69205		Clear outer ear canal	1.20	WD	(e)		(a)	1.20
69210		Remove impacted ear wax	0.61	WD	(e)		(a)	0.61
69220		Clean out mastoid cavity	0.83	WD	(e)		(a)	0.83
69222		Clean out mastoid cavity	1.40	WD	(e)		(a)	1.40
69300		Revise external ear	6.36	WD	(e)		(a)	6.36
69310		Rebuild outer ear canal	10.79	WD	(e)		(a)	10.79
69320		Rebuild outer ear canal	16.96	WD	(e)		(a)	16.96
69400		Inflate middle ear canal	0.83	WD	(e)		(a)	0.83
69401		Inflate middle ear canal	0.63	WD	(e)		(a)	0.63
69405		Catheterize middle ear canal	2.63	WD	(e)		(a)	2.63
69410		Inset middle ear (baffle)	0.33	WD	(e)		(a)	0.33
69420		Incision of eardrum	1.33	WD	(e)		(a)	1.33
69421		Incision of eardrum	1.73	WD	(e)		(a)	1.73
69424		Remove ventilating tube	0.85	WD	(e)		(a)	0.85
69433		Create eardrum opening	1.52	WD	(e)		(a)	1.52
69436		Create eardrum opening	1.96	WD	(e)		(a)	1.96
69440		Exploration of middle ear	7.57	WD	(e)		(a)	7.57
69450		Eardrum revision	5.57	WD	(e)		(a)	5.57
69501		Mastoidectomy	9.07	WD	(e)		(a)	9.07
69502		Mastoidectomy	12.38	WD	(e)		(a)	12.38
69505		Remove mastoid structures	12.99	WD	(e)		(a)	12.99
69511		Extensive mastoid surgery	13.52	WD	(e)		(a)	13.52
69530		Extensive mastoid surgery	19.19	WD	(e)		(a)	19.19
69535		Remove part of temporal bone	36.14	WD	(e)		(a)	36.14
69540		Remove ear lesion	1.20	WD	(e)		(a)	1.20
69550		Remove ear lesion	10.99	WD	(e)		(a)	10.99
69552		Remove ear lesion	19.46	WD	(e)		(a)	19.46
69554		Remove ear lesion	33.16	WD	(e)		(a)	33.16
69601		Mastoid surgery revision	13.24	WD	(e)		(a)	13.24
69602		Mastoid surgery revision	13.58	WD	(e)		(a)	13.58
69603		Mastoid surgery revision	14.02	WD	(e)		(a)	14.02
69604		Mastoid surgery revision	14.02	WD	(e)		(a)	14.02
69605		Remove mastoid structures	18.49	WD	(e)		(a)	18.49
69610		Repair of eardrum	4.43	WD	(e)		(a)	4.43
69620		Repair of eardrum	5.89	WD	(e)		(a)	5.89
69631		Rebuild eardrum structures	9.86	WD	(e)		(a)	9.86
69632		Rebuild eardrum structures	12.75	WD	(e)		(a)	12.75
69633		Rebuild eardrum structures	12.10	WD	(e)		(a)	12.10
69635		Repair eardrum structures	13.33	WD	(e)		(a)	13.33
69636		Rebuild eardrum structures	15.22	WD	(e)		(a)	15.22
69637		Rebuild eardrum structures	15.11	WD	(e)		(a)	15.11
69641		Revise middle ear & mastoid	12.71	WD	(e)		(a)	12.71
69642		Revise middle ear & mastoid	16.84	WD	(e)		(a)	16.84
69643		Revise middle ear & mastoid	15.32	WD	(e)		(a)	15.32
69644		Revise middle ear & mastoid	16.97	WD	(e)		(a)	16.97
69645		Revise middle ear & mastoid	16.38	WD	(e)		(a)	16.38
69646		Revise middle ear & mastoid	17.99	WD	(e)		(a)	17.99
69650		Release middle ear bone	9.66	WD	(e)		(a)	9.66
69660		Revise middle ear bone	11.90	WD	(e)		(a)	11.90
69661		Revise middle ear bone	15.74	WD	(e)		(a)	15.74
69662		Revise middle ear bone	15.44	WD	(e)		(a)	15.44
69666		Repair middle ear structures	9.75	WD	(e)		(a)	9.75
69667		Repair middle ear structures	9.76	WD	(e)		(a)	9.76
69670		Remove mastoid air cells	11.51	WD	(e)		(a)	11.51
69676		Remove middle ear nerve	9.52	WD	(e)		(a)	9.52
69700		Close mastoid fistula	8.23	WD	(e)		(a)	8.23
69711		Remove/repair hearing aid	10.44	WD	(e)		(a)	10.44
69720		Release facial nerve	14.38	WD	(e)		(a)	14.38
69725		Release facial nerve	25.38	WD	(e)		(a)	25.38
69740		Repair facial nerve	15.96	WD	(e)		(a)	15.96
69745		Repair facial nerve	16.69	WD	(e)		(a)	16.69

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TABLE 1.—FIVE-YEAR REVIEW OF WORK RELATIVE VALUE UNITS—Continued

CPT/ HCPCS code [1]	Mod	Descriptor	2000 work RVU	Requested work RVU	RUC REC	HCPAC REC	HCFA decision	Proposed work RVU
69801		Incise inner ear	8.56	WD	(e)		(a)	8.56
69802		Incise inner ear	13.10	WD	(e)		(a)	13.10
69805		Explore inner ear	13.82	WD	(e)		(a)	13.82
69806		Explore inner ear	12.35	WD	(e)		(a)	12.35
69820		Establish inner ear window	10.34	WD	(e)		(a)	10.34
69840		Revise inner ear window	10.26	WD	(e)		(a)	10.26
69905		Remove inner ear	11.10	WD	(e)		(a)	11.10
69910		Remove inner ear & mastoid	13.63	WD	(e)		(a)	13.63
69915		Incise inner ear nerve	21.23	WD	(e)		(a)	21.23
69930		Implant cochlear device	16.81	WD	(e)		(a)	16.81
69950		Incise inner ear nerve	25.64	WD	(e)		(a)	25.64
69955		Release facial nerve	27.04	WD	(e)		(a)	27.04
69960		Release inner ear canal	27.04	WD	(e)		(a)	27.04
69970		Remove inner ear lesion	30.04	WD	(e)		(a)	30.04
69990		Microsurgery add-on	3.47	N/A	3.47		agree	3.47
72275		Epidurography	0.76	0.83	0.83		(b)	0.76
76005		Fluoroguide for spine inject	0.60	0.60	10.60		agree	0.60
76065		X-rays, bone evaluation	0.28	0.60	0.70		agree	0.70
76090		Mammogram, one breast	0.58	0.64	0.70		agree	0.70
76091		Mammogram, both breasts	0.69	0.76	0.87		agree	0.87
76095		Stereotactic breast biopsy	1.59	3.58	1.59		agree	1.59
88170		Fine needle aspiration	1.27	3.28	1.27		agree	1.27
88171		Fine needle aspiration	1.27	2.63	1.27		agree	1.27
90901		Biofeedback train, any meth	0.41	N/A		0.41	agree	0.41
90911		Biofeedback peri/uro/rectal	0.89	N/A	0.89		agree	0.89
90935		Hemodialysis, one evaluation	1.22	N/A	CPT		CPT	1.22
90937		Hemodialysis, repeated eval	2.11	N/A	CPT		CPT	2.11
90945		Dialysis, one evaluation	1.28	N/A	CPT		CPT	1.28
90947		Dialysis, repeated eval	2.16	N/A	CPT		CPT	2.16
90989		Dialysis training, complete	0.00	N/A	CPT		CPT	0.00
90993		Dialysis training, incompl	0.00	N/A	CPT		CPT	0.00
90997		Hemoperfusion	1.84	N/A	CPT		CPT	1.84
92018		New eye exam & treatment	1.51	N/A	2.50		agree	2.50
93350		Echo transthoracic	0.78	N/A	1.48		agree	1.48
94640		Airway inhalation treatment	0.00	N/A	0.00		agree	0.00
94664		Aerosol or vapor inhalations	0.00	N/A	CPT		CPT	0.00
94665		Aerosol or vapor inhalations	0.00	N/A	CPT		CPT	0.00
96100		Psychological testing	0.00	2.00		(a)	agree	0.00
96105		Assessment of aphasia	0.00	2.00		(a)	agree	0.00
96110		Developmental test, lim	0.00	2.00		(a)	agree	0.00
96115		Neurobehavior status exam	0.00	2.20		(a)	agree	0.00
96117		Neuropsych test battery	0.00	2.20		(a)	agree	0.00
97542		Wheelchair mngmnt training	0.25	0.45		0.45	agree	0.45
99233		Subsequent hospital care	1.51	N/A	1.51		agree	1.51
99273		Confirmatory consultation	1.19	N/A	1.19		agree	1.19
99274		Confirmatory consultation	1.73	N/A	1.73		agree	1.73
99291		Critical care, first hour	3.60	4.00	4.00		agree	4.00
99291		Critical care, first hour	3.60	5.50	4.00		agree	4.00
99291		Critical care, first hour	3.60	N/A	4.00		agree	4.00
99292		Critical care, addl 30 min	1.80	2.00	2.00		agree	2.00
99292		Critical care, addl 30 min	1.80	2.77	2.00		agree	2.00
99292		Critical care, addl 30 min	1.80	N/A	2.00		agree	2.00
99295		Neonatal critical care	16.00	N/A	16.00		agree	16.00
99296		Neonatal critical care	8.00	N/A	8.00		agree	8.00
99297		Neonatal critical care	4.00	N/A	4.00		agree	4.00
99298		Neonatal critical care	2.75	N/A	2.75		agree	2.75
99436		Attendance, birth	1.50	N/A	1.50		agree	1.50
99440		Newborn resuscitation	2.93	N/A	2.93		agree	2.93
G0127		Trim nail(s)	0.11	N/A		(a)	(a)	0.11

B. Discussion of Comments by Clinical Area

1. Vascular Surgery

Comment: The Society for Vascular Surgery (SVS) and the North American Chapter of the International Society for Cardiovascular Surgery requested increases in work RVUs for 95 codes. Both groups commented that vascular surgery procedures were undervalued in the original Harvard Study and that only a small number of these RVUs have been adjusted since that time.

The SVS's recommendations were based on surveys, a full RUC survey of 39 higher volume codes and minisurveys for 56 less frequently performed codes. (The full and minisurveys included estimates for each code of pre-, intra-, and postservice times and visits as well as estimates of physician work. The effect of these recommendations would be to correct current rank-order anomalies, while avoiding creation of new rank-order anomalies.) The SVS used a building-block approach to validate the survey results for each of their codes.

RUC Recommendation

Of the 95 codes, the RUC recommended increases for 91 codes, a decrease for 1 code and no changes for 3 codes. In 60 percent of cases, the RUC recommendations to increase the work RVUs were based on physician surveys. The recommendations were based on either the 25th percentile or the median of survey responses. In almost all other cases, the RUC recommendation for a specific code work RVU was based on the work value of another comparable code. The building-block approach was used only to corroborate findings from the surveys or validate a comparison to another procedure. The following are the RUC recommendations for the codes submitted. (Please note that throughout this document the value in parentheses represents the RUC-recommended work RVUs unless they are shown in columns.)

CPT codes	Work RVUs
Family 1 Aneurysm Repairs in Abdomen	
35111	25.00
35131	25.00
35112	30.00
35132	30.00
35121	30.00
35122	35.00
35082	38.50
35103	40.50
35092	45.00
Family 2 Bypass Grafts in the Abdomen	
35665	21.00
35663	22.00
35565	23.20
35563	24.20
35636	29.50
35536	31.70
35560	32.00
35631	34.00
35531	36.20
Family 3 Embolectomy/Thrombectomy in the Abdomen	
34401	25.00
34151	25.00
34451	27.00
Family 4 Endarterectomy in the Abdomen	
35351	23.00
35331	26.20
35361	28.20
35363	30.20
Family 5 Repair Blood Vessels in the Abdomen	
37660	21.00
37617	22.06
35221	24.39
35281	28.00
35251	30.20
Family 6 Explorations, Revisions, Other in Chest & Abdomen	
35189	28.00
35182	30.00
35905	31.25
35907	35.00

CPT codes	Work RVUs
Family 7 Extra-anatomic Bypass Grafts	
35661	19.00
35650	19.00
35621	20.00
35558	21.20
35511	21.20
35518	21.20
35623	24.00
35521	22.20
35654	25.00
35533	28.00
Family 8 Arterial Bypass Grafts in Extremities	
35666	22.19
35671	19.23
35571	24.06
35587	24.75
Family 9 Embolectomy/Thrombectomy by Extremity Incision	
34490	9.86
34111	10.00
34201	10.03
34101	10.00
34421	12.00
34203	16.50
Family 10 Aneurysm Repairs in the Extremity	
35045	17.57
35011	18.00
35141	20.00
35013	22.00
35151	22.64
35142	23.30
35152	25.62
Family 11 Endarterectomy of Extremity Arteries	
35371	14.72
35321	16.00
35372	18.00
35355	18.50
Family 12 Arteriovenous Fistula Repairs in the Extremities	
35190	No change in work RVUs
35184	18.00
Family 13 Peripheral Artery and Vein Ligations	
35721	7.18
37650	7.80
35741	8.00
37618	No change in work RVUs
37565	10.88
37600	11.25
35701	8.50
37605	13.11
37615	No change in work RVUs
Family 14 Vessel/Repairs in Extremities and Neck	
35201	16.14
35206	13.25
35226	14.50
35266	14.91
35261	17.80
35286	16.16
35236	17.11
35231	20.00
35256	18.36

CPT codes	Work RVUs
Family 15 Reconstruction for Chronic Venous Disease	
34501	16.00
34520	17.95
34510	18.95
34530	16.64 (decrease)
Family 16 Repairs, Bypass Grafts, Endarterectomies in the Chest	
35276	24.25
35246	26.45
35626	27.75
35526	29.95
35311	27.00
Family 17 Ligation or Biopsy of Temporal Artery	
37609	3.00
Family 18 Untitled	
35081	28.01
35556	21.76

The RUC recommended the following codes be submitted to the CPT Editorial Panel for further consideration: 35381, 35541, 35546, 35551, 35582, 35641, 35646, 35840, 35860, 37615, 37618, 37700, 37730, 37735, 37760, 37785.

HCFA Proposal:

We have reviewed and propose to accept all of the RUC recommendations for the vascular surgery codes. We believe that relativity is maintained, and the RVUs more appropriately reflect the work involved.

2. General Surgery/Colon and Rectal Surgery

Comment: The American Society of General Surgeons (ASGS) submitted 55 codes it believed to be undervalued. The ASGS recommended work RVUs for each service. After submitting the codes, the specialty society ultimately chose not to pursue review of RVUs for the following codes under the 5-year review: 20605, 34001, and 29881.

The following codes 49505, 32440, 46320, 46924, 31622, 44140 (no change), 38500, 32480, 37609, 43239, 43638, 60220, 44050, 48150, and 38100 were also submitted for review by other specialty groups and are discussed in other sections. (Note that codes 56305, 56341, 56300, 56340, and 56306 are laparoscopic surgery codes also submitted for review by the specialty group; however, these services were deleted or renumbered by CPT for 2000.)

RUC Recommendation:

The RUC recommended that the work RVUs for the following codes be increased (the RUC-recommended work RVUs are in parentheses):

Code 36489, *Placement of central venous catheter (subclavian, jugular, or other vein (eg, for central venous pressure, hyperalimentation, hemodialysis, or chemotherapy)); percutaneous, age 2 years or under* (2.50) to correct a rank-order anomaly; 60100, *Biopsy thyroid, percutaneous core needle* (1.56), to appropriately reflect the work involved and fit in the range of biopsy codes; and 31600, *Tracheostomy, planned (separate procedure)* (7.18), based on the building-block approach and the comparison to similar procedures.

For the following codes, the RUC stated that there was no compelling evidence provided to support increasing the work RVUs. Therefore, it recommended maintaining the current work RVUs for the following codes: 19100, 88170, 57410, 76095, 88171, 32000, 21800, 46083, 19000, 19125, 45330, 19160, 13101, 11402, 12011, 11642, 27590, 45378, 36625, 45309, 45305, 35081, 19240, 58150, 43246, 19162, and 35556. The RUC also recommended maintaining the current work RVUs for codes 49321 and 49322 because these services had recently been reviewed by the RUC.

The RUC recommended that the following codes be referred to the CPT Editorial Panel for review or clarification: 37720 and 43215.

HCFA Proposal:

We have reviewed and propose to accept all of the RUC recommendations for these surgery codes.

Comment:

The American College of Surgeons (ACS) submitted general surgery codes for review that account for approximately 50 percent of general surgery's Medicare-allowed charges for services categorized as surgery under our ''type of service'' classification. The procedures are predominantly performed by general surgeons, and they involve the gastrointestinal tract, abdominal organs, thyroid, lymph system, and endocrine system. Requests for review of some of these codes were also submitted by other specialty groups.

In its comments, the ACS emphasized that its analysis determined that the work of codes in general surgery has been systematically undervalued.

The ACS used a building-block approach with panel-assigned intraoperative work intensities for procedures. Preoperative work RVUs were determined based on an assigned intensity multiplied by the number of preservice minutes. The assigned preservice work intensity was below that of an evaluation and management service. A panel of ASC members assigned intraservice work intensity to each code using a scale. The intensity of an evaluation and management service was the low end of the scale, and liver resection services were on the high end of the scale. The ends of the scale were chosen to represent ''average'' work intensity throughout a procedure. The ACS maintains that the work intensity of any surgical procedure is greater than the work intensity of an evaluation and management service. Postservice work RVUs were calculated using current work RVUs for hospital visits and discounted work RVUs for office visits. Pre, intra-, and postwork RVUs were summed to equal the new work RVUs that the ACS developed for each code.

The ACS assigned over 300 codes to 31 families of similar services (for example, all codes related to hernia repair were in one family). It conducted a traditional RUC survey for 32 codes (either high volume services or the service most representative of the family of codes). A minisurvey, which did not include a respondent-recommended work value, was conducted for the remaining codes, with participation from other specialty groups. The ACS indicated that the survey respondents tended to overvalue codes at the low end of the scale and undervalue codes at the high end of the scale. As a result, ACS recommended using the 25th percentile of survey results at the low end and the 75th percentile for work RVUs at the high end of the scale for fully-surveyed codes. However, they stated that acceptance of these survey results without adjustments to other codes in the family that were not fully surveyed would distort the relativity within and across families. They recommended a regression methodology to extrapolate the fully-surveyed code results to the other codes.

RUC Recommendation:

The RUC workgroup reviewed the data collected for the 32 fully-surveyed ACS codes. It also reviewed the families of services proposed by ACS and modified the families that were too dissimilar to permit appropriate comparison within the family. After the anchor code was reviewed, each family was reviewed to determine whether the change to the anchor code should be applied to the entire family of codes. In some instances the RUC agreed that the recommended change in the anchor code should be extrapolated to the entire family to ensure that rank-order and relativity distortions were not created by a change to the anchor code. In other instances the RUC determined that the recommendation for the anchor code did not apply to the family of codes. In these instances, either new RVUs were recommended or the present work RVUs were maintained. The following are the code-specific RUC recommendations:

CPT codes	Work RVUs
Family 1A & B Thyroid/Endocrine	
60220	11.90
60252	20.57
60254	26.99
60260	17.47
60270	20.27
60271	16.83
60540	No change
60545	No change
Family 2 Lymphadenectomy	
38740	8.42
38745	11.00
38760	10.88
38765	19.98
Family 3 Lymph Nodes and Lymphatic Channels—Incision/Excision	
38300	1.99
38305	6.00
38308	6.45
38500	3.75
38510	6.43
38520	6.67
38525	6.07
38530	7.98
Family 4 Intestines—Excision/Incision	
44005	16.23
44010	12.52
44020	13.99
44021	14.08
44025	14.28
44050	14.03
44110	11.81
44111	14.29
44120	17.00
44125	17.54
44130	14.49
44160	18.62
44800	11.23
44820	12.09
Family 5 Intestines—External Fistulization	
44300	12.11
44310	15.95
44312	8.02
44314	15.05
44316	21.09

CPT codes	Work RVUs
44320	17.64
44340	17.72
44345	15.43
44346	16.99
Family 6 Intestines—Colectomy	
Codes 44140, 44143, 44144, 44145, 44146, 44150, 44151, 44152, 44153, 44155, and 44156. The RUC made no changes to any of these codes based on the lack of compelling evidence.	
Family 7 intestines—Repair	
44602	11.91
44603	15.72
44604	16.03
44605	17.25
44615	15.93
44620	12.20
44625	15.05
44626	25.36
44640	16.65
44650	17.12
44660	16.42
44661	19.07
44680	15.40
44700	16.11
44850	10.74
Family 8 Anus/Rectum—Hemorrhoids/Fistula	
45000	3.88
45020	4.05
45100	3.16
45108	4.09
46040	4.26
46045	3.71
46060	4.89
46250	3.89
46255	4.60
46257	5.40
46258	5.73
46260	6.37
46261	7.08
46262	7.50
46270	3.20
46275	3.92
46280	5.14
46288	6.13
46934	3.51
46936	3.69
46945	1.84
46946	2.58
Note: All of the work RVUs for Family 8 reflect a recommended decrease from the CY 2000 work RVUs.	
Family 9 A B &C Anus/Rectum, Anus (destruction)—10-day global	
45900	2.61
45905	2.30
45910	2.80
45915	3.14
46221	2.04
46754	2.20
Note: Based on the lack of compelling evidence, the RUC recommended that no changes be made to the following Family 9 codes: 46083, 46230, 46320, 46935, 46940, 46942, 46900, 46910, 46916, 46917, 46922, and 46924.	
Family 10 Anus/Rectum Repair	
45505	7.58
45540	16.27
45541	13.40
45550	23.00
45560	10.58
45562	15.38
45563	23.47

CPT codes	Work RVUs
45800	17.77
45805	20.78
45820	18.48
45825	21.25
46700	9.13
46750	10.25
46753	8.29
46760	14.43
46761	13.84
46762	12.71
Family 11 Hernia	
49500	5.48
49501	8.88
49505	7.60
49507	9.57
49520	9.63
49521	11.97
49525	8.57
49540	10.39
49550	8.63
49553	9.44
49555	9.03
49557	11.15
49560	11.57
49561	14.25
49565	11.57
49566	14.40
49570	5.69
49572	6.73
49580	4.11
49582	6.65
49585	6.23
49587	7.56
49590	8.54
Family 12 A & B Stomach—Gastrectomy and Gastrectomy/Vagotomy	
43620	30.04
43621	30.73
43622	32.53
43638	29.00
43639	29.65
43631	22.59
43632	22.59
43633	23.10
43634	25.12
43640	17.02
43641	17.27
Family 13 A & B Stomach—Incision/Excision/Repair	
43500	11.05
43501	20.04
43502	23.13
43510	13.08
43520	9.99
43605	11.98
43610	14.60
43611	17.84
43800	13.69
43810	14.65
43820	15.37
43825	19.22
43830	9.53
43832	15.60
43840	15.56
43870	9.69
43842	18.47
43843	18.65
43846	24.05
43847	26.92
43848	29.39

CPT codes	Work RVUs
43850	24.72
43855	26.16
43860	25.00
43865	26.52
43880	24.65
Family 14 A Abdomen, Peritoneum, Omentum	
The RUC recommended no changes for codes 49000, 49002, 49010, 49200, 49201, 49220, 49255, 49900, 49421, 49422, 49425, 49426, and 49429.	
Family 14 B Abdomen, Peritoneum, Omentum	
49020	20.73
49040	12.27
49060	14.40
49085	11.03
Family 14 C Abdomen, Peritoneum, Omentum	
49428	6.06
Family 15 Appendix	
44900	10.14
44950	10.00
44960	12.34
Family 16 Rectum—Proctectomy/Excision	
45110	28.00
45112	30.54
45113	30.58
45114	27.32
45116	24.58
45119	30.84
45123	16.71
45126	45.16
45130	16.44
45135	19.28
45160	15.32
45170	11.49
45190	9.74
Family 17 Biliary Tract	
47420	19.88
47425	19.83
47460	18.04
47480	10.82
47600	13.58
47605	14.69
47610	18.82
47612	18.78
47620	20.64
47711	23.03
47712	30.24
47715	18.80
47716	16.44
47720	15.91
47721	19.12
47740	18.48
47741	21.34
47760	25.85
47765	24.88
47780	26.50
47785	31.18
47800	23.30
47801	15.17
47802	21.55
47900	19.90
Family 18 Esophagus—Repair/Reconstruction	
43320	19.93

CPT codes	Work RVUs
43324	20.57
43325	20.06
43326	19.74
43330	19.77
43331	20.13
43340	19.61
43341	20.85
43350	15.78
43351	18.35
43352	15.26
43360	35.70
43361	40.50
43400	21.20
43401	22.09
43405	20.01
43410	13.47
43415	25.00
43420	14.35
43425	21.03
Family 19 Liver	
47010	16.01
47015	15.11
47100	11.67
47120	35.50
47122	55.13
47125	49.19
47130	53.35
47300	15.08
47350	19.56
47360	26.92
47361	47.12
47362	18.51
47400	32.49
Family 20 A & B Spleen—Incision/Excision/Repair and Pancreatitis Management	
38100	14.50
38101	15.31
38115	15.82
48000	28.07
48001	35.45
48005	42.17
Family 21 Pancreatectomy	
48020	15.70
48100	12.23
48120	15.85
48140	22.94
48145	24.02
48146	26.40
48148	17.34
48150	48.00
48152	43.75
48153	47.89
48154	44.10
48155	24.64
48180	24.72
48500	15.28
48510	14.31
48520	15.59
48540	19.72
48545	18.18
48547	25.83
Family 22 Laparoscopy	
The RUC recommended no changes to the following codes based on lack of compelling evidence: 43651, 43652, 44200, 44970, 47562, 47563, 47564, 47570, 49320, 49650, and 49651.	

The RUC also recommended that the following codes be referred to the CPT Editorial Panel for review and clarification: 36533, 36534, 36535, 49495, and 49496.

HCFA Proposal:

The ACS conducted full surveys of 32 codes, and we agreed with the RUC analysis for most of the 32 codes. For the other codes the ACS did minisurveys that included pre-, intra-, and postservice times as well as the number and type of postservice visits. These minisurveys did not include an estimate of the relative work for the procedure. For this reason, the RUC used an extrapolation methodology to arrive at its work RVU recommendations for all codes that did not have a full RUC survey. To make appropriate extrapolations, the RUC divided all of the general surgery codes into families of related procedures. At least one code in each family was fully surveyed. After the RUC recommended work RVUs for each surveyed code, it applied the percent change for that code to all of the other codes in the family. When more than one code was fully surveyed within a family of services, the RUC extrapolated the percentage from the fully surveyed code that would produce the least increase in work RVUs.

The validity of this extrapolation methodology relies on at least two things—first, that the relative work values of all codes in the family were correct before the extrapolation (or else the extrapolation perpetuates and magnifies any pre-existing anomalies), and second, that the relative misvaluation of each code in a family is similar.

We did an analysis of all the families of codes in the general surgery group to determine whether the relative valuations in the 2001 physician fee schedule contained any anomalies. If any anomalies existed, we reviewed the RUC recommendations to determine whether the anomalies were addressed by the RUC recommendations. If the anomalies were not corrected, we took steps to correct them.

We also analyzed all of the recommended values for general surgery to ensure that the percentage changes for each family were appropriate. To determine if the extrapolation for each family was correct, we compared each extrapolated code to codes in other families, and to codes in other specialties. We compared extrapolated codes to codes whose current or RUC recommended work RVUs (from the 5-year-review) were similar to the extrapolated code. We then compared the preservice, intraservice, and postservice physician times as well as the number of postoperative visits. In addition, we generally determined whether the survey vignette was typical for the procedure. The following is an example of our review of the general surgery codes. Code 35132 (*Direct repair of aneurysm, false aneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for ruptured aneurysm, iliac artery (common, internal, external*) (30.00 work RVUs) with a preservice time of 67 minutes, intraservice time of 180 minutes, seven hospital visits, and three office visits is similar to codes 47712 (*Excision of bile duct tumor, with or without primary repair of bile duct; intrahepatic*) (30.24 work RVUs) with a preservice time of 75 minutes, intraservice time of 210 minutes, one intensive care unit visit, nine hospital visits, and three office visits and 43638 (*Gastrectomy, partial, proximal, thoracic or abdominal approach and esophagogastrostomy with vagotomy*) (29.00 work RVUs) with a preservice time of 75 minutes, intraservice time of 210 minutes, 10 hospital visits, and 4 office visits. A review of these codes demonstrates the similarity in preservice and intraservice time and the proposed RVUs maintain relativity across surgical specialties.

Upon completion of this analysis, we propose to accept the RUC recommendations for the following families of services:

Family 1A and 1B Thyroid and Endocrine.
Family 3 Lymph Nodes and Lymphatic Channels—Incision/Excision.
Family 4 Intestines—Excision/Incision.
Family 5 Intestines—External Fistulization.
Family 9 Anus/Rectum—10-day global period.
Family 10 Anus/Rectum—Repair.
Family 11 Hernia.
Family 12 Stomach—Gastrectomy/Vagotomy.
Family 13 Stomach—Incision/Excision/Repair.
Family 14A and C Abdomen, Peritoneum, Omentum.
Family 15 Appendectomy.
Family 16 Rectum-Proctectomy/Excision.
Family 17 Biliary Tract.
Family 18 Esophagus—Repair/Reconstruction.
Family 19 Liver.
Family 20 Pancreas/Spleen—Incision/Excision/Repair.
Family 21 Pancreatectomy.
Family 22 Laparoscopy.

For the above families, adopting the RUC-recommended RVUs maintains relativity of the codes based upon a comparison of the codes to procedures in other families and within the family.

For other families of services, the extrapolation methodology inappropriately values codes or does not address current rank-order anomalies. Application of the percentage increases derived from the RUC's extrapolation methodology would only exacerbate any current rank-order anomalies within families. Below, we have outlined, for each family of services, our proposed work RVUs to rectify these problems.

Family 2 Lymphadenectomy

The RUC recommended an increase in work RVUs for the fully surveyed code 38745 (*Axillary lymphadenectomy; complete*) from 8.84 to 11.0 RVUs based on comparisons with codes 60210 (*Partial thyroid lobectomy, unilateral, with or without isthmusectomy*), and 32100 (*Thoracotomy, major with exploration and biopsy*). We disagree. Although codes 38745 and 60210 are performed in the outpatient setting and 32100 is not, code 38745 requires more postoperative wound care. Additionally, the RUC compared 38745 to the pre-5-year review value of 32100. Subsequently the RUC reviewed code 32100 for the 5-year review and is recommending an RVU increase to 15.24 RVUs. Because the intraservice times for codes 38745 and 32100 are identical and 38745 requires more postoperative wound care, a clear rank order anomaly would exist if 38745 was valued at 11.00 work RVUs and 32100 was valued at 15.24 work RVUs. Therefore, we are assigning the median survey RVUs of 13.00 to code 38745. We would also note that the survey RVU spread from the 25th percentile to the 75th percentile ranged from 12.15 to 14.29 RVUs, which is relatively small. An RVU of 13.00 places code 38745 in the correct rank order to the comparison codes. To maintain relativity within this family, we are extrapolating the 47 percent increase in work RVUs of code 38745 to codes 38740 (*Axillary lymphadenectomy; superficial*) and 38760 (*Inguinofemoral lymphadenectomy, superficial, including Cloquets node (separate procedure)*) for proposed work RVUs of 10.02 and 12.94, respectively. However, code 38765 (*Inguinofemoral lymphadenectomy, superficial, in continuity with pelvic lymphadenectomy, including external iliac, hypogastric, and obturator nodes (separate procedure)*) represents a rank-order anomaly as it is currently valued too high relative to the other codes in the family. Therefore, we are accepting

the RUC recommendation for code 38765 of 19.98 work RVUs.

Family 6 Colectomy

The RUC recommended no change in the work RVUs for this family of codes based on lack of compelling evidence for changing the RVUs of the fully surveyed code 44140 (*Partial colectomy*). Moreover, the intraservice time for code 44140 had not changed since the last 5-year review. Additionally, the RUC compared code 44140 to code 32480 (*Removal of lung, other than total pneumonectomy; single lobe (lobectomy)*) and code 50230 (*Nephrectomy, including partial ureterectomy, any approach including rib resection; radical, with regional lymphadenectomy and/or vena caval thrombectomy*) that have similar work RVUs to 44140 and were believed to be longer, more intense procedures with more postoperative care. We disagree with this recommendation. If the RVUs for procedures in this family are not changed, the procedures will be significantly undervalued compared to other general surgery codes (Family 5 and Family 7) and vascular surgery codes. As an example, we note that the RUC-recommended work RVU for code 44153 *Colectomy, total, abdominal, without proctectomy; with rectal mucosectomy, ileoanal anastomosis, creation of ileal reservoir (S or J), with or without loop,* will significantly undervalue this code compared to code 45113, *Proctectomy, partial, with rectal mucosectomy, ileoanal anastomosis, creation of ileal reservoir (S or J), with our without loop ileostomy,* thus creating a rank-order anomaly.

We compared code 44140 to code 32480 for which the RUC is recommending a work RVU increase to 23.75. These procedures have similar intraservice times, and the postoperative visits show that although the initial care required for code 32480 is more intense, the length of stay for code 44140 is frequently longer. We also compared code 44140 to codes 37617, *Ligation, major artery (eg post-traumatic, rupture); abdomen,* and 35221, *Repair blood vessel, direct; intra-abdominal.* Code 37617, for which the RUC recommended work RVUs of 22.06, is an emergency operation with a slightly shorter intraservice time and shorter hospital stay. Code 35221, which has RUC-recommended work RVUs of 24.39, is also an emergency operation with an intraservice time and length of stay identical to code 44140. Based on these comparisons, we believe that the survey's 25th percentile work RVUs of 21.00 are appropriate and correctly rank code 44140 to the comparison procedures. This increase is 14 percent greater than the current work RVUs and, with the exception of the two codes discussed below, applying this 14 percent increase to the other codes in this family will place them in proper relationship to other comparable procedures.

Family 6 contains two current rank-order anomalies: code 44151, *Colectomy, total, abdominal, without proctectomy; with continent ileostomy,* has lower work RVUs than code 44150, *Colectomy, total, abdominal, without proctectomy; with ileostomy or ileoproctostomy,* and 44156, *Colectomy, total, abdominal, with proctectomy; with continent ileostomy,* has lower work RVUs than code 44155, Colectomy, total, abdominal, with proctectomy; with ileostomy. Code 44151 is identical to code 44150, and code 44156 is identical to code 44155, except that codes 44151 and 44156 involve the creation of a ''continent ileostomy'' instead of an ''ileostomy or ileoproctostomy.'' The work of creating a ''continent ileostomy'' is greater than the work of creating an ''ileostomy or ileoproctostomy.'' To correct this rank-order anomaly, we applied the 14 percent increase discussed above to codes 44150 and 44155. Next, we determined the proper incremental increase in work for creation of a ''continent ileostomy'' by looking to codes 44310, *Ileostomy or jejunostomy, non-tube (separate procedure),* and 44316, *Continent Ileostomy (Kock procedure) (separate procedure),* because the work RVUs of 44316 are the same as the work RVUs of 44310 with the addition of creating a continent ileostomy. We subtracted the RUC-recommended work RVUs of 15.95 for code 44310 from the RUC-recommended work RVUs of 21.09 for code 44316 and divided by 50 percent (50 percent approximates the intraservice portion of the extra work). This resulted in work RVUs of 2.57 that we increased by 14 percent to yield work RVUs of 2.93. We then added 2.93 work RVUs to the RVUs for codes 44150 and 44155 to yield proposed work RVUs of 26.88 for code 44151 and 30.79 for code 44156.

In summary, we propose the following work RVUs for the codes in this family:

Code	Work RVUs
44140	21.00
44143	22.99
44144	21.53
44145	26.42
44146	27.54
44150	23.95
44151	26.88
44152	27.83
44153	30.59
44155	27.86
44156	30.79

With these assigned work RVUs, we believe that Family 6 is ranked appropriately in relation to other general and vascular surgery codes.

Family 7 Intestines—Repair

The RUC recommended an increase of 14 percent for all work RVUs in this family based on a recommended increase in a fully surveyed code 44604 *(Suture of large intestine (colorrhaphy) for perforated ulcer, diverticulum, wound, injury or rupture (single or multiple perforations); without colostomy)* from 14.28 work RVUs to 16.03 work RVUs.

We agree with the increase in work RVUs for code 44604 but note that there are several rank-order anomalies currently in this family of codes that would be exacerbated by an across-the-board increase in work RVUs. Therefore, we propose to correct the rank-order anomalies as follows:

We propose 16.03 work RVUs for 44602 *(Suture of small intestine (enterorrhaphy) for perforated ulcer, diverticulum, wound, injury or rupture; single perforation).* The work RVUs for code 44602 are identical to the work RVUs for code 44604 because they describe the same procedure except code 44604 is for the large intestine.

We propose work RVUs of 19.53 for code 44605 *(Suture of large intestine (colorrhaphy) for perforated ulcer, diverticulum, wound, injury or rupture (single or multiple perforations); with colostomy).* The work RVUs for code 44605 are identical to the work RVUs for code 44604 except that code 44605 includes creating a colostomy with the attendant increase in postoperative wound care. The intraservice work of creating a colostomy is captured by subtracting the work RVUs for code 44140 from code 44143, which leaves 1.99 RVUs. In addition, there is one extra postoperative visit required for code 44605 that we believe is equivalent to code 99233 that has 1.51. work RVUs. Therefore, we added 1.99 and 1.51 work RVUs to the work RVUs for code 44604 to arrive at 19.53 work RVUs for code 44605.

We propose 18.66 work RVUs for code 44603 *(Suture of small intestine (enterorrhaphy) for perforated ulcer, diverticulum, wound, injury or rupture; multiple perforations).* The additional work required for code 44603 as compared to code 44602 is similar to the additional work required for code 44605

as compared to code 44604 except, since there is no actual colostomy, the additional postoperative visit is comparable to code 99231 with 0.64 work RVUs. Therefore, we added work RVUs of 1.99 and 0.64 to the work RVUs of code 44602 to arrive at 18.66 work RVUs for code 44603.

The current work RVUs for codes 44640 *(Closure of intestinal cutaneous fistula);* 44650 *(Closure of enteroenteric or enterocolic fistula);* 44660 *(Closure of enterovesical fistula; without intestinal or bladder resection);* and 44661 *(Closure of enterovesical fistula; with bowel and/or bladder resection)* are rank-order anomalies as they are undervalued compared to code 44604. However, relativity among codes 44640, 44650, 44660, and 44661 is appropriate. To correct the anomalies, we compared codes 44650 to 50525 *(Closure of nephrovisceral fistula (eg renocolic) including visceral repair; abdominal approach),* which involves similar intraoperative and postoperative work. The intraoperative work for code 50525 is greater than that of code 44650 because code 50525 involves visceral repair but the postoperative work for code 44650 is greater than the postoperative work for code 50525 because the fistula is enteroenteric or enterocolic as opposed to renovisceral (that is, renocolic). Therefore, we propose to assign 22.27 work RVUs to code 44650 and, to keep the current relativity with the other codes, we propose 21.65 work RVUs for code 44640, 21.36 work RVUs for code 44660, and 24.81 work RVUs for code 44661. We propose to accept the RUC recommendations for the remaining codes (44615, 44620, 44625, 44626, 44680, 44700, and 44850).

Family 8 Anus/Rectum—Hemorrhoids/ Fistula

The RUC extrapolated a 14 percent decrease in work RVUs to all codes in this family based upon a decrease in work RVUs for the fully surveyed code 46262, *Hemorrhoidectomy, internal and external, complex or extensive; with fistulectomy, with or without fissurectomy.* We agree with the RUC recommendation for the surveyed code, but disagree with the extrapolation to the anal fistula repair codes and the anal abscess treatment codes. The surveyed intraoperative time for code 46262 is not consistent with the surveyed intraoperative times for many of the other codes in the family. Moreover, the work RVUs for many of the codes subject to the minisurveys are significantly less than for code 46262 and are not comparable. Therefore, we propose to maintain the current RVUs for codes 46270, 46275, 46280, 46288, 45000, 45020, 45100, 45108, 46040, 46045, and 46060. We agree with the RUC recommendations and propose to decrease the work RVUs for other codes in this family of codes (46250, 46255, 46257, 46258, 46260, 46261, 46262, 46934, 46936, 46945, and 46946).

Family 14B Abdomen, Peritoneum, Omentum

The RUC recommended an increase for the fully-surveyed code 49020, *(Drainage of peritoneal abscess or localized peritonitis, exclusive of appendiceal abscess; open,)* from 16.79 work RVUs to 20.73 work RVUs, the 25th percentile of surveyed work RVUs, based on a comparison to code 61312 *(Craniectomy or craniotomy for evacuation of hematoma, supratentorial; extradural or subdural).* We disagree and propose the surveyed median work RVUs of 22.84. We compared code 49020 to code 35151 *(Direct repair of aneurysm, false aneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for aneurysm, false aneurysm and associated occlusive disease, popliteal artery),* 48000 *(Placement of drains, peripancreatic, for acute pancreatitis),* and code 48140 *(Pancreatectomy, distal subtotal, with our without splenectomy; without pancreaticojejunostomy).* Code 48000 involves sicker patients but the intraoperative time (120 minutes) and postoperative visits (10-day length of stay for code 48000 with two critical care visits versus an 11-day length of stay for code 49020 with one critical care visit) are similar, and code 48000 has RUC-recommended work RVUs of 28.07. Code 48140, with RUC-recommended work RVUs of 22.94, has a longer intraoperative time (150 minutes) with a shorter length of stay (9 days with one critical care visit) and involves less sick patients. Code 35151, with RUC-recommended work RVUs of 22.64, involves patients not nearly as ill as patients for whom code 49020 is reported, has a surveyed intraoperative time of 150 minutes, and a 5-day length of stay with no critical care visits. Therefore, we propose the median surveyed work RVUs of 22.84 for code 49020. Since the current relativity within this family is correct, we propose to extrapolate this increase of 36 percent to the other codes in this family and value the work as follows: 49040 (13.52), 49060 (15.86), and 49085 (12.14).

Comment: The American Society of Colon and Rectal Surgeons collaborated with the ACS and submitted 12 codes for review that they believe to be undervalued. They also expressed support for the methodology proposed by ACS to value services. The specific codes referenced were: 44130, 44144, 44147, 44151, 44156, 44394, 45111, 45113, 45337, 45339, 45910, and 46258.

RUC Recommendation:

The RUC recommended increasing the work RVUs for the following codes: 44130 (14.49), 45113 (30.58), and 45910 (2.80) to retain current rank-order and relativity within the grouping of services. However, for code 46258, the RUC recommended decreasing the work RVUs to 5.73 to retain the current rank-order and relativity within these services.

For codes 44147, 44394, 45111, 45337, 45339, 44144, 44151, and 44156, the RUC did not receive compelling evidence to suggest an increase was needed in the work RVUs; therefore, the RUC recommended that the current work RVUs for these codes be maintained.

HCFA Proposal: We propose to accept all but one of the RUC recommendations for the surgical codes submitted by the American Society of Colon and Rectal Surgeons. For code 44147, *Colectomy, partial; abdominal and transanal approach,* we are proposing to increase the work RVUs by 14 percent to 20.71. This is similar to the increase applied to ACS family 6 and will prevent a rank-order anomaly.

Comment: The American Academy of Otolaryngology-Head and Neck Surgery submitted codes, on behalf of the American Otological Society and the American Academy of Facial Plastic and Reconstructive Surgery, that they believe to be undervalued, along with suggested new work RVUs for each service. However, subsequent to the submission of their comments, the specialty society chose not to pursue revaluing of the following codes: (69450, 69436, 69440, 69631, 69205, 69801, 69633, 69501, 69632, 69905, 69666, 69650, 69806, 69667, 69720, 69641, 69550, 69636, 69637, 69643, 69140, 69505, 69635, 69502, 69645, 69511, 69601, 69602, 69642, 69603, 69644, 69910, 69660, 69604, 69646, 69662, 69661, 69930, 69145, 69676, 69310, 69620, 69805, 69670, 69700, 69802, 69320, 69530, 69820, 68711, 69840, 69540, 69421, 69552, 69150, 69915, 69605, 69300, 69000, 69005, 69020, 69711, 69100, 69105, 69110, 69120, 69140, 69145, 691500, 69155, 69200, 69205, 69210, 69220, 69222, 69300, 69310, 69320, 69400, 69401, 69405, 69410, 69420, 69421, 69424, 69433, 69436, 69535, 69554, 69610, 69725, 69740, 69745, 69950, 69955, 69960, 69970).

RUC Recommendation: For codes 69990, 11642, 13131, and 13132, the RUC recommends no change to the current RVUs for these services, as compelling evidence was not provided to demonstrate the need for an increase.

HCFA Proposal: We have reviewed and propose to accept all of the RUC recommendations for the surgical codes submitted by the American Academy of Otolaryngology-Head and Neck Surgery.

3. Thoracic Surgery

Comment: In their comments, the Society of Thoracic Surgeons (STS) indicated that there have been major changes in the practice of thoracic surgery since the initial development of the physician fee schedule. These major changes in surgical techniques, along with changes in the typical patient, have had an impact on physician work. Time and intensity of a number of procedures, including the reference procedures used by STS, have been affected.

The STS grouped codes into three categories: general thoracic surgery, adult cardiac surgery, and congenital thoracic surgery. These three categories were grouped into 23 families of codes. Each family had an anchor code that received a full RUC survey. Each of the remaining codes in a family received a minisurvey. The minisurvey collected information on time and the number of postoperative visits. The minisurvey also asked respondents to estimate work RVUs for the procedure based on the reference service for the family of codes.

The RUC had a number of concerns with the STS approach. They are as follows: (1) The RUC concluded that STS inappropriately had the same survey respondents review and estimate both misvalued services and reference services. (2) In many instances, the respondents valued the code under review relative to their perception of what the reference code value should be, not the current value of the reference code. (3) The STS also used too many minisurveys and too few full surveys. (4) Within a family of codes, the STS inappropriately mixed codes with different global periods.

To overcome these methodological problems, the RUC first reviewed the reference service that was used for each family, and the resulting value was compared to the codes in each family. For the adult cardiac surgery codes, the RUC developed a building-block methodology to validate the survey results. For the congenital thoracic codes, previous RUC reviews of the codes were used to determine how the work has changed since the last 5-year review. In addition, for the pediatric thoracic codes, the specialty's society's presenter offered additional information demonstrating that the patient population has changed, (for example, more neonates) leading to a higher intensity of work.

Additionally, The STS subsequently chose not to pursue review of code 33207 under the 5-year review.

RUC Recommendations: The RUC reviewed 89 thoracic surgery codes. Of this total, the RUC recommended increases for 44 codes, no changes for 43 codes, and decreases for 2 codes. The recommendations by family are as follows:

Family 1: The RUC generally found that the STS had not furnished compelling evidence or that the STS inappropriately compared codes with a zero global period to codes with a 90-day global period. The RUC recommended no increase in work RVUs for codes 32000, 32005, 32020, 32035, 32225, 32602, 32651, and 32652. The RUC recommended increases in work RVUs for code 32220 (24.00) and code 32320 (24.00), based on the median surveyed work RVUs which would place these codes in proper rank order.

Family 2: The RUC recommended increases for code 32440 (25.00) based on the median survey value, and code 32480 (23.75) based on the value of 43415. The RUC also recommended increases in work RVUs for codes 32100 (15.24) and 32110 (23.00) based on a comparison to code 58150. These values place all these codes in proper rank order.

Family 3: The RUC recommended increases in codes 32482 (25.00) and 32500 (22.00), based on the STS surveyed median work RVUs for each code, which would create the proper rank order within the family of codes.

Family 4: The RUC recommended no increase for code 32655 because the STS had not furnished compelling evidence for an increase in work. The RUC recommended increases for codes 31600 (7.18) and 32500 (22.00) based on survey data, a sicker patient population, and, in the case of 31600, comparison to 35474.

Family 5: The RUC recommended increases for codes 38746 (4.89) based on the work RVU for 38747, but recommended no increases for codes 39010, 39220 or 39400 due to lack of compelling evidence or inappropriate comparisons to codes with 90-day global periods.

Family 6: The RUC agreed with the STS analysis of work for codes 43107 (40.00) and 43112 (43.50) and stated that using the survey median for each code correctly rank ordered these codes in the family of esophagectomy codes.

Family 7: The RUC recommended an increase for code 43117 (40.00) after comparing it to the reference service code 43361 which had similar data. The RUC also recommended an increase for code 43122 (40.00) based on the survey median of 40.00 work RVUs which correctly rank ordered this code in the family of esophagectomy codes.

Family 8: The RUC recommended no increase for codes 31625 or 31645 because the STS did not furnish compelling evidence for an increase in work.

Family 9: The RUC recommended increases for the following codes: 33400 (28.50), 33405 (35.00), 33406 (37.50), 33411 (36.25), 33412 (42.00), and 33413 (43.50), based on a building-block approach that used code 33405 as the anchor code for this family.

Family 10: The RUC recommended increases for the following codes: 33426 (33.00), 33427 (40.00), 33430 (33.50), and 33475 (33.00), based on a building-block approach that used code 33427 as the anchor code for this family. The RUC recommended no increases for codes 33425 or 33468 because the building-block approach did not support the STS's requested increase.

Family 11: The RUC recommended increases for the following codes: 33510 (29.00), 33511 (30.00), 33512 (31.80), and 33513 (32.00), based on a building-block approach that used code 33512 as the anchor code for the family. The RUC recommended decreases for codes 33514 (32.75) and 33516 (35.00). These were the values recommended by the STS and validated through the building-block approach.

Family 12: The RUC recommended no increases for the following add-on codes: 33517, 33518, 33519, 33521, 33522, 33523, and 33530, because it believes that they were inappropriately surveyed as 90-day global procedure codes and the results were not reliable.

Family 13: The RUC recommended increases in work RVUs for the following codes: 33533 (30.00), 33534 (32.20), 33535 (34.50), and 33536 (37.50), based on a building-block approach that used code 33533 as the anchor code for the family of codes. The RUC recommended no increase for code 33530 because it is an add-on code and was inappropriately surveyed as a 90-day global surgical procedure.

Family 14: The RUC recommended increases in work RVUs in the following codes: 33860 (38.00), 33861 (42.00), 33863 (45.00), and 33870 (44.00) based on a building-block approach that used code 33860 as the anchor code for the family. The RUC recommended no increase for code 33945 because the building-block approach did not

support the higher value requested by the STS.

Family 15: The RUC recommended no increases in work RVUs for the following codes: 33750, 33820, and 33840, due to lack of compelling evidence to support an increase.

Family 16: The RUC recommended an increase in code 33660 (30.00) based on intraservice work RVUs for 33401 and pre- and postservice work RVUs for 33641. The RUC recommended no increase in code 33641 as it did not find any compelling evidence to warrant a change in the work RVUs.

Family 17: The RUC recommended no increase in work RVUs for code 33415, because it did not believe that the typical patient for this procedure has changed, and the minisurvey did not provide compelling evidence to justify a change in the work RVUs. However, the RUC recommended an increase in work RVUs in code 33681 (30.61), because the intraservice intensity of 33681 is more complex than it was 5 years ago.

Family 18: The RUC recommended increases in the following codes: 33615 (34.00), 33670 (35.00), and 33730 (34.25) based on a comparison to code 33412.

Family 19: The RUC recommended increases in work RVUs for the following codes: 33611 (34.00), 33612 (35.00), 33694 (34.00) and 33697 (36.00). The RUC compared the intraservice time of code 33611 to the family anchor code of 33694 and recommended 34.00 work RVUs to maintain proper rank order in the family. The RUC compared code 33612 to code 33611 and agreed code 33612 was equivalent to 33611 plus 1 additional work RVU. The RUC compared code 33694 to 33412 and concluded that all measures of physician work were greater for 33694. The RUC compared code 33697 to 33694 and recommended 36.00 work RVUs to maintain rank order. The RUC recommended no increase for 33767 because there was no compelling evidence for a change in the work RVUs.

Family 20: The RUC recommended an increase in code 33617 (37.00), after comparing it to code 33412 and noting that 33617 has greater intraservice time and higher intensity ranking than code 33412.

Family 21: The RUC recommended an increase in code 33619 (45.00) after comparing it to codes 48150 and 62530.

Family 22: The RUC recommended an increase in code 33506 (35.50) to preserve proper rank order within this family. The RUC recommended an increase in code 33770 (37.00) after finding that the work of this code is more than that of the comparison code 33697. The RUC recommended an increase in code 33778 (40.00), after comparing it to 33870, and 33412 which are less intense procedures. The RUC recommended an increase in code 33780 (41.75), based on a comparison to 33778. 33780 involves more work and warrants an additional 1.75 RVUs due to the additional 35 minutes of intraservice time.

Family 23: The RUC recommended an increase in code 33786 (39.00) after comparing it to 33412, which has less time and intensity. Given the limited specialty survey data, the RUC believed that the recommended increase in code 33919 to 40.00 work RVUs was warranted, but that the survey did not support a value higher than the median survey value.

Based on information supplied to the RUC, the RUC did not recommend a change in RVUs for codes 32520, 33917, 31622, and 32657. For codes 32095, 33410 and 32491, the RUC indicated that it had recently reviewed these codes, and thus it recommended no change. The RUC recommended that codes 33875, 33877, 43107, and 43112 be referred to the CPT Editorial Panel.

HCFA Proposal:

We validated the RUC recommendations by comparing the thoracic surgery codes to vascular surgery and general surgery codes and propose to use the RUC-recommended work RVUs for the thoracic codes based on our own analysis. The following is an example of our review of the thoracic surgery codes. We compared code 32440 (*Removal of lung, total pneumonectomy*) (25.00 work RVUs) with a preservice time of 90 minutes, intraservice time of 160 minutes, one intensive care unit visit, six hospital visits, and three office visits with the following surgical codes in other surgical specialties: code 34151 (*Embolectomy or thrombectomy, with or without catheter; renal, celiac, mesentery, aortoiliac artery, by abdominal incision*) (25.00 work RVUs) with a preservice time of 75 minutes, intraservice time of 150 minutes, seven hospital visits, and three office visits and code 44150 (*Colectomy, total, abdominal, without proctectomy; with ileostomy or ileoproctostomy*) (23.95 work RVUs) with a preservice time of 63 minutes, intraservice time of 200 minutes, eight hospital visits, and three office visits. A review of these codes demonstrates the similarity in preservice time and intraservice time and the proposed RVUs maintains relativity across surgical specialties.

4. Orthopedic Surgery

Comment: The American Academy of Orthopaedic Surgeons forwarded 42 codes for review. It indicated that these codes were undervalued when compared to their respective reference codes.

RUC Recommendation:

The RUC recommended increasing the work RVUs for the following codes: 29883 (11.05) because this service consists of two procedures; 29889 (16.00) based on increase in post and intraservice work; 29450 (2.08) based on the increased intraservice time for manipulating the foot of the patient; code 28299 (9.18) which is of value equal to the reference code, with the understanding that the code be sent to CPT Editorial Panel to better define the code; code 28705 (18.80), which more accurately reflects the work of the two distinct services of this procedure (ankle fusion and triple arthrodesis); code 23472 (21.10) to correct a rank-order anomaly; code 26562 (15.00) to correct a rank-order anomaly; code 20245 (8.50) to correct a rank-order anomaly; code 27075 (35.00) noting that this is a major operation and there is increased intraservice time with respect to the reference code; code 27077 (40.00) noting that this a major operation and there is increased intraservice time with respect to the reference code; 27284 (23.45) because this is the value for code 27227 that has identical pre-, intra-, and postservice times; code 27286 (23.45) to avoid creating a rank-order anomaly due to the recommended work RVUs increase of code 27284; code 27822 (11.00) to correct an existing rank-order anomaly; code 27823 (13.00) to avoid creating a rank-order anomaly caused by increasing code 27822; code 28445 (15.62) to correct a rank-order anomaly and appropriately reflect the work involved; code 27724 (18.20) to reflect the work for obtaining a graft that was not included in the last 5-year review.

The RUC believed that the commenter provided no compelling evidence to revise the work RVUs for codes 27280, 27282, 23585, 23615, 23630, 23680, 24545, 27216, 27217, 27218, 27226, 27236, 27513, 27536, 27828, 23485, 24435, 27472, 28322, and 28420. Therefore, the RUC recommended the current work RVUs be maintained for these codes.

The RUC referred the following codes to the CPT Editorial Panel for clarification: 23076, 24076, 25076, 27048, 27328, 27619, and 20205, because these codes are being reported incorrectly.

HCFA Proposal:

We propose to accept all but one of the of the RUC recommendations for the orthopedic surgery codes. For code 20245, (*Biopsy, bone, excisional; deep (eg, humerus, ischium, femur*), the RUC recommended an increase from 3.95 work RVUs to 8.5 work RVUs and compared code 20245 to codes 27635 (*Excision or curettage of bone cyst or benign tumor, tibia or fibula*), and 27607 (*Incision (eg, osteomyelitis or bone abscess), leg or ankle*) (work RVUs of 7.78 and 7.97, respectively), because it believed the work required for code 20245 was similar to the work required for these codes. The survey for code 20245 compared the code to code 27635. The intraservice times were similar (90 versus 85 minutes) and the amount of postservice was similar (169 versus 163 minutes). However, the survey median work RVUs were 13 and the 25th percentile RVUs were 8.5. The RUC recommended the 25th percentile RVUs because the RVUs were reasonably close to the RVUs for code 27635. We agree that the current work RVUs are a rank-order anomaly with code 20240 (*Biopsy, bone, excisional; superficial (eg, ilium, sternum, spinous process, ribs, trochanter or femur*)); however, we disagree with the RUC recommendation. The intraservice work of a deep excisional bone biopsy is similar to the work of excising a bone cyst or benign tumor from the tibia and fibula (code 27635). This is reflected in the similarity in their pre-, intra-, and postservice times. Moreover, the vignette used for code 20245 was atypical in that it involved an ischial lesion, whereas the code is also to be reported for lesions of the humerus and femur. Lesions of the humerus and femur require less dissection and would be more comparable to lesions of the tibia and fibula. Moreover, code 27635 requires complete removal of a known lesion, whereas code 20245 is only an excisional biopsy. Additionally, we are concerned about the spread of work RVUs in the work survey (25th percentile was 8.5 RVUs and 50th percentile was 13.0 work RVUs) and lack of consistency with the time data from the survey. We do not believe there is compelling evidence that the work of code 20245 is greater than the work of code 27635 and are therefore proposing to assign 7.78 work RVUs to code 20245, which is identical to work RVUs for the reference service code 27635.

5. Ophthalmology

Comment: The American Academy of Ophthalmology submitted comments requesting nine codes be reviewed, including one code for evaluation of the global period and not the work RVU. The specialty society subsequently chose not to pursue review of codes 66170, 66172, and 67108.

RUC Recommendation:

The RUC agreed with the request from the specialty society to change the global period from 90 days to 10 days for code 65855 (*Laser surgery of eye*) and also reduced the work RVUs to 3.85 to account for this reduction in the global period. The RUC noted that code 67218 includes two procedures, and the specialty society indicated that this was not reflected in the original valuation. To correct this error, a building-block approach was used to arrive at new RVUs more reflective of the work of both procedures. The RUC recommended work RVUs of 18.53 for this service. For code 92018, the RUC acknowledged that the preservice work of this service was greater than the standard office procedure because of the need for anesthesia. While concerned about the reliability of the data provided, the RUC recommended that the work RVUs be increased to 2.50, as it suggested during the first 5-year review, with the understanding that the code would be sent to the CPT Editorial Panel for clarification.

For codes 66180, 66986, 67028, and 67904, the RUC believed that the commenters provided no compelling evidence to justify an increase in the work RVUs; therefore, the RUC recommended maintaining the current value for this code.

HCFA Proposal:

We have reviewed and propose to accept all of the RUC recommendations for the ophthalmology codes.

6. Urology

Comment: The American Urological Association presented four codes for review: 50230, 51595, 51596, and 38780. They believed that the work RVUs for these codes do not account for all the in-hospital and office-based postoperative care.

RUC Recommendation:

The RUC questioned the arguments for an increase in RVUs, noting that there was no compelling evidence presented for recommending an increase for three of these codes (51595, 51596 and 38780). However, the RUC noted that the code descriptor for code 50230 includes the term ''and/or vena caval thrombectomy'' which impacts the work RVU. The RUC agreed to refer this code back to the CPT Editorial Panel to separate these two distinct services so each may be reported and valued appropriately.

HCFA Proposal:

We have reviewed and propose to accept all of the RUC recommendations for the urology codes.

7. Obstetrics/Gynecology

a. Specialty Comments

Comment: The American College of Obstetrics and Gynecology (ACOG) referenced 35 codes in their written comments submitted to us. The specialty society chose not to pursue the review of work RVUs for code 57555, as well as the work RVUs for codes 59150 and 59151.

RUC recommendation:

The RUC recommended increases in the RVUs for the following codes: 38572 (16.59) that would align the code relative to the work of other laparoscopic codes; 56515 (2.76), which was not the value requested by the specialty group but was the value assigned to code 46924, which has comparable work and intraservice time; 56740 (4.57) based on a modified building-block approach, which was similar to ACOG's approach; 57100 (1.20) as presented by the specialty society; 58152 (20.60) in recognition that the current work RVUs are less than the RVUs for code 58150 performed alone even though 58152 combines the work of codes 58150 and 58840; 58260 (12.98) to reflect work of additional office visits included in the procedure; 58262 (14.77) to accurately reflect the work of its component procedures; 58263 (16.06), 58275 (15.76), 58270 (14.26) and 58280 (17.01) to maintain relativity within family of hysterectomy codes; 58267 (17.04) because the procedure is currently undervalued since it encompasses three separate components; 58285 (22.26), which was lower than requested by the specialty group, but which the RUC believed was more reflective of the work for the procedure; 58600 (5.60) based on similarity of this procedure to code 58670; 58605 (5.00) to reflect the slightly lower pre-, intra-, and post-times for this code as compared to 58670; 58611 (1.45) to appropriately reflect the increase in preservice work; 58700 (12.05) reflecting the higher technical skill associated with this procedure (removing only fallopian tube versus ovary and fallopian tube); 58740 (14.00) to reflect increase in intra-service time and postoperative work; 58825 (10.98) which aligns the work value with other codes with similar work; 58920 (11.36) to correct a rank-order anomaly; 58950 (16.93) which combines both codes 58720 and 49255 and applies the multiple procedure rule; 58951 (22.38) based on the similarity of work to 58285 which has the same

recommended value; 59812 (4.01) based on the similarity of work to code 59820; 59870 (6.01) based on increased physician work and postoperative time.

The RUC indicated that the commenter provided no compelling evidence to support an increase in the work RVUs for codes 38571, 57130, 57292, 57307, 57505, 58323, 58400, and 58805.

For code 58820, the RUC indicated that this service had recently been reviewed by the RUC and, therefore, the current work RVUs should be maintained.

HCFA Proposal:

We have reviewed and propose to accept all of the RUC recommendations for the obstetrics/gynecology codes.

b. Other Concerns

We have been alerted to concerns that certain female-specific procedures may be undervalued. Our staff has reviewed the work RVUs associated with a number of female-specific procedures, including major and minor surgical procedures as well as several laparoscopic procedures and has determined that, for the most part, the RVUs assigned seem reasonable and consistent with the time, intensity, and postoperative care involved with the procedures. However, there were several codes that seemed to be inappropriately valued as compared to other similar procedures. These procedures are: code 56515 (*Destruction of vulvar lesions, extensive*); code 57100 (*Biopsy of vagina*); code 56605 (*Biopsy of vulva*); code 58100 (*Biopsy of endometrium*); and code 56810 (*Perineoplasty*).

We forwarded two of these codes (codes 56515 and 57100) to the RUC for review under the 5-year refinement process, and the RUC has recommended an increase in work RVUs for both of these codes.

We have referred the remaining three codes that appear to be misvalued to the RUC for review, and we anticipate receiving a response from the RUC that we can consider in the November 1, 2001 final rule.

8. Gastroenterology

Comment: The American Society for Gastrointestinal Endoscopy (ASGE), American College of Gastroenterology (ACG), and the American Gastrointestinal Association (AGA) provided comments describing gastrointestinal services that they believed to be misvalued. Their comments focused on the identification of specific services whose work RVUs they believe are too low in comparison to other gastroenterology services when comparing time and intensity of the procedures. They also expressed concern that the work RVUs for all gastroenterology procedures involving conscious sedation are substantially undervalued and need to be increased because of the added requirements associated with conscious sedation.

RUC Recommendation:

With regard to conscious sedation, the RUC was concerned about—(1) The need to break out different levels of physician work for conscious sedation, and (2) many gastroenterology codes have been previously valued with conscious sedation included and some codes were not valued with conscious sedation included. Therefore, the RUC agreed to create a joint RUC and CPT workgroup to review and define the issues related to conscious sedation. Based upon information presented by the specialty at the February 2001 RUC meeting, the RUC agreed that elements of conscious sedation have changed over the past 5 years; however, the RUC was not able to quantify the change in physician work. While the RUC did not recommend a specific increase, it did recommend and urge us to allow separate reporting and payment of conscious sedation codes 99141 and 99142 when conscious sedation is not inherently included as a component of the physician work of the procedure.

Based on technological advances, increased complexity in procedure, and changes in patient population the RUC recommended an increase in work RVUs for the following codes: 43219 (3.18); 43239 (2.87); 43244 (5.05); 43247 (3.59): 43249 (3.35); 43255 (4.82); 43259 (8.59); 43263 (7.29); 43265 (10.02); 43269 (8.21); 44388 (3.70); 44389 (4.26); 44390 (4.81); 44391 (5.18); 44392 (4.81); 44393 (5.00); and 45380 (4.44).

Based on the lack of compelling evidence to increase the work RVUs, the RUC recommended that the current work RVUs be maintained for the following codes: 43217, 43228, 43246, 43251, 43258, 44394, 45383, 45384, and 45385.

HCFA Proposal:

The RUC reviewed a selected series of gastrointestinal endoscopy codes for the 5-year review. These codes included endoscopy of the esophagus, stomach, duodenum, small intestine, large intestine, stoma, and biliary tree. The RUC recommended increases in work RVUs for some of the codes and no change in work for other codes. Unfortunately, the RUC could not review all of the endoscopy codes in each family and, therefore, was in the position of having to make recommendations that would likely cause new rank-order anomalies or exacerbate existing rank-order anomalies within and among these families. Furthermore, creation of rank-order anomalies across specialties was also likely. For example, a bronchoscopic biopsy would be valued significantly less than a gastrointestinal endoscopic biopsy if the gastrointestinal endoscopic biopsy was increased in value.

Although we are concerned that some of these endoscopy codes may be misvalued, we are proposing to keep all work RVUs for gastrointestinal endoscopy codes unchanged. However, we believe that a comprehensive review of the work RVUs for all gastrointestinal endoscopy codes is warranted. Therefore, we are asking the RUC to perform a comprehensive review of all gastrointestinal endoscopy codes to ensure that all codes are properly valued, and that no rank-order anomalies within and across specialties are created or exacerbated. We hope to receive recommendations from the RUC for these codes in time for the proposed physician fee schedule regulation in 2002.

Below we discuss our reasons for proposing to reject the recommended work increases for each code. However, we note that many new gastrointestinal endoscopy CPT codes were created for use in 2002 and reviewed by the RUC concurrent with the 5-year review. Recommendations for these new codes were made by comparing them to the current work RVUs of existing gastrointestinal endoscopy codes, some of which were reviewed as part of the 5-year review. Therefore, any increases in work RVUs for codes in the 5-year review will likely invalidate the work RVUs for many of the new codes reviewed by the RUC. Furthermore, proposals have been made for even more gastrointestinal endoscopy CPT codes for CYs 2002 and 2003. We want to ensure that these new codes are properly reviewed and appropriate work RVUs assigned. Until a comprehensive review of all gastrointestinal endoscopy codes is performed we do not believe this is possible.

Code 43219, *Esophagoscopy, rigid or flexible; with insertion of plastic tube or stent:*

The RUC recommended an increase in work RVUs from 2.8 to 3.18 based upon the increased complexity of the condition of patients receiving these stents. The current work increment between this code and 43200 (1.21 RVUs) has been used extensively by the RUC to make recommendations for other endoscopic stent placement procedures. Therefore, in spite of this recommendation, it appears that the RUC and the specialists who perform

this procedure agree that the correct increment for stent placement is 1.21 work RVUs. If the work RVUs for code 43219 were accepted, many other recommendations from the RUC would need to be reevaluated. Furthermore, it is unclear from the vignette used to value this procedure whether or not predilation of the esophagus was included in the work of this code. Currently, code 43226 describes the work of predilation and may be billed in addition to code 43219. The incremental work for placing a tracheal stent with predilation (the difference in work between codes 31622 and 31631) is 1.59 work RVUs. This is significantly less than the current work increment for esophageal stent placement with predilation, 1.96 (1.21 + .75). Additionally, the vignette describes placement of an expandable wire mesh stent but the code is also used for plastic stents, placement of which may require less work. We propose maintaining the current RVU for this code in view of these concerns and the rank-order anomalies that would be created by accepting the RUC recommendation.

Code 43239 (Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with biopsy, single or multiple):

The RUC recommended an increase in work RVUs from 2.69 to 2.87 based on a larger number of biopsies obtained during a procedure. The RUC also stated that technological advances allowing for greater precision and detail in finding abnormalities have increased the need for this service. The RUC also stated that technological advances have allowed for more immediacy of results which increases the post service work in conveying the biopsy information and treatment guidance to the patient. We would note that the current work increments for all endoscopic gastrointestinal biopsy codes (described as the base procedure with ''biopsy, single or multiple'') are 0.3 RVUs. Accepting the RUC recommendation would increase this increment to 0.48 work RVUs while keeping all the other biopsy increments at 0.3 work RVUs, creating a clear rank-order anomaly. Furthermore, this code is used for ''single'' biopsies, and, with the increase in work, these biopsies would be overvalued. We also do not understand how technological advances in locating lesions and getting more immediate results increases the work of the procedure itself. Therefore, we propose maintaining the current work RVU for this procedure.

Code 43244 (Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with band ligation of esophageal and/or gastric varices) and 43255 (Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with control of bleeding, any method):

The RUC recommended an increase in work RVUs for code 43255 from 4.4 to 4.82 work RVUs based on new technology, such as lasers, to control bleeding. The RUC also states that this new technology increases the intensity of the procedure. However, the vignette used to survey code 43255 describes use of cautery to control bleeding. The work for this code must be appropriate for all methods of controlling bleeding and the vignette must represent the typical case. The current work increment for ''control of bleeding, any method'' for gastrointestinal endoscopic procedures is 2.01 work RVUs. Acceptance of the RUC recommendation for code 43255 would make this work increment 2.43 RVUs, for upper gastrointestinal endoscopy only, creating a clear rank-order anomaly.

The RUC recommended an increase in work RVUs for code 43244 from 4.59 to 5.05 RVUs, based on the increased number of bands used to treat esophageal varices. However, the RUC agreed that the work RVUs for code 43244 were similar to the work RVUs for code 43255. Therefore, accepting the RUC recommendation for code 43244 and not code 43255 would create a clear rank-order anomaly. We believe that these two codes should have similar work RVUs. Therefore, we propose to maintain the current work RVUs for these procedures.

Code 43247 (Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with removal of foreign body):

The RUC recommended an increase in work RVUs for this code from 3.39 to 3.59 work RVUs based on increased complexity of the condition of patients undergoing this procedure with a concomitant increase in risk of morbidity. The RUC used a building-block approach to validate its acceptance of the median work RVUs from the survey. We do not fully understand the building-block analysis the RUC used but believe it was invalid. Moreover, the current work increment for ''removal of foreign body'' for gastrointestinal endoscopy procedures is 1.0 work RVUs. Acceptance of the RUC recommendation would create a clear rank-order anomaly. Therefore, we propose to maintain the current work RVUs for this procedure.

Code 43249 (Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with balloon dilation of esophagus (less than 30mm diameter)):

The RUC recommended an increase from 2.9 to 3.35 work RVUs for this code based on increased complexity of the condition of patients undergoing this procedure. The current work increment for ''balloon dilation of esophagus (less than 30 mm diameter)'' is 0.51 RVUs for both the esophagus and upper gastrointestinal endoscopy families. Since this is the same procedure in both families, it is unclear why the work should be increased to 0.96 work RVUs for the upper gastrointestinal family only. Accepting the RUC recommendation would create a clear rank-order anomaly. Therefore, we are proposing to maintain the current work RVUs for this code.

Code 43259 (Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; with endoscopic ultrasound examination):

The RUC recommended an increase in work RVUs from 4.59 to 8.59 based on the complexity of the equipment and the skill and judgement required. The RUC also noted that the survey results supported this procedure as more difficult than an *endoscopic retrograde cholangio-pancreatography (ERCP).* The RUC then used the following building-block methodology: (1) The RUC added 1.5 work RVUs, which was approximately 75 percent of the difference between the RUC recommendation from the last 5-year review (6.11 work RVUs) and the work RVUs that we assigned (4.0 work RVUs). (2) The RUC then added 2.2 work RVUs, which are the work RVUs of code 93312. Not only do we disagree with the RUC methodology for this recommendation, but we also note that the RUC has used the current work RVUs for code 43259 to value not only other gastrointestinal transendoscopic ultrasound procedures but also many transendoscopic ultrasound guided biopsy codes. We would also note that the RUC has recently re-evaluated code 43231, *Esophagoscopy, rigid or flexible; with endoscopic ultrasound examination,* and will be sending a new recommendation to us regarding the work valuation of this procedure. Accepting the RUC recommendation for this code would be inconsistent with the RUC's reevaluation of code 43231, would invalidate the work valuation of many other gastrointestinal endoscopy

codes, and would create numerous rank-order anomalies. Therefore, we propose to maintain this code at its current work RVUs.

Codes 43263 (Endoscopic retrograde cholangio-pancreatography (ERCP); with pressure measurement of sphincter of Oddi (pancreatic duct or common bile duct)), 43265 *(ERCP; with endoscopic retrograde destruction, lithotripsy of stone(s), any method),* and 43269 *(ERCP; with endoscopic retrograde removal of foreign body and/or change of tube or stent):*

The RUC recommended an increase in work RVUs from 6.19 to 7.29 for code 43263 based on the need to measure pressures in both the biliary and pancreatic sphincters as well as the need for prolonged postoperative monitoring. The RUC arrived at its recommendation by adding 1.1 work RVUs (the value of code 99214) to the current work RVUs. We disagree with valuing a post procedure observation period as equal to an evaluation and management service. Furthermore, increasing the value of this code while not adjusting the values of codes 43262, 43267, and 43268 creates clear rank-order anomalies.

The RUC recommended an increase in work RVUs from 8.9 to 10.02 for code 43265 based on a rank-order anomaly with code 43264. The RUC compared survey times to the Harvard study times for this code and used a building-block method to arrive at its recommendation. We do not fully understand the RUC methodology and disagree with the conclusion. The Harvard study time data show less time for code 43265 than for code 43264, which would indicate that the current valuations of these codes are correct. Moreover, increasing the value of 43265 while not adjusting codes 43264, 43267, and 43268 would create clear rank-order anomalies.

The RUC recommended an increase in work RVUs from 6.04 to 8.21 for code 43269 based on a rank-order anomaly between this code and code 43268. The RUC used a building-block methodology adding 0.82 work RVUs to the work RVUs of code 43268 (7.39) to arrive at its recommendation. We disagree with the RUC methodology of using an evaluation and management service to arrive at its recommendation since this is an invasive procedure. Furthermore, we believe increasing the value of this code creates a rank-order anomaly with codes 43271 and 43272. Therefore, we are proposing maintaining the current work RVUs of all three of these codes.

Codes 44388 (Colonoscopy through stoma; diagnostic with or without collection of specimen(s) by brushing or washing (separate procedure)), 44389 *(Colonoscopy through stoma; with biopsy, single or multiple),* 44390 *(Colonoscopy through stoma; with removal of foreign body),* 44391 *(Colonoscopy through stoma; with control of bleeding, any method)* 44392 *(Colonoscopy through stoma; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps or bipolar cautery),* and 44393 *(Colonoscopy through stoma; with ablation of tumor(s), polyp(s), or other lesion(s) not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique).*

These codes are in the same family of codes, and the RUC recommended increases in work RVUs for all these codes based on a misvaluation of the base code in this family of codes, code 44388. The RUC valued it similarly to code 45378. We disagree. We think this creates a clear rank-order anomaly between the value of this family and the value of the colonoscopy family of codes beginning with code 45378. Colonoscopy through a stoma is clearly less work than colonoscopy of the complete colon and it has been valued as such since the inception of the physician fee schedule. We question the accuracy of the surveyed intraservice time for this service. Because of our nonacceptance of the increase in work RVUs for the base code in this family, we must also not accept the recommendations for all other increases in work RVUs for other codes in this family. Moreover, the recommendations create increments of work for ''biopsy, single or multiple,'' ''removal of foreign body,'' ''control of bleeding, any method,'' ''removal of tumors,'' and ''ablation of tumors,'' which are inconsistent with the same increments for the colonoscopy family of codes beginning with code 45378. Accepting these RUC recommendations would create clear rank-order anomalies that do not currently exist. Therefore, we are proposing to maintain the current work RVUs for these procedures.

Code 45380 (Colonoscopy, flexible, proximal to splenic flexure; with biopsy, single or multiple).

The RUC recommended an increase in work RVUs from 3.98 to 4.44 for this code based on the increased number of biopsies generally taken during this procedure and the increased difficulty in removing these polyps. The current work increment for ''biopsy, single or multiple'' for gastrointestinal endoscopic procedures is 0.3 work RVUs. Accepting the RUC recommendation would create a clear rank-order anomaly. Moreover, we note that this code is also used for single biopsies that would become significantly overvalued if we accepted the RUC recommendation. Therefore, we are proposing to maintain the current work RVUs for this code.

In summary, we believe the only way to accurately value gastrointestinal endoscopy procedures is to evaluate the entire series of codes, including all families of codes (esophagus, upper gastrointestinal, ERCP, and colonoscopy etc.) at the same time. Only then can appropriate incremental work RVUs be determined without creating rank-order anomalies. We would also suggest that the RUC consider reorganization of all these codes to facilitate more accurate coding (for example, to determine whether every family of codes needs a code for ''removal of foreign body'' or whether the base code be revalued to include more procedures than it currently does).

We suggest that while the RUC is reevaluating these codes that it delay making recommendations on any new codes for this series so that conflicting recommendations are not made and the chance of creating rank-order anomalies is minimized.

With respect to the RUC recommendation concerning reporting and payment of conscious sedation codes 90141 and 90142, we will be reviewing data concerning this issue. Any proposals we would have concerning payment and reporting of conscious sedation codes would be the subject of future rulemaking.

9. Pulmonary Medicine/Critical Care

Comment: Several specialty groups, including the societies for pulmonary medicine and critical care, indicated that codes 36620 and 36489 were undervalued. Commenters indicated that the work RVUs for code 36489 should be greater than the work RVUs for the reference service code, 36010, because there is more work involved. Commenters also stated that code 36620 is undervalued as compared to the reference code 36140, because there are more variables affecting the work involved with this procedure.

These specialty groups also requested that codes 99291 and 99292 be evaluated because the groups claimed they were undervalued.

RUC Recommendation:

For code 36489, the RUC noted that there is additional work and postoperative time involved in this procedure as compared to that of the reference service code 36010, and recommended work RVUs of 2.50 which are higher than the reference service code 36010 (2.43), which corrects the rank-order anomaly. With respect to 36620, the RUC compared this

procedure to the reference service (code 36140) and agreed that this service appeared to be undervalued. However, the RUC was concerned that anesthesiologists who perform this procedure over 80 percent of the time did not comment or participate in the survey conducted by the specialty groups. The RUC concluded that code 36620 should be referred to the CPT Editorial Panel to clarify the appropriate use of this code.

The RUC recommended maintaining the work RVUs for critical care services (codes 99291 and 99292) due to the lack of compelling evidence to recommend an increase in the work RVUs above the 2001 work RVUs of 4.00 and 2.00, respectively.

HCFA Proposal:

We have reviewed and propose to accept all of the RUC recommendations for the pulmonary medicine and critical care codes.

10. Cardiology

Comment: The American College of Cardiology (ACC) recommended review of three procedure codes under the 5-year refinement. They are code 93350, which was not reviewed during the first 5-year review but which the ACC believes is undervalued; and codes 33234 and 33235, which ACC argues are undervalued because it does not believe the codes reflect the level of difficulty associated with the procedures.

RUC Recommendation:

The RUC supported an increase in the work RVUs for code 93350 to account for the increased work and more complex conditions of the patient population as supported by survey information submitted. The RUC recommendation was to increase the work RVUs to 1.48. For codes 33234 and 33235, they recommended that no change be made in the work RVUs because both procedures had been recently reviewed by the RUC.

HCFA Proposal:

We have reviewed and propose to accept all of the RUC recommendations for the cardiology codes.

11. Pediatrics

Comment: The American Academy of Pediatrics (AAP) submitted approximately 40 codes involving several specialty areas and indicated that they believed these services are undervalued, particularly when they are provided to the pediatric population. A few of these codes were also submitted by other specialty groups and are discussed under those areas (codes 29450, 99291, and 99292). The AAP subsequently indicated to the RUC that they were not interested in pursuing the review of the work RVUs for the following codes for this 5-year review: 11100, 11730, 17000, 17003, 17004, 20600, 36600, 52300, 52327, and 52340.

RUC Recommendation:

For codes 36400 and 36405, the RUC agreed that an increase in the work RVUs appeared to be warranted and recommended work RVUs of 0.38 and 0.32, respectively. However, for codes 94640, 99440, 99233, 99273, and 99274, the RUC indicated that compelling evidence was not provided to suggest a recommendation to increase the work RVUs and thus the current RVUs should be maintained for these services.

The RUC recommended that the following codes be submitted to the CPT Editorial panel for further consideration: 12001, 12002, 36406, 36520, 50200, 90935, 90937, 90945, 90947, 90989, 90993, 90997, 94664, and 94665.

For codes 99295, 99296, 99297, 99298, and 99436, the RUC recommended no change in the work RVUs for these services because these services had recently been reviewed by the RUC.

HCFA Proposal:

We have reviewed and propose to accept all but two of the RUC recommendations for the pediatric codes.

For code 36400 *(Venipuncture, under age 3 years; femoral, jugular or sagittal sinus)*, the RUC recommended an increase in work RVUs from 0.18 to 0.38. The RUC survey compared this code to code 36410 *(Drawing blood, child over 3 or adult, necessitating physician's skill (separate procedure), for diagnostic or therapeutic purposes)* (work RVUs of 0.18). The survey times indicated that the pre-, intra-, and postservice times for code 36400 were less than the times for code 36410. The median work RVUs from the survey were 0.71, and the 25th percentile work RVUs were 0.30. The specialty society recommended work RVUs of 0.71, citing the change in population of patients requiring this procedure (being younger and smaller). The RUC also compared code 36400 to code 99212 (Office/outpatient visit, established patient) with work RVUs of 0.45 and believed the work RVUs of code 36400 were comparable to the work RVUs of code 99212). The RUC then recommended work RVUs between the 25th percentile of the survey and the work RVUs of code 99212. We do not believe it is appropriate to compare the work RVUs of a venipuncture to the work of an evaluation and management service. Furthermore, we are concerned about the spread in the survey work RVUs from 0.30 at the 25th percentile to 0.71 at the median. In view of the survey times being less than the reference code (with work RVUs of 0.18), the inconsistency of the survey times with the survey RVUs, and the inappropriate comparison to an evaluation and management service, we are proposing to continue the work RVUs of code 36400 as 0.18 work RVUs.

For code 36405 *(Venipuncture, under age 3 years; scalp vein)*, the RUC recommended an increase in work RVUs from 0.18 to 0.32. The survey compared code 36405 to code 36410. The pre-, intra-, and postservice times for code 36405 were less than the times for the reference code. The survey RVUs were widely spread with the 25th percentile work RVUs being 0.2 and the median work RVUs being 0.4. The RUC also compared code 36405 to code 99212 (0.45) and recommended a value between the survey 25th percentile work RVUs and the work RVUs for code 99212. Our concerns about this recommendation are similar to the concerns about the recommendation for code 36400. In view of the survey times, the wide range of survey work RVUs, and the inappropriate comparison to an evaluation and management service, we are proposing to continue the work RVUs of code 36405 at 0.18.

12. Pediatric Surgery

Comment: The American Pediatric Surgical Association (APSA) stated that the pediatric surgery procedure codes are misvalued and included recommended work RVUs. While they suggested reductions in the work RVUs of codes 46705 and 46715 to retain relativity in the family of services, they believed that the majority of the codes they provide are significantly undervalued. The association justifies the need to increase the work RVUs for these services based on one or more of the following rationales:

- A change in practice and technology.
- A change in the patient population for which the code is most frequently applied.
- An undervaluation of the postservice work in the global period.
- Rank-order anomalies.
- Extended postoperative critical care. It is the provision of very intensive, prolonged services with long episodes of critical care and long hospital stays that account for the very high work RVUs recommended for some procedures. APSA subsequently indicated that they did not want to pursue review of two codes under the 5-year review: 43305 and 60280.

RUC Recommendation:

The RUC recommended that the suggested decreases in the work RVUs

for codes 46705 and 46715 be implemented. The recommended work RVUs are 6.90 for code 46705 and 7.20 for code 46715.

Based on the information provided by the specialty society, the RUC recommended increasing work RVUs for the following codes to address the undervalued physician work in the intra- and postservice periods, the extended critical care services, and a change in patient population: 39503 (95.00); 44055 (22.00); 46716 (15.07); 46730 (26.75); 46735 (32.17); 46740 (30.00); 46742 (35.80); 46744 (52.63); 46746 (58.22); 46748 (64.21); 49215 (33.50); and 49605 (76.00).

The RUC did not receive compelling evidence to suggest that an increase is needed in the work RVUs for these codes: 36822, 45120, 45121, 47701, and 49606.

The RUC recommended that the following codes be referred to the CPT Editorial Panel for clarification and review: 21740, 43310, 43312, 49495, and 49496. In some instances, new codes may need to be created to accurately value services performed on the pediatric and adult population.

HCFA Proposal:

We propose to accept all but two of the RUC recommendations for the pediatric surgery codes. The RUC recommended large increases in work RVUs for codes 39503 *(Repair, neonatal hernia, with or without chest tube insertion and with or without creation of ventral hernia)* and 49605 *(Repair of large omphalocele or gastrochsis; with or without prosthesis)* for both of these procedures (an increase from 37.54 to 95.0 work RVUs for code 39503 and from 24.94 to 76.0 work RVUs for code 49605). These increases were based entirely on the increase of postoperative work required for these procedures, resulting in an increase of approximately 50 work units for each code. Both procedures are performed on neonates who require prolonged stays in the intensive care unit postoperatively. We understand that the postoperative care may be performed by the surgeon, the intensivist, or both physicians. In situations where the postoperative care is provided by both physicians, we could make duplicate payments for postoperative care if we continue to value these as 90-day global procedures. To permit the physician who is performing the postoperative care to be appropriately paid, but prevent duplicate payment for the same services, we are considering a reduction in the global period (for example, making the global period 10 or 0 days). If we shortened the global period for these services, appropriate work RVUs consistent with this change would need to be developed. If the surgeon provides postoperative care outside of the 10-day global period (that is, 10 days after the date of surgery)or outside of the 0-day global period (that is, the day after surgery) he or she would bill separately for those services. Moreover, if the intensivist provides the postoperative care, then the intensivist would bill for the service, and there would be no duplicate payment to the surgeon.

Based on the above discussion, we are proposing to maintain the current RVUs for these two CPT codes (39503 and 49605) as an interim for 2002 and would ask the RUC to submit work RVU recommendations for these codes valued with reduced global periods (a 0-day or 10-day period). We would consider the RUC recommendations and make a proposal to initiate a change to the global period as well as associated RVUs in next year's proposed rule. We invite comments on the issue of reducing the global period for these services and welcome any alternative suggestions that we could consider that address our concerns of eliminating duplicate payment.

13. Radiology

Comment: The American College of Radiology (ACR) identified three codes that they believe are undervalued. The code 76065, radiologic examination of an infant, is most commonly performed in the situation of alleged child abuse and requires a significant amount of physician work. Additionally, radiologists indicated that the work RVUs for two mammography procedure codes (codes 76090 and 76091) are not reflective of the amount of physician work necessary to perform all the requirements for the government regulated procedures and ACR standards. The level of quality control and quality assurance requirements instituted by the Food and Drug Administration (FDA) and Mammography Quality Standards Act of 1992 (MQSA) have increased the level of physician time outside of the direct patient care time. The current work RVUs assigned to these codes are not adequate to perform this procedure in accordance with Federal regulations or ACR standards. ACR contended the combination of increased mental effort and judgement, psychological stress, time, and intensity mandate that the work RVUs for these codes should be increased.

RUC Recommendation:

The RUC noted that the intensity for code 76065 is higher than the reference service code 76062 and that for intraservice work the physician typically reviews more films. The RUC recommended work RVUs of 0.70 for code 76065. For the mammography procedure codes, the RUC was in agreement that as a result of the revisions of the MQSA requirements, which require the physician to code radiologic results using BIRADs terminology and require that separate reports be sent to the patient and referring physician, the codes result in increased physician time, mental effort, and judgement. In addition, code 76091 is a bilateral mammography requiring two studies to be performed. Based on survey information, the RUC determined the 25th percentile of the survey was the appropriate value and recommended work RVUs of 0.70 for code 76090 and 0.87 for code 76091.

HCFA Proposal:

We have reviewed and propose to accept all of the RUC recommendations for the radiology codes discussed above.

We would also note that section 104 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Public Law 106–554) puts screening mammography under the physician fee schedule for services furnished beginning January 1, 2002. We will include our recommendation of the work RVUs for this service for CY 2002 as part of the physician fee schedule proposed rule for CY 2002.

Because this will be a new code in the physician fee schedule, we have asked the RUC to recommend work RVUs for screening mammography.

14. Plastic Surgery

Comment: The American Society of Plastic Surgery (ASPS) requested that codes 42205 and 49905 be reviewed under the 5-year review. ASPS indicated that there currently is a rank-order anomaly for code 42205 that was created when other codes in the family of codes were reviewed and increased during the first 5-year review. They recommended an increase to the work RVUs (9.59 to 12.0) for this code that would reestablish rank-order in the cleft palate family of codes. With respect to code 49905, ASPS stated that this code is currently designated as an add-on code, which was not the intent of the specialty group when they submitted the proposal to the AMA CPT Editorial Panel in 1991 for creation of this code. They also disagree with our assumption that pre- and postoperative work was included in the RUC-recommended work RVUs that we reduced. ASPA recommended that code 49905 be changed from an add-on to a primary procedure code with a 90-day global period and be assigned work RVUs

comparable to those of code 15374 (17.79).

RUC Recommendation:

The RUC reviewed code 42205 and recommended an increase in the work RVUs (for work RVUs of 13.29), which will correct the existing rank-order anomaly in this family of codes. The RUC recommended that code 49905 be referred to the CPT Editorial Panel for review.

HCFA Proposal:

We have reviewed and proposed to accept the RUC recommendations for the plastic surgery codes.

C. Other Comments

1. Anesthesia Services

The American Society of Anesthesiologists (ASA) contended that the work of anesthesia services is undervalued by almost 31 percent. (This initial request was subsequently adjusted based on additional discussions with the RUC.)

As required by law, we base Medicare payments for anesthesia services on allowable base and time units. We have developed a uniform relative value guide in which the base unit per anesthesia code is largely based on the American Society of Anesthesiologists' 1988 relative value guide. Anesthesiologists report the actual anesthesia time for each procedure on the claim, and the carrier converts the time to time units. The carriers then multiply the sum of the base units and time units by the anesthesia conversion factor.

We used the results of the original Harvard Study on work to determine the adjustment to the anesthesia CF under the physician fee schedule in 1992. (Anesthesia services do not have work RVUs. Therefore, if work RVUs of other physician services are increased an adjustment has to be made to the anesthesia CF so that the work of anesthesia services remains on the same scale as other physician work.)

In the first 5-year review of work, we accepted the RUC's recommendation that the work of anesthesia services was undervalued by 22.76 percent, which resulted in a 16 percent increase in the anesthesia CF.

The approach to this 5-year review used by the ASA involves a physician survey and a consensus panel review. The survey was sent to 262 members of the ASA in a geographically representative sample. Eighty-five surveys were returned from respondents who were geographically representative of the specialty as a whole. The findings of the survey were presented to an expert consensus panel of 16 practicing anesthesiologists from the ASA's Relative Value System (RVS) Committee. The work of the anesthesia service was uniformly divided into five components. These components are—preoperative evaluation, equipment and supply preparation, induction period, postinduction anesthesia period, and postoperative care and visits. The survey median times were assigned to each of the five components. The consensus panel assigned the work RVUs of an evaluation and management code, usually codes 99202 or 99201, to the preoperative evaluation. The consensus panel developed a code-specific survey time estimate and intensity value for equipment and supply preparation. For postoperative care and visits, the consensus panel assigned work RVUs equivalent to those of an evaluation and management code, usually code 99211 or 99231. The survey median time for the postinduction anesthesia period was divided in quintiles and each quintile was assigned intensity work RVUs ranging from 0.026 to 0.085. The consensus panel identified the typical anesthetic by procedure code and generally used the intensity of code 31500, *Intubation, endotracheal, emergency procedure,* a similar CPT code, to value the work. This methodology was used for 19 high-volume surgical codes requiring anesthesia and representing a reasonable variety of surgical services.

The following illustrates this approach for anesthesia code 00404 and the underlying surgical code 19240 (Modified radical mastectomy):

	Work RVUs
Preanesthesia Median Time	15 min.
• Preanesthesia reference code 99202	0.88
Equipment and Supply Preparation Median Time	10 min. 0.14
Induction Period Procedure Time	10 min. 0.93
Post Induction Anesthesia Period:	
Level 1 Time	87 min.
Level 2 Time	10 min.
Level 3 Time	10 min.
Level 4 Time	0 min.
Level 5 Time	0 min. 3.09
Postanesthesia Time	14 min.
• Postanesthesia Reference Code 99231	0.64
Total Work RVUs	5.68

For each code, the total work RVUs were compared to a Medicare fee schedule imputed work value. The Medicare imputed work value is computed by multiplying the average allowed anesthesia charge per code by the anesthesia work share and dividing by the national CF. The average anesthesia allowed charge is determined by surgical code from HCFA's 5 percent Beneficiary File.

Based on this analysis, the ASA requested a 24 percent increase in anesthesia work.

RUC Recommendation:

The RUC furnished no recommendation on anesthesia services; instead it assigned to a newly created workgroup the responsibility for reviewing anesthesia services in the context of the physician fee schedule. The ASA will be working with this workgroup on clinical issues, such as induction and postinduction intensity RVUs.

HCFA Proposal:

We propose to make no changes to the anesthesia CF at this time to reflect the 5-year review of physician work for anesthesia services. However, we may make changes in response to recommendations the RUC may provide.

2. Spine Injection Procedures

Comment: The American Society of Anesthesiologists submitted a request for re-evaluation of seven spinal injection codes that they, along with several other medical associations, had expressed concern about when the codes were revalued for CY 2000. They continue to believe the work RVUs

assigned by the RUC in 1999 and forwarded to HCFA were appropriate.

RUC recommendation:

In 1999, when the RUC forwarded revised work RVUs, we agreed with the relativity of the four injection codes (62310, 62311, 62318, and 62319), but applied a budget-neutrality factor that the specialties believe is inappropriate. In 1999, we also decreased the RUC-recommended work RVUs for codes 72275, 62263, and 76005 based on our belief that the values were too high. The RUC has now reviewed the original surveys and subsequent recommendations and continues to believe that its 1999 recommendations for work RVUs for these codes are appropriate. They recommended the following work RVUs for these services: 62310 (2.20); 62311 (1.78); 62318 (2.35); 62319 (2.15); 62263 (7.20); 72275 (0.83) and 76005 (0.60). (Note: for code 76005, the work RVUs were 0.60 for this service on the CY 2000 fee schedule)

HCFA Proposal:

We propose to reject the RUC recommendations for these codes for the following reasons:

Codes 62310 *(Single injection (not via indwelling catheter), not including neurolytic substances, with or without contrast (for either localization or epidurography), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), epidural or subarachnoid; cervical or thoracic)),* 62311 *(Single injection (not via indwelling catheter), not including neurolytic substances, with or without contrast (for either localization or epidurography), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodoic, opioid, steroid, other solution), epidural or subarachnoid, lumbar, sacral(caudal)),* 62318 *(Injection, including catheter placement, continuous infusion or intermittent bolus, not including neurolytic substances, with or without contrast(for either localization or epidurography), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), epidural or subarachnoid; cervical or thoracic), and* 62319 *(Injection, including catheter placement, continuous infusion or intermittent bolus, not including neurolytic substances, with or without contrast (for either localization or epidurography), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodoic, opioid, steroid, other solution), epidural or subarachnoid; lumbar, sacral (caudal)).*

These were new codes for CY 2000. The RUC submitted recommendations for these codes in CY 1999. We accepted the RUC recommendations and made a work-neutrality adjustment because these new codes replaced codes under which these services were billed before 2000. The RUC and several specialty societies disagreed with the data we used in making our work-neutrality adjustment. (Work-neutrality adjustments ensure that the recommendations for work RVUs for new and revised services are adjusted so that the sum of the new or revised work RVUs (weighted by projected frequency of use).) for a family of codes will be the same as the sum of the current work RVUs (weighted by frequency of use). We have reviewed the data used to make our work-neutrality adjustment and have determined that the adjustment made was accurate. The RUC work recommendations for the 5-year review are identical to the recommendations we received and evaluated in CY 1999. In view of this, we are proposing to maintain the current work RVUs for these services.

Code 62263 *(Percutaneous lysis of epidural adhesions using solution injection (eg, hypertonic saline, enzyme) or mechanical means (eg, spring-wound catheter) including radiologic localization (includes contrast when administered).*

This was a new code for CY 2000. We received RUC recommendations in CY 1999 for this code and disagreed with them. The RUC recommendation was 7.20 work RVUs, and we made the interim work RVUs 6.02 for CY 2000. In the summer of 2000, we convened a multispecialty review panel that reviewed this code in detail and recommended work RVUs of 6.14. We finalized the multispecialty review panel recommendation of 6.14 work RVUs for CY 2001. The current RUC recommendation is identical to the RUC recommendation from CY 1999. We find no compelling reason to change the RVUs for this procedure, especially since this procedure was reviewed by a multispecialty panel less than 1 year ago. We propose to continue the current work RVUs for this procedure.

Code 72275 *(Epidurography, radiological supervision and interpretation).*

This code was new for CY 2000. The RUC submitted a recommendation for 0.83 RVUs. We disagreed with this recommendation and made the interim work RVUs 0.54 for CY 2000. We submitted this code to a multispecialty review panel that recommended an increase to 0.76 work RVUs that we implemented for CY 2001. The RUC now submits a recommendation of 0.83 work RVUs for this procedure, identical to its prior recommendation. In the absence of compelling reasons to change the current work RVUs, and because this code was reviewed by an objective multispecialty panel less than 1 year ago, we are proposing to continue the current work RVUs.

Additionally, codes 62310, 62311, 62318, 62319, 62263, and 72275 were reviewed and finalized in the July 2000 Multispecialty Refinement Panels for new and/or revised services. Since the RUC recommendations have offered no evidence in addition to that which was presented at the July 2000 Multispecialty Refinement Panel Meeting, we propose to retain the existing work RVUs.

3. Biofeedback

Comment: One organization, Medcare, requested review of the work and practice expense RVUs for biofeedback codes 90911 and 90901, as it believes that these codes currently are undervalued.

RUC Recommendation:

The RUC reviewed the original survey data for code 90911 and noted that while we had decreased the original RUC-recommended work RVUs, we received no further information to indicate that our rationale for reducing the work RVUs was inappropriate, and the specialty societies that perform the service did not present new information in response to the decrease. The RUC recommended that the current RVUs be maintained since it received no compelling evidence to recommend an increase in work RVUs.

HCPAC Recommendation:

The HCPAC recommended that the current work RVUs be maintained for code 90901 because we received no additional information from the specialists who perform this service to warrant an increase in work RVUs.

HCFA Proposal:

We reviewed and propose to accept the RUC and HCPAC recommendations for biofeedback services.

4. Surgical Management of Burn Wounds

Comment: The American Burn Association (ABA) submitted codes commonly used for the surgical management of burn wounds (codes 15000 through 15641). The ABA requested assignment of RVUs for these codes that more appropriately reflect the work involved. ABA also requested the creation of more specific codes that would obviate the need for ''G'' codes. The ABA indicated that these codes should be exempt from CPT payment policies with respect to the 90-day global period, multiple procedures and

staged procedures due to the unique clinical case management of burns.

RUC Recommendation:

The RUC recommended that the following codes be reviewed by the CPT Editorial Panel: 15000, 15001, 15100, 15101, 15120, 15121, 15350, 15351, 15400, and 15401.

HCFA Proposal:

We have reviewed and proposed to accept the RUC recommendation for these codes.

5. Transplantation

Comment: The American Society for Transplant Surgeons requested reassessment of the work RVUs for code 47134 because the current work RVUs do not accurately reflect the work involved (it contended that over 50 percent of these procedures involve right lobectomies that are more labor intensive than left lobectomies, on which the current work RVUs are based). As an alternative, the American Society for Transplant Surgeons also suggested referral to the CPT Editorial Panel for consideration of creation of an additional code.

RUC Recommendation:

The RUC recommended that code 47134 be forwarded to the CPT Editorial Panel for further consideration.

HCFA Proposal:

We have reviewed and propose to accept the RUC recommendation for this code.

6. Arthroscopy Services

Comment: The Arthroscopy Association of North America (AANA) requested that work for other arthroscopy services be reconsidered in light of the increase in work RVUs for code 29848 in the last 5-year review. The AANA also requested a specific increase in the work RVUs for code 29889. Subsequently, the specialty society chose not to pursue its request for consideration for code 29881.

RUC Recommendations:

For code 29883, the RUC noted that this service consisted of two procedures, medial and lateral meniscus repair. Because this service encompassed the work involved in code 29882 plus additional work for the lateral meniscus repair, and using the building-block approach, the RUC recommended work RVUs of 11.05 for this service. For code 29889, the RUC indicated that, due to the increase in post-and intraservice time, the work RVUs should be increased to 16.00.

HCFA Proposal:

We have reviewed and propose to accept the RUC recommendation for this code.

7. Wheelchair Management

Comment: The American Physical Therapy Association requested review of code 97542.

HCPAC Proposal: We had revised the recommended work RVUs for this code when it was previously reviewed by the HCPAC in 1995, based on a comparison of code 97542 to code 97032 rather than to code 97110. The HCPAC concluded that our comparison was incorrect because code 97032 is the application of a modality, while code 97542 requires additional skills because the patients requiring this service have cognitive, sensory, and physical disabilities. In addition, HCPAC indicated that we may not have understood that this procedure is reported very infrequently. The HCPAC supports its original recommendation of 0.45 work RVUs for this service.

HCFA Proposal:

We have reviewed and propose to accept the HCPAC recommendation for this code.

8. Psychological Testing

Comment: The American Psychological Association recommended that we review five psychological testing codes (96100, 96105, 96110, 96115, and 96117).

HCPAC Recommendation:

The HCPAC did not have any recommendations for these codes at this time. However, it indicated that the American Psychological Association may request HCPAC to review these services at a future date once additional information is collected.

HCFA Proposal:

We propose to make no changes at this time. We believe more precise definitions of these services may be necessary to value them properly and to ensure proper coding and billing of these services.

9. Podiatric Services

Comment: The American Podiatric Medical Association submitted five codes (trim skin lesions/trim nails) for review (11719, 11055, 11056, 11057, and G0127) indicating that they are undervalued and do not accurately reflect the level of physician work involved.

HCPAC Recommendation:

The HCPAC reviewed these codes and had no information to support an increase in work RVUs. However, the HCPAC requested that we review our current utilization data to ensure that the original utilization assumptions were correct. The HCPAC recommended that the current review of data should be based on actual 1999 utilization data since these codes were not fully implemented until April 1, 1998.

HCFA Proposal:

Taking into account the recommendation of the HCPAC, we propose to review utilization data associated with the aforementioned codes to ensure the original assumptions are still correct. We will publish our final decision in the November 2001 final rule.

D. Other Issues

1. Critical Care Services in a Global Period

Validation of RUC recommendations for the work of many surgical procedures included the use of a ''building-block'' methodology as previously described. Before this 5-year review, the RUC compared the work of a postoperative intensive care unit visit by the surgeon to a level three subsequent hospital visit (code 99233) which is valued at 1.51 work RVUs. Now, for the first time since the inception of the physician fee schedule, one of the ''building blocks'' the RUC used to validate postoperative work by the surgeon in the intensive care unit is code 99291 (*Critical care, evaluation and management of the critically ill or critically injured patient, first 30–74 minutes*), which is valued at 4.00 work RVUs. Specifically, the RUC validated the postoperative work of several thoracic, vascular, and general surgical procedures by comparing the surgeon's intensive care unit visits to code 99291.

Current Medicare policy allows separate payment to the surgeon for postoperative critical care services during the surgical global period only when the patient has suffered trauma or burns. If the surgeon provides critical care services during the global period, for reasons unrelated to the surgery, that is separately payable as well.

The RUC recommendations have raised several issues for which we are considering future action. In view of our desire to ensure that Medicare beneficiaries have appropriate access to critical care services, and to ensure that we make appropriate payments to physicians furnishing postoperative critical care services to Medicare beneficiaries, we are soliciting information and comments on the following questions and issues:

1. If critical care (as described in CPT 2001) is provided postoperative, who typically provides this care? The surgeon, an intensivist, other physicians?

2. Do surgeons typically meet the CPT requirements for billing critical care services (as described in CPT 2001)

when making intensive care unit visits on their postoperative patients?

3. Are surgeons currently performing more, or less, critical care on their postoperative patients than they were at the time of the last 5-year review?

4. What is, or will be, the effect of ''closed'' intensive care units (a unit staffed by dedicated intensivists who manage the care for all patients in the intensive care unit) on who performs postoperative critical care services?

5. What is the likelihood of making duplicate payment for critical care services if the surgical global period is valued with the inclusion of critical care in the postoperative work (for example, if we also pay an intensivist for postoperative critical care services)?

6. If valuation of the surgical global period includes postoperative critical care, are there concerns about additional carrier scrutiny being applied to claims from intensivists for postoperative critical care services?

7. Does valuation of the surgical global period with the inclusion of postoperative critical care create an incentive for the surgeon to either (a) not perform postoperative critical care services if there is an intensivist available or (b) to not consult an intensivist if one is available?

Below are some of the options we are considering:

• Removing work RVUs for critical care services from the surgical global period, valuing these services as subsequent hospital visits and allowing surgeons to bill separately for critical care (for an identified subset of surgical procedures where there is a high likelihood that the surgeon is typically providing critical care services).

• Removing the work RVUs for critical care services from the surgical global period, valuing these services as subsequent hospital visits and not allowing surgeons to bill separately for critical care services.

• Leaving the work RVUs for critical care services in the surgical global period, not allowing surgeons to bill separately for critical care services, requiring surgeons to follow documentation rules for critical care services and instructing carriers to make payment for medically necessary critical care services furnished by other physicians. (This option would facilitate tracking of critical care services, permit appropriate medical record review, and provide a basis to re-evaluate the work of the procedure.)

Valuing the surgeon's postoperative intensive care unit visits as critical care services has raised a number of issues. We believe these issues will require a change in payment policy to ensure that postoperative critical care is appropriately paid. Therefore, we are proposing to make the work RVUs for those surgical codes where any postoperative intensive care unit visits were valued as critical care, interim, until we address the issues discussed above.

2. Codes Referred to CPT

As discussed in sections B and C above, there were some codes that commenters had submitted for review that the RUC recommended be referred to the CPT Editorial Panel for clarification or consideration of definitional changes. These codes are listed in Table 2, which follows.

TABLE 2.—CODES REFERRED TO CPT EDITORIAL PANEL FROM FIVE-YEAR REVIEW OF WORK RELATIVE VALUE UNITS

CPT/ HCPCS code [1]	Mod	Descriptor
12001		Repair superficial wound(s)
12002		Repair superficial wound(s)
15000		Skin graft
15001		Skin graft add-on
15100		Skin split graft
15101		Skin split graft add-on
15120		Skin split graft
15121		Skin split graft add-on
15350		Skin homograft
15351		Skin homograft add-on
15400		Skin heterograft
15401		Skin heterograft add-on
20205		Deep muscle biopsy
21740		Reconstruction of sternum
23076		Removal of shoulder lesion
24076		Remove arm/elbow lesion
25076		Removal of forearm lesion
27048		Remove hip/pelvis lesion
27328		Removal of thigh lesion
27619		Remove lower leg lesion
33875		Thoracic aortic graft
33877		Thoracoabdominal graft
35381		Rechanneling of artery
35541		Artery bypass graft
35546		Artery bypass graft
35551		Artery bypass graft
35582		Vein bypass graft
35641		Artery bypass graft
35646		Artery bypass graft
35840		Explore abdominal vessels
35860		Explore limb vessels
36406		Drawing blood
36520		Plasma and/or cell exchange
36533		Insertion of access device
36534		Revision of access device
36535		Removal of access device
36620		Insertion catheter, artery
37615		Ligation of neck artery
37618		Ligation of extremity artery
37700		Revise leg vein
37720		Removal of leg vein
37730		Removal of leg veins
37735		Removal of leg veins/lesion
37760		Revision of leg veins
37785		Revision secondary varicosity
43215		Esophagus endoscopy
43310		Repair of esophagus
43312		Repair esophagus and fistula
47134		Partial removal, donor liver
49495		Repair inguinal hernia, init
49496		Repair inguinal hernia, init
49905		Omental flap
50200		Biopsy of kidney
50230		Removal of kidney
90935		Hemodialysis, one evaluation
90937		Hemodialysis, repeated eval
90945		Dialysis, one evaluation
90947		Dialysis, repeated eval
90989		Dialysis training, complete
90993		Dialysis training, incompl
90997		Hemoperfusion
94664		Aerosol or vapor inhalations
94665		Aerosol or vapor inhalations

3. Budget Neutrality

Section 1848(c)(2)(B) of the Act requires that increases or decreases in relative value units may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve budget neutrality. This year, budget-neutrality adjustments will be required for changes in work relative value units resulting from the 5-year refinement. Revisions in payment policies, including the establishment of interim and final relative value units for coding changes that will be announced later this year, may result in additional budget-neutrality adjustments.

We considered making the statutorily required budget-neutrality adjustments

to account for the 5-year review of physician work by reducing all work RVUs. We estimate that all work RVUs would have to be reduced by 0.7 percent under this option. Alternatively, we considered making an adjustment to the physician fee schedule CF to meet the provisions of section 1848(c)(2)(B). This option would require an estimated 0.3 percent reduction in the conversion factor. For the 5-year review, we are proposing to reduce the conversion factor by 0.3 percent to meet the provisions of section 1848(c)(2)(B).

HCFA Proposal:

We propose to make the budget-neutrality adjustment by reducing the CF.

4. Calculation of Practice Expense and Malpractice Expense RVUs

As we noted in the November 2, 1999 final rule (64 FR 59427), practice expense and malpractice expense RVUs were not subject to comment and will not be recalculated (other than the change to practice expense RVUs that result from changes in work) as part of the 5-year review of work RVUs. Section 4505 of the BBA also provides for the gradual 4-year transition for resource-based practice expenses, with resource-based practice expenses becoming fully effective in CY 2002. We are currently in the process of developing our annual physician fee schedule proposed rule that will continue the 4-year refinement process for resource-based practice expense RVUs.

Section 4505(f) of the Balanced Budget Act of 1997 (BBA) amended section 1848(c)(2)(C) of the Act and requires us to implement resource-based malpractice RVUs for services furnished beginning in CY 2000. A methodology for establishing resource-based malpractice RVUs was included in the November 1999 final rule and implemented January 1, 2000. In addition, based on concerns expressed by commenters, updated premium data used under this methodology were obtained and used to calculate malpractice RVUs for CY 2001.

Since resource-based malpractice RVUs were recently implemented, and resource-based practice expenses are in the final phase of transition to a fully resource-based system, these components are not being included in this 5-year review. However, as stated above we expect to publish our annual physician fee schedule proposed rule that will propose continuing refinements to resource-based practice expense RVUs.

5. Nature and Format of Comments on Work RVUs

We will accept comments on the proposed work RVUs for the codes identified in the Addendum of this notice. We will also accept comments on the anesthesia codes. Comments should discuss how the work associated with a given CPT or HCPCS code is analogous to the work in other services or discuss the rationale for disagreeing with the proposed work RVU. We are especially interested in information or arguments that were not presented in earlier comments.

III. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*)

IV. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comment received by the date and time specified in the **DATES** section of this preamble, and we will respond to the comments in the physician fee schedule final rule.

V. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this proposed notice as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 9, 1980 Public Law 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity).

A regulatory impact analysis must be prepared for major rules with economically significant effects ($100 million or more annually). While the changes in the Medicare physician fee schedule due to the 5-year review are budget neutral, they do involve a redistribution of Medicare spending among procedures that will exceed $100 million. For this reason, we are considering this to be a major rule. We estimate that the aggregate amount of payments being redistributed among specialties as a result of the 5-year review will be over $200 million.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $7.5 million or less annually for physicians and $5 million or less for other practitioners. For purposes of the RFA and based on small business administration data for 1997 we estimate that there are 162,000 physician organizations that meet the definition of a small entity. There are about 700,000 physicians and other practitioners who receive Medicare payment under the physician fee schedule. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. We have determined that this rule has no consequential effect on State, local or tribal governments. We believe the private sector costs of this rule will fall below this threshold as well.

For purposes of Executive Order 12866 and the RFA, we have prepared the following analysis, which, together with the rest of this preamble, meets all four assessment requirements. It explains the rationale for and purpose of the proposed notice, details the costs and benefits of the proposed notice, analyzes alternatives, and presents the measures we considered to minimize burden on small entities. Section 1848(c)(2)(B) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded,

we make adjustments to preserve budget neutrality. This year, budget-neutrality adjustments will be required for changes in work relative value units resulting from the 5-year refinement. Revisions in payment policies, including the establishment of interim and final relative value units for coding changes that will be announced later this year, may result in additional budget-neutrality adjustments.

We considered making the statutorily required budget-neutrality adjustments to account for the 5-year review of physician work by reducing all work RVUs. We estimate that all work RVUs would have to be reduced by 0.7 percent under this option. Alternatively, we considered making an adjustment to the physician fee schedule CF to meet the provisions of section 1848(c)(2)(B) of the Act. This option would require an estimated 0.3 percent reduction in the CF. For the 5-year review, we are proposing to reduce the CF by 0.3 percent to meet the provisions of section 1848(c)(2)(B) of the Act.

TABLE 3.—PERCENT CHANGE IN TOTAL PAYMENTS BY SPECIALTY RESULTING FROM THE 5 YEAR REVIEW OF WORK

Specialty	Allowed charges (billions)	Percent change in total payments from increase in work	Percent change in total payments from change in PE	Total percent change in payments from 5 year review
Anesthesiology	1.5	1	0	1
Cardiac Surgery	0.3	5	1	6
Cardiology	4.2	0	−1	−1
Chiropractor	0.4	0	0	0
Clinics	1.6	0	0	0
Dermatology	1.4	0	0	0
Emergency Medicine	1.0	0	0	0
Family Practice	3.3	0	0	0
Gastroenterology	1.2	0	0	0
General Practice	1.0	0	0	0
General Surgery	2.0	3	1	4
Hematology Oncology	0.6	0	−1	−1
Internal Medicine	7.1	0	0	0
Nephrology	1.0	0	0	0
Neurology	0.9	0	0	0
Neurosurgery	0.4	0	0	0
Nonphysician Practitioner	1.2	0	0	0
Obstetrics/Gynecology	0.4	0	0	0
Ophthalmology	3.9	0	0	0
Optometrist	0.5	0	0	0
Orthopedic Surgery	2.3	0	0	0
Other Physician	1.6	0	0	0
Otolaryngology	0.6	0	0	0
Pathology	0.6	0	0	0
Plastic Surgery	0.2	0	0	0
Podiatry	1.1	0	0	0
Psychiatry	1.1	0	0	0
Pulmonary	1.1	0	0	0
Radiation Oncology	0.7	0	−1	−1
Radiology	3.3	0	−1	−1
Rheumatology	0.3	0	0	0
Suppliers	0.5	0	0	−1
Thoracic Surgery	0.5	4	1	5
Urology	1.3	0	0	0
Vascular Surgery	0.3	2	0	2

Note: This table incorporates two separate budget neutrality adjustments. The increase in practice expense relative value units is incorporated through a rescaling of all practice expense RVUs. In addition, all physician fee schedule payments (not the work RVUs) are reduced to make the increase in physician work RVUs budget neutral.

The table above shows the specialty level payment impact of changes in work and practice expense relative values resulting from the 5-year review. The table includes the effect of budget-neutrality adjustments applied to the physician fee schedule CF. Since the practice expense RVUs are based, in part, on physician work, the table also reflects changes in practice expense RVUs that will result from the 5-year review of physician work. The changes in practice expense RVUs resulting from the changes in physician work RVUs were made budget neutral by rescaling all practice expense RVUs. This table shows the impact on payments per service at the specialty level that would result only from the 5-year review of physician work RVUs.

We are in the process of developing our annual physician fee schedule proposed rule that will make refinements in practice expense RVUs and other policies that will affect payment for physician fee schedule services in CY 2002. As part of the physician fee schedule proposed rule, we expect to use revised physician times submitted to us by the RUC in the methodology for determining practice expense RVUs. The RUC is recommending that we use new time data for codes in which they recommended a change in work RVUs. In addition, the RUC is recommending a revision of the time data for many other codes. For some specialties, we expect that use of the revised times will change the impacts shown here.

In particular, it appears that the revised times submitted to us by the

RUC are less than the times included in our database for many heart and chest procedures. Our expectation is that use of the RUC recommended times will result in a reduction in the practice expense RVUs for these services that are predominantly performed by cardiac and thoracic surgeons. This means that our expectation is that the total payment increase shown here for these specialties will be less when the revised times are used to determine the practice expense RVUs. In addition, there may be other refinements to the practice expense RVUs or other changes in policies that may result in a specialty level payment impact for 2002 that we will announce in our proposed rule. We will show the combined payment impact by specialty, as a result of the revised times and other proposed policy changes, in our notice of proposed rulemaking that we expect to be published shortly.

We will show the combined impact of all policy changes affecting physician fee schedule payments in 2002 in one final rule that we expect to be published no later than November 1, 2001.

Federalism: Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have determined that this rule will not impose substantial direct requirement costs on State and local governments, preempt State law, or otherwise have Federalism implications.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

(42 U.S.C. 1395k(a)(2)(F) and 1395l(i)(1) and (2)); 42 CFR 416.120, 416.125, and 416.130)

(Catalog of Federal Domestic Assistance Programs No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: April 17, 2001.

Michael McMullan,

Acting Deputy Administrator, Health Care Financing Administration.

Dated: April 23, 2001.

Tommy G. Thompson,

Secretary.

ADDENDUM—CODES SUBJECT TO COMMENT

CPT/ HCPCS code [1]	Mod	Descriptor	Proposed work RVU
G0127		Trim nail(s)	0.11
11055		Trim skin lesion	0.27
11056		Trim skin lesion, 2 to 4	0.39
11057		Trim skin lesions, over 4	0.50
11402		Removal of skin lesion	1.61
11642		Removal of skin lesion	2.93
11642		Removal of skin lesion	2.93
11719		Trim nail(s)	0.11
12001		Repair superficial wound(s)	1.70
12002		Repair superficial wound(s)	1.86
12011		Repair superficial wound(s)	1.76
13101		Repair of wound or lesion	3.92
13131		Repair of wound or lesion	3.79
13132		Repair of wound or lesion	5.95
15000		Skin graft	4.00
15001		Skin graft add-on	1.00
15100		Skin split graft	9.05
15101		Skin split graft add-on	1.72
15120		Skin split graft	9.83
15121		Skin split graft add-on	2.67
15350		Skin homograft	4.00
15351		Skin homograft add-on	1.00
15400		Skin heterograft	4.00
15401		Skin heterograft add-on	1.00
19000		Drainage of breast lesion	0.84
19100		Biopsy of breast	1.27
19125		Excision, breast lesion	6.06
19160		Removal of breast tissue	5.99
19162		Remove breast tissue, nodes	13.53
19240		Removal of breast	16.00
20205		Deep muscle biopsy	2.35
20245		Bone biopsy, excisional	7.78
21740		Reconstruction of sternum	16.50
21800		Treatment of rib fracture	0.96
23076		Removal of shoulder lesion	7.63
23472		Reconstruct shoulder joint	21.10
23485		Revision of collar bone	13.43
23585		Treat scapula fracture	8.96
23615		Treat humerus fracture	9.35
23630		Treat humerus fracture	7.35
23680		Treat dislocation/fracture	10.06
24076		Remove arm/elbow lesion	6.30
24435		Repair humerus with graft	13.17

[1] All CPT codes and descriptors copyright 2000 American Medical Association

ADDENDUM—CODES SUBJECT TO COMMENT—Continued

CPT/ HCPCS code [1]	Mod	Descriptor	Proposed work RVU
24545		Treat humerus fracture	10.46
25076		Removal of forearm lesion	4.92
26562		Repair of web finger	15.00
27048		Remove hip/pelvis lesion	6.25
27075		Extensive hip surgery	35.00
27077		Extensive hip surgery	40.00
27216		Treat pelvic ring fracture	15.19
27217		Treat pelvic ring fracture	14.11
27218		Treat pelvic ring fracture	20.15
27226		Treat hip wall fracture	14.91
27236		Treat thigh fracture	15.60
27280		Fusion of sacroiliac joint	13.39
27282		Fusion of pubic bones	11.34
27284		Fusion of hip joint	23.45
27328		Removal of thigh lesion	5.57
27472		Repair/graft of thigh	17.72
27513		Treatment of thigh fracture	17.92
27536		Treat knee fracture	15.65
27590		Amputate leg at thigh	12.03
27619		Remove lower leg lesion	8.40
27724		Repair/graft of tibia	18.20
27822		Treatment of ankle fracture	11.00
27823		Treatment of ankle fracture	13.00
27828		Treat lower leg fracture	16.23
28299		Correction of bunion	9.18
28322		Repair of metatarsals	8.34
28420		Treat/graft heel fracture	16.64
28445		Treat ankle fracture	15.62
28705		Fusion of foot bones	18.80
29450		Application of leg cast	2.08
29450		Application of leg cast	2.08
29883		Knee arthroscopy/surgery	11.05
29889		Knee arthroscopy/surgery	16.00
29889		Knee arthroscopy/surgery	16.00
31600		Incision of windpipe	7.18
31622		Dx bronchoscope/wash	2.78
31622		Dx bronchoscope/wash	2.78
31625		Bronchoscopy with biopsy	3.37
31645		Bronchoscopy, clear airways	3.16
32000		Drainage of chest	1.54
32000		Drainage of chest	1.54
32005		Treat lung lining chemically	2.19
32020		Insertion of chest tube	3.98
32035		Exploration of chest	8.67
32095		Biopsy through chest wall	8.36
32100		Exploration/biopsy of chest	15.24
32110		Explore/repair chest	23.00
32220		Release of lung	24.00
32225		Partial release of lung	13.96
32320		Free/remove chest lining	24.00
32440		Removal of lung	25.00
32440		Removal of lung	25.00
32480		Partial removal of lung	23.75
32480		Partial removal of lung	23.75
32482		Bilobectomy	25.00
32491		Lung volume reduction	21.25
32500		Partial removal of lung	22.00
32520		Remove lung & revise chest	21.68
32602		Thoracoscopy, diagnostic	5.96
32651		Thoracoscopy, surgical	12.91
32652		Thoracoscopy, surgical	18.66
32655		Thoracoscopy, surgical	13.10
32657		Thoracoscopy, surgical	13.65
33234		Removal of pacemaker system	7.82
33235		Removal of pacemaker electrode	9.40
33400		Repair of aortic valve	28.50

[1] All CPT codes and descriptors copyright 2000 American Medical Association

ADDENDUM—CODES SUBJECT TO COMMENT—Continued

CPT/ HCPCS code [1]	Mod	Descriptor	Proposed work RVU
33405		Replacement of aortic valve	35.00
33406		Replacement of aortic valve	37.50
33410		Replacement of aortic valve	32.46
33411		Replacement of aortic valve	36.25
33412		Replacement of aortic valve	42.00
33413		Replacement of aortic valve	43.50
33415		Revision, subvalvular tissue	27.15
33425		Repair of mitral valve	27.00
33426		Repair of mitral valve	33.00
33427		Repair of mitral valve	40.00
33430		Replacement of mitral valve	33.50
33468		Revision of tricuspid valve	30.12
33475		Replacement, pulmonary valve	33.00
33506		Repair artery, translocation	35.50
33510		CABG, vein, single	29.00
33511		CABG, vein, two	30.00
33512		CABG, vein, three	31.80
33513		CABG, vein, four	32.00
33514		CABG, vein, five	32.75
33516		Cabg, vein, six or more	35.00
33517		CABG, artery-vein, single	2.57
33518		CABG, artery-vein, two	4.85
33519		CABG, artery-vein, three	7.12
33521		CABG, artery-vein, four	9.40
33522		CABG, artery-vein, five	11.67
33523		Cabg, art-vein, six or more	13.95
33530		Coronary artery, bypass/reop	5.86
33533		CABG, arterial, single	30.00
33534		CABG, arterial, two	32.20
33535		CABG, arterial, three	34.50
33536		Cabg, arterial, four or more	37.50
33611		Repair double ventricle	34.00
33612		Repair double ventricle	35.00
33615		Repair, simple fontan	34.00
33617		Repair, modified fontan	37.00
33619		Repair single ventricle	45.00
33641		Repair heart septum defect	21.39
33660		Repair of heart defects	30.00
33670		Repair of heart chambers	35.00
33681		Repair heart septum defect	30.61
33694		Repair of heart defects	34.00
33697		Repair of heart defects	36.00
33730		Repair heart-vein defect(s)	34.25
33750		Major vessel shunt	21.41
33767		Major vessel shunt	24.50
33770		Repair great vessels defect	37.00
33778		Repair great vessels defect	40.00
33780		Repair great vessels defect	41.75
33786		Repair arterial trunk	39.00
33820		Revise major vessel	16.29
33840		Remove aorta constriction	20.63
33860		Ascending aortic graft	38.00
33861		Ascending aortic graft	42.00
33863		Ascending aortic graft	45.00
33870		Transverse aortic arch graft	44.00
33875		Thoracic aortic graft	33.06
33877		Thoracoabdominal graft	42.60
33917		Repair pulmonary artery	24.50
33919		Repair pulmonary atresia	40.00
33945		Transplantation of heart	42.10
34101		Removal of artery clot	10.00
34111		Removal of arm artery clot	10.00
34151		Removal of artery clot	25.00
34151		Removal of artery clot	25.00
34201		Removal of artery clot	10.03
34201		Removal of artery clot	10.03

[1] All CPT codes and descriptors copyright 2000 American Medical Association

ADDENDUM—CODES SUBJECT TO COMMENT—Continued

CPT/ HCPCS code [1]	Mod	Descriptor	Proposed work RVU
34203		Removal of leg artery clot	16.50
34203		Removal of leg artery clot	16.50
34401		Removal of vein clot	25.00
34401		Removal of vein clot	25.00
34421		Removal of vein clot	12.00
34421		Removal of vein clot	12.00
34451		Removal of vein clot	27.00
34451		Removal of vein clot	27.00
34490		Removal of vein clot	9.86
34501		Repair valve, femoral vein	16.00
34510		Transposition of vein valve	18.95
34520		Cross-over vein graft	17.95
34530		Leg vein fusion	16.64
35011		Repair defect of artery	18.00
35011		Repair defect of artery	18.00
35013		Repair artery rupture, arm	22.00
35013		Repair artery rupture, arm	22.00
35045		Repair defect of arm artery	17.57
35045		Repair defect of arm artery	17.57
35081		Repair defect of artery	28.01
35082		Repair artery rupture, aorta	38.50
35082		Repair artery rupture, aorta	38.50
35092		Repair artery rupture, aorta	45.00
35092		Repair artery rupture, aorta	45.00
35103		Repair artery rupture, groin	40.50
35103		Repair artery rupture, groin	40.50
35111		Repair defect of artery	25.00
35111		Repair defect of artery	25.00
35112		Repair artery rupture, spleen	30.00
35112		Repair artery rupture, spleen	30.00
35121		Repair defect of artery	30.00
35121		Repair defect of artery	30.00
35122		Repair artery rupture, belly	35.00
35122		Repair artery rupture, belly	35.00
35131		Repair defect of artery	25.00
35131		Repair defect of artery	25.00
35132		Repair artery rupture, groin	30.00
35132		Repair artery rupture, groin	30.00
35141		Repair defect of artery	20.00
35141		Repair defect of artery	20.00
35142		Repair artery rupture, thigh	23.30
35142		Repair artery rupture, thigh	23.30
35151		Repair defect of artery	22.64
35151		Repair defect of artery	22.64
35152		Repair artery rupture, knee	25.62
35152		Repair artery rupture, knee	25.62
35182		Repair blood vessel lesion	30.00
35184		Repair blood vessel lesion	18.00
35189		Repair blood vessel lesion	28.00
35190		Repair blood vessel lesion	12.75
35201		Repair blood vessel lesion	16.14
35201		Repair blood vessel lesion	16.14
35206		Repair blood vessel lesion	13.25
35221		Repair blood vessel lesion	24.39
35221		Repair blood vessel lesion	24.39
35226		Repair blood vessel lesion	14.50
35226		Repair blood vessel lesion	14.50
35231		Repair blood vessel lesion	20.00
35231		Repair blood vessel lesion	20.00
35236		Repair blood vessel lesion	17.11
35236		Repair blood vessel lesion	17.11
35246		Repair blood vessel lesion	26.45
35246		Repair blood vessel lesion	26.45
35251		Repair blood vessel lesion	30.20
35251		Repair blood vessel lesion	30.20
35256		Repair blood vessel lesion	18.36

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ADDENDUM—CODES SUBJECT TO COMMENT—Continued

CPT/ HCPCS code [1]	Mod	Descriptor	Proposed work RVU
35261		Repair blood vessel lesion	17.80
35261		Repair blood vessel lesion	17.80
35266		Repair blood vessel lesion	14.91
35266		Repair blood vessel lesion	14.91
35276		Repair blood vessel lesion	24.25
35276		Repair blood vessel lesion	24.25
35281		Repair blood vessel lesion	28.00
35281		Repair blood vessel lesion	28.00
35286		Repair blood vessel lesion	16.16
35311		Rechanneling of artery	27.00
35311		Rechanneling of artery	27.00
35321		Rechanneling of artery	16.00
35321		Rechanneling of artery	16.00
35331		Rechanneling of artery	26.20
35331		Rechanneling of artery	26.20
35351		Rechanneling of artery	23.00
35351		Rechanneling of artery	23.00
35355		Rechanneling of artery	18.50
35355		Rechanneling of artery	18.50
35361		Rechanneling of artery	28.20
35361		Rechanneling of artery	28.20
35363		Rechanneling of artery	30.20
35363		Rechanneling of artery	30.20
35371		Rechanneling of artery	14.72
35371		Rechanneling of artery	14.72
35372		Rechanneling of artery	18.00
35372		Rechanneling of artery	18.00
35381		Rechanneling of artery	15.81
35511		Artery bypass graft	21.20
35511		Artery bypass graft	21.20
35518		Artery bypass graft	21.20
35518		Artery bypass graft	21.20
35521		Artery bypass graft	22.20
35521		Artery bypass graft	22.20
35526		Artery bypass graft	29.95
35526		Artery bypass graft	29.95
35531		Artery bypass graft	36.20
35531		Artery bypass graft	36.20
35533		Artery bypass graft	28.00
35533		Artery bypass graft	28.00
35536		Artery bypass graft	31.70
35536		Artery bypass graft	31.70
35541		Artery bypass graft	25.80
35546		Artery bypass graft	25.54
35551		Artery bypass graft	26.67
35556		Artery bypass graft	21.76
35556		Artery bypass graft	21.76
35558		Artery bypass graft	21.20
35558		Artery bypass graft	21.20
35560		Artery bypass graft	32.00
35560		Artery bypass graft	32.00
35563		Artery bypass graft	24.20
35563		Artery bypass graft	24.20
35565		Artery bypass graft	23.20
35565		Artery bypass graft	23.20
35571		Artery bypass graft	24.06
35571		Artery bypass graft	24.06
35582		Vein bypass graft	27.13
35587		Vein bypass graft	24.75
35587		Vein bypass graft	24.75
35621		Artery bypass graft	20.00
35621		Artery bypass graft	20.00
35623		Bypass graft, not vein	24.00
35623		Bypass graft, not vein	24.00
35626		Artery bypass graft	27.75
35626		Artery bypass graft	27.75

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ADDENDUM—CODES SUBJECT TO COMMENT—Continued

CPT/ HCPCS code [1]	Mod	Descriptor	Proposed work RVU
35631		Artery bypass graft	34.00
35631		Artery bypass graft	34.00
35636		Artery bypass graft	29.50
35636		Artery bypass graft	29.50
35641		Artery bypass graft	24.57
35646		Artery bypass graft	25.81
35650		Artery bypass graft	19.00
35650		Artery bypass graft	19.00
35654		Artery bypass graft	25.00
35654		Artery bypass graft	25.00
35661		Artery bypass graft	19.00
35661		Artery bypass graft	19.00
35663		Artery bypass graft	22.00
35663		Artery bypass graft	22.00
35665		Artery bypass graft	21.00
35665		Artery bypass graft	21.00
35666		Artery bypass graft	22.19
35666		Artery bypass graft	22.19
35671		Artery bypass graft	19.33
35671		Artery bypass graft	19.33
35701		Exploration, carotid artery	8.50
35701		Exploration, carotid artery	8.50
35721		Exploration, femoral artery	7.18
35741		Exploration popliteal artery	8.00
35840		Explore abdominal vessels	9.77
35860		Explore limb vessels	5.55
35905		Excision, graft, thorax	31.25
35905		Excision, graft, thorax	31.25
35907		Excision, graft, abdomen	35.00
35907		Excision, graft, abdomen	35.00
36400		Drawing blood	0.18
36405		Drawing blood	0.18
36406		Drawing blood	0.18
36489		Insertion of catheter, vein	2.50
36489		Insertion of catheter, vein	2.50
36520		Plasma and/or cell exchange	1.74
36533		Insertion of access device	5.32
36534		Revision of access device	2.80
36535		Removal of access device	2.27
36620		Insertion catheter, artery	1.15
36625		Insertion catheter, artery	2.11
36822		Insertion of cannula(s)	5.42
37565		Ligation of neck vein	10.88
37565		Ligation of neck vein	10.88
37600		Ligation of neck artery	11.25
37600		Ligation of neck artery	11.25
37605		Ligation of neck artery	13.11
37605		Ligation of neck artery	13.11
37609		Temporal artery procedure	3.00
37609		Temporal artery procedure	3.00
37615		Ligation of neck artery	5.73
37615		Ligation of neck artery	5.73
37617		Ligation of abdomen artery	22.06
37618		Ligation of extremity artery	4.84
37650		Revision of major vein	7.80
37660		Revision of major vein	21.00
37700		Revise leg vein	3.73
37720		Removal of leg vein	5.66
37730		Removal of leg veins	7.33
37735		Removal of leg veins/lesion	10.53
37760		Revision of leg veins	10.47
37785		Revision secondary varicosity	3.84
38100		Removal of spleen, total	14.50
38100		Removal of spleen, total	14.50
38101		Removal of spleen, partial	15.31
38115		Repair of ruptured spleen	15.82

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ADDENDUM—CODES SUBJECT TO COMMENT—Continued

CPT/ HCPCS code [1]	Mod	Descriptor	Proposed work RVU
38300		Drainage, lymph node lesion	1.99
38305		Drainage, lymph node lesion	6.00
38308		Incision of lymph channels	6.45
38500		Biopsy/removal, lymph nodes	3.75
38500		Biopsy/removal, lymph nodes	3.75
38510		Biopsy/removal, lymph nodes	6.43
38520		Biopsy/removal, lymph nodes	6.67
38525		Biopsy/removal, lymph nodes	6.07
38530		Biopsy/removal, lymph nodes	7.98
38571		Laparoscopy, lymphadenectomy	12.38
38572		Laparoscopy, lymphadenectomy	16.59
38740		Remove armpit lymph nodes	10.02
38745		Remove armpit lymph nodes	13.00
38746		Remove thoracic lymph nodes	4.89
38760		Remove groin lymph nodes	12.94
38765		Remove groin lymph nodes	19.98
38780		Remove abdomen lymph nodes	16.59
39010		Exploration of chest	11.79
39220		Removal chest lesion	17.42
39400		Visualization of chest	5.61
39503		Repair of diaphragm hernia	34.85
42205		Reconstruct cleft palate	13.29
43107		Removal of esophagus	40.00
43112		Removal of esophagus	43.50
43117		Partial removal of esophagus	40.00
43122		Parital removal of esophagus	40.00
43215		Esophagus endoscopy	2.60
43217		Esophagus endoscopy	2.90
43219		Esophagus endoscopy	2.80
43228		Esoph endoscopy, ablation	3.77
43239		Upper GI endoscopy, biopsy	2.69
43239		Upper GI endoscopy, biopsy	2.87
43244		Upper GI endoscopy/ligation	4.59
43246		Place gastrostomy tube	4.33
43246		Place gastrostomy tube	4.33
43247		Operative upper GI endoscopy	3.39
43249		Esoph endoscopy, dilation	2.90
43251		Operative upper GI endoscopy	3.70
43255		Operative upper GI endoscopy	4.40
43258		Operative upper GI endoscopy	4.55
43259		Endoscopic ultrasound exam	4.89
43263		Endo cholangiopancreatograph	6.19
43265		Endo cholangiopancreatograph	8.90
43269		Endo cholangiopancreatograph	6.04
43310		Repair of esophagus	25.39
43312		Repair esophagus and fistula	28.42
43320		Fuse esophagus & stomach	19.93
43324		Revise esophagus & stomach	20.57
43325		Revise esophagus & stomach	20.06
43326		Revise esophagus & stomach	19.74
43330		Repair of esophagus	19.77
43331		Repair of esophagus	20.13
43340		Fuse esophagus & intestine	19.61
43341		Fuse esophagus & intestine	20.85
43350		Surgical opening, esophagus	15.78
43351		Surgical opening, esophagus	18.35
43352		Surgical opening, esophagus	15.26
43360		Gastrointestinal repair	35.70
43361		Gastrointestinal repair	40.50
43400		Ligate esophagus veins	21.20
43401		Esophagus surgery for veins	22.09
43405		Ligate/staple esophagus	20.01
43410		Repair esophagus wound	13.47
43415		Repair esophagus wound	25.00
43420		Repair esophagus opening	14.35
43425		Repair esophagus opening	21.03

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ADDENDUM—CODES SUBJECT TO COMMENT—Continued

CPT/ HCPCS code [1]	Mod	Descriptor	Proposed work RVU
43500		Surgical opening of stomach	11.05
43501		Surgical repair of stomach	20.04
43502		Surgical repair of stomach	23.13
43510		Surgical opening of stomach	13.08
43520		Incision of pyloric muscle	9.99
43605		Biopsy of stomach	11.98
43610		Excision of stomach lesion	14.60
43611		Excision of stomach lesion	17.84
43620		Removal of stomach	30.04
43621		Removal of stomach	30.73
43622		Removal of stomach	32.53
43631		Removal of stomach, partial	22.59
43632		Removal of stomach, partial	22.59
43633		Removal of stomach, partial	23.10
43634		Removal of stomach, partial	25.12
43638		Removal of stomach, partial	29.00
43638		Removal of stomach, partial	29.00
43639		Removal of stomach, partial	29.65
43640		Vagotomy & pylorus repair	17.02
43641		Vagotomy & pylorus repair	17.27
43651		Laparoscopy, vagus nerve	10.15
43652		Laparoscopy, vagus nerve	12.15
43800		Reconstruction of pylorus	13.69
43810		Fusion of stomach and bowel	14.65
43820		Fusion of stomach and bowel	15.37
43825		Fusion of stomach and bowel	19.22
43830		Place gastrostomy tube	9.53
43832		Place gastrostomy tube	15.60
43840		Repair of stomach lesion	15.56
43842		Gastroplasty for obesity	18.47
43843		Gastroplasty for obesity	18.65
43846		Gastric bypass for obesity	24.05
43847		Gastric bypass for obesity	26.92
43848		Revision gastroplasty	29.39
43850		Revise stomach-bowel fusion	24.72
43855		Revise stomach-bowel fusion	26.16
43860		Revise stomach-bowel fusion	25.00
43865		Revise stomach-bowel fusion	26.52
43870		Repair stomach opening	9.69
43880		Repair stomach-bowel fistula	24.65
44005		Freeing of bowel adhesion	16.23
44010		Incision of small bowel	12.52
44020		Exploration of small bowel	13.99
44021		Decompress small bowel	14.08
44025		Incision of large bowel	14.28
44050		Reduce bowel obstruction	14.03
44050		Reduce bowel obstruction	14.03
44055		Correct malrotation of bowel	22.00
44110		Excision of bowel lesion(s)	11.81
44111		Excision of bowel lesion(s)	14.29
44120		Removal of small intestine	17.00
44125		Removal of small intestine	17.54
44130		Bowel to bowel fusion	14.49
44130		Bowel to bowel fusion	14.49
44140		Partial removal of colon	21.00
44140		Partial removal of colon	21.00
44143		Partial removal of colon	22.99
44144		Partial removal of colon	21.53
44144		Partial removal of colon	21.53
44145		Partial removal of colon	26.42
44146		Partial removal of colon	27.54
44147		Partial removal of colon	20.71
44150		Removal of colon	23.95
44151		Removal of colon/ileostomy	26.88
44151		Removal of colon/ileostomy	26.88
44152		Removal of colon/ileostomy	27.83

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ADDENDUM—CODES SUBJECT TO COMMENT—Continued

CPT/ HCPCS code [1]	Mod	Descriptor	Proposed work RVU
44153		Removal of colon/ileostomy	30.59
44155		Removal of colon/ileostomy	27.86
44156		Removal of colon/ileostomy	30.79
44156		Removal of colon/ileostomy	30.79
44160		Removal of colon	18.62
44200		Laparoscopy, enterolysis	14.44
44300		Open bowel to skin	12.11
44310		Ileostomy/jejunostomy	15.95
44312		Revision of ileostomy	8.02
44314		Revision of ileostomy	15.05
44316		Devise bowel pouch	21.09
44320		Colostomy	17.64
44340		Revision of colostomy	7.72
44345		Revision of colostomy	15.43
44346		Revision of colostomy	16.99
44388		Colon endoscopy	2.82
44389		Colonoscopy with biopsy	3.13
44390		Colonoscopy for foreign body	3.83
44391		Colonoscopy for bleeding	4.32
44392		Colonoscopy and polypectomy	3.82
44393		Colonoscopy, lesion removal	4.84
44394		Colonoscopy w/snare	4.43
44394		Colonoscopy w/snare	4.43
44602		Suture, small intestine	16.03
44603		Suture, small intestine	18.66
44604		Suture, large intestine	16.03
44605		Repair of bowel lesion	19.53
44615		Intestinal stricturoplasty	15.93
44620		Repair bowel opening	12.20
44625		Repair bowel opening	15.05
44626		Repair bowel opening	25.36
44640		Repair bowel-skin fistula	21.65
44650		Repair bowel fistula	22.57
44660		Repair bowel-bladder fistula	21.36
44661		Repair bowel-bladder fistula	24.81
44680		Surgical revision, intestine	15.40
44700		Suspend bowel w/prosthesis	16.11
44800		Excision of bowel pouch	11.23
44820		Excision of mesentery lesion	12.09
44850		Repair of mesentery	10.74
44900		Drain app abscess, open	10.14
44950		Appendectomy	10.00
44960		Appendectomy	12.34
44970		Laparoscopy, appendectomy	8.70
45000		Drainage of pelvic abscess	4.52
45020		Drainage of rectal abscess	4.72
45100		Biopsy of rectum	3.68
45108		Removal of anorectal lesion	4.76
45110		Removal of rectum	28.00
45111		Partial removal of rectum	16.48
45112		Removal of rectum	30.54
45113		Partial proctectomy	30.58
45114		Partial removal of rectum	27.32
45116		Partial removal of rectum	24.58
45119		Remove rectum w/reservoir	30.84
45120		Removal of rectum	24.60
45121		Removal of rectum and colon	27.04
45123		Partial proctectomy	16.71
45126		Pelvic exenteration	45.16
45130		Excision of rectal prolapse	16.44
45135		Excision of rectal prolapse	19.28
45160		Excision of rectal lesion	15.32
45170		Excision of rectal lesion	11.49
45190		Destruction, rectal tumor	9.74
45305		Proctosigmoidoscopy & biopsy	1.01
45309		Proctosigmoidoscopy	2.01

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ADDENDUM—CODES SUBJECT TO COMMENT—Continued

CPT/ HCPCS code [1]	Mod	Descriptor	Proposed work RVU
45330		Diagnostic sigmoidoscopy	0.96
45337		Sigmoidoscopy & decompress	2.36
45339		Sigmoidoscopy	3.14
45378		Diagnostic colonoscopy	3.70
45380		Colonoscopy and biopsy	4.01
45383		Lesion removal colonoscopy	5.87
45384		Colonoscopy	4.70
45385		Lesion removal colonoscopy	5.31
45505		Repair of rectum	7.58
45540		Correct rectal prolapse	16.27
45541		Correct rectal prolapse	13.40
45550		Repair rectum/remove sigmoid	23.00
45560		Repair of rectocele	10.58
45562		Exploration/repair of rectum	15.38
45563		Exploration/repair of rectum	23.47
45800		Repair rect/bladder fistula	17.77
45805		Repair fistula w/colostomy	20.78
45820		Repair rectourethral fistula	18.48
45825		Repair fistula w/colostomy	21.25
45900		Reduction of rectal prolapse	2.61
45905		Dilation of anal sphincter	2.30
45910		Dilation of rectal narrowing	2.80
45910		Dilation of rectal narrowing	2.80
45915		Remove rectal obstruction	3.14
46040		Incision of rectal abscess	4.96
46045		Incision of rectal abscess	4.32
46060		Incision of rectal abscess	5.69
46083		Incise external hemorrhoid	1.40
46083		Incise external hemorrhoid	1.40
46221		Ligation of hemorrhoid(s)	2.04
46230		Removal of anal tabs	2.57
46250		Hemorrhoidectomy	3.89
46255		Hemorrhoidectomy	4.60
46257		Remove hemorrhoids & fissure	5.40
46258		Remove hemorrhoids & fistula	5.73
46258		Remove hemorrhoids & fistula	5.73
46260		Hemorrhoidectomy	6.37
46261		Remove hemorrhoids & fissure	7.08
46262		Remove hemorrhoids & fistula	7.50
46270		Removal of anal fistula	3.72
46275		Removal of anal fistula	4.56
46280		Removal of anal fistula	5.98
46288		Repair anal fistula	7.13
46320		Removal of hemorrhoid clot	1.61
46320		Removal of hemorrhoid clot	1.61
46700		Repair of anal stricture	9.13
46705		Repair of anal stricture	6.90
46715		Repair of anovaginal fistula	7.20
46716		Repair of anovaginal fistula	15.07
46730		Construction of absent anus	26.75
46735		Construction of absent anus	32.17
46740		Construction of absent anus	30.00
46742		Repair of imperforated anus	35.80
46744		Repair of cloacal anomaly	52.63
46746		Repair of cloacal anomaly	58.22
46748		Repair of cloacal anomaly	64.21
46750		Repair of anal sphincter	10.25
46753		Reconstruction of anus	8.29
46754		Removal of suture from anus	2.20
46760		Repair of anal sphincter	14.43
46761		Repair of anal sphincter	13.84
46762		Implant artificial sphincter	12.71
46900		Destruction, anal lesion(s)	1.91
46910		Destruction, anal lesion(s)	1.86
46916		Cryosurgery, anal lesion(s)	1.86
46917		Laser surgery, anal lesions	1.86

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ADDENDUM—CODES SUBJECT TO COMMENT—Continued

CPT/ HCPCS code [1]	Mod	Descriptor	Proposed work RVU
46922		Excision of anal lesion(s)	1.86
46924		Destruction, anal lesion(s)	2.76
46924		Destruction, anal lesion(s)	2.76
46934		Destruction of hemorrhoids	3.51
46935		Destruction of hemorrhoids	2.43
46936		Destruction of hemorrhoids	3.69
46940		Treatment of anal fissure	2.32
46942		Treatment of anal fissure	2.04
46945		Ligation of hemorrhoids	1.84
46946		Ligation of hemorrhoids	2.58
47010		Open drainage, liver lesion	16.01
47015		Inject/aspirate liver cyst	15.11
47100		Wedge biopsy of liver	11.67
47120		Partial removal of liver	35.50
47122		Extensive removal of liver	55.13
47125		Partial removal of liver	49.19
47130		Partial removal of liver	53.35
47134		Partial removal, donor liver	39.15
47300		Surgery for liver lesion	15.08
47350		Repair liver wound	19.56
47360		Repair liver wound	26.92
47361		Repair liver wound	47.12
47362		Repair liver wound	18.51
47400		Incision of liver duct	32.49
47420		Incision of bile duct	19.88
47425		Incision of bile duct	19.83
47460		Incise bile duct sphincter	18.04
47480		Incision of gallbladder	10.82
47562		Laparoscopic cholecystectomy	11.09
47563		Laparoscopic cholecystectomy	11.94
47564		Laparo cholecystectomy/explr	14.23
47570		Laparo cholecystoenterostomy	12.58
47600		Removal of gallbladder	13.58
47605		Removal of gallbladder	14.69
47610		Removal of gallbladder	18.82
47612		Removal of gallbladder	18.78
47620		Removal of gallbladder	20.64
47701		Bile duct revision	27.81
47711		Excision of bile duct tumor	23.03
47712		Excision of bile duct tumor	30.24
47715		Excision of bile duct cyst	18.80
47716		Fusion of bile duct cyst	16.44
47720		Fuse gallbladder & bowel	15.91
47721		Fuse upper gi structures	19.12
47740		Fuse gallbladder & bowel	18.48
47741		Fuse gallbladder & bowel	21.34
47760		Fuse bile ducts and bowel	25.85
47765		Fuse liver ducts & bowel	24.88
47780		Fuse bile ducts and bowel	26.50
47785		Fuse bile ducts and bowel	31.18
47800		Reconstruction of bile ducts	23.30
47801		Placement, bile duct support	15.17
47802		Fuse liver duct & intestine	21.55
47900		Suture bile duct injury	19.90
48000		Drainage of abdomen	28.07
48001		Placement of drain, pancreas	35.45
48005		Resect/debride pancreas	42.17
48020		Removal of pancreatic stone	15.70
48100		Biopsy of pancreas	12.23
48120		Removal of pancreas lesion	15.85
48140		Partial removal of pancreas	22.94
48145		Partial removal of pancreas	24.02
48146		Pancreatectomy	26.40
48148		Removal of pancreatic duct	17.34
48150		Partial removal of pancreas	48.00
48150		Partial removal of pancreas	48.00

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ADDENDUM—CODES SUBJECT TO COMMENT—Continued

CPT/ HCPCS code [1]	Mod	Descriptor	Proposed work RVU
48152		Pancreatectomy	43.75
48153		Pancreatectomy	47.89
48154		Pancreatectomy	44.10
48155		Removal of pancreas	24.64
48180		Fuse pancreas and bowel	24.72
48500		Surgery of pancreas cyst	15.28
48510		Drain pancreatic pseudocyst	14.31
48520		Fuse pancreas cyst and bowel	15.59
48540		Fuse pancreas cyst and bowel	19.72
48545		Pancreatorrhaphy	18.18
48547		Duodenal exclusion	25.83
49000		Exploration of abdomen	11.68
49002		Reopening of abdomen	10.49
49010		Exploration behind abdomen	12.28
49020		Drain abdominal abscess	22.84
49040		Drain, open, abdom abscess	13.52
49060		Drain, open, retrop abscess	15.86
49085		Remove abdomen foreign body	12.14
49200		Removal of abdominal lesion	10.25
49201		Removal of abdominal lesion	14.84
49215		Excise sacral spine tumor	33.50
49215		Excise sacral spine tumor	33.50
49220		Multiple surgery, abdomen	14.88
49255		Removal of omentum	11.14
49320		Diag laparo separate proc	5.10
49321		Laparoscopy; biopsy	5.40
49322		Laparoscopy; aspiration	5.70
49421		Insert abdominal drain	5.54
49422		Remove perm cannula/catheter	6.25
49425		Insert abdomen-venous drain	11.37
49426		Revise abdomen-venous shunt	9.63
49428		Ligation of shunt	6.06
49429		Removal of shunt	7.40
49495		Repair inguinal hernia, init	5.89
49495		Repair inguinal hernia, init	5.89
49496		Repair inguinal hernia, init	8.79
49496		Repair inguinal hernia, init	8.79
49500		Repair inguinal hernia	5.48
49501		Repair inguinal hernia, init	8.88
49505		Repair inguinal hernia	7.60
49505		Repair inguinal hernia	7.60
49507		Repair inguinal hernia	9.57
49520		Rerepair inguinal hernia	9.63
49521		Repair inguinal hernia, rec	11.97
49525		Repair inguinal hernia	8.57
49540		Repair lumbar hernia	10.39
49550		Repair femoral hernia	8.63
49553		Repair femoral hernia, init	9.44
49555		Repair femoral hernia	9.03
49557		Repair femoral hernia, recur	11.15
49560		Repair abdominal hernia	11.57
49561		Repair incisional hernia	14.25
49565		Rerepair abdominal hernia	11.57
49566		Repair incisional hernia	14.40
49570		Repair epigastric hernia	5.69
49572		Repair epigastric hernia	6.73
49580		Repair umbilical hernia	4.11
49582		Repair umbilical hernia	6.65
49585		Repair umbilical hernia	6.23
49587		Repair umbilical hernia	7.56
49590		Repair abdominal hernia	8.54
49605		Repair umbilical lesion	22.66
49606		Repair umbilical lesion	18.60
49650		Laparo hernia repair initial	6.27
49651		Laparo hernia repair recur	8.24
49900		Repair of abdominal wall	12.28

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ADDENDUM—CODES SUBJECT TO COMMENT—Continued

CPT/ HCPCS code [1]	Mod	Descriptor	Proposed work RVU
49905		Omental flap	6.55
50200		Biopsy of kidney	2.63
50230		Removal of kidney	22.07
51595		Remove bladder/revise tract	37.14
51596		Remove bladder/create pouch	39.52
56515		Destruction, vulva lesion(s)	2.76
56740		Remove vagina gland lesion	4.57
57100		Biopsy of vagina	1.20
57130		Remove vagina lesion	2.43
57292		Construct vagina with graft	13.09
57307		Fistula repair & colostomy	15.93
57410		Pelvic examination	1.75
57505		Endocervical curettage	1.14
58150		Total hysterectomy	15.24
58152		Total hysterectomy	20.60
58260		Vaginal hysterectomy	12.98
58262		Vaginal hysterectomy	14.77
58263		Vaginal hysterectomy	16.06
58267		Hysterectomy & vagina repair	17.04
58270		Hysterectomy & vagina repair	14.26
58275		Hysterectomy/revise vagina	15.76
58280		Hysterectomy/revise vagina	17.01
58285		Extensive hysterectomy	22.26
58323		Sperm washing	0.23
58400		Suspension of uterus	6.36
58600		Division of fallopian tube	5.60
58605		Division of fallopian tube	5.00
58611		Ligate oviduct(s) add-on	1.45
58700		Removal of fallopian tube	12.05
58740		Revise fallopian tube(s)	14.00
58805		Drainage of ovarian cyst(s)	5.88
58820		Drain ovary abscess, open	4.22
58825		Transposition, ovary(s)	10.98
58920		Partial removal of ovary(s)	11.36
58950		Resect ovarian malignancy	16.93
58951		Resect ovarian malignancy	22.38
59150		Treat ectopic pregnancy	11.67
59151		Treat ectopic pregnancy	11.49
59812		Treatment of miscarriage	4.01
59870		Evacuate mole of uterus	6.01
60100		Biopsy of thyroid	1.56
60220		Partial removal of thyroid	11.90
60220		Partial removal of thyroid	11.90
60252		Removal of thyroid	20.57
60254		Extensive thyroid surgery	26.99
60260		Repeat thyroid surgery	17.47
60270		Removal of thyroid	20.27
60271		Removal of thyroid	16.83
60540		Explore adrenal gland	17.03
60545		Explore adrenal gland	19.88
62263		Lysis epidural adhesions	6.14
62310		Inject spine c/t	1.91
62311		Inject spine l/s (cd)	1.54
62318		Inject spine w/cath, c/t	2.04
62319		Inject spine w/cath l/s (cd)	1.87
65855		Laser surgery of eye	3.85
66180		Implant eye shunt	14.55
66986		Exchange lens prosthesis	12.28
67028		Injection eye drug	2.52
67218		Treatment of retinal lesion	18.53
67904		Repair eyelid defect	6.26
69990		Microsurgery add-on	3.47
72275		Epidurography	0.76
76005		Fluoroguide for spine inject	0.60
76065		X-rays, bone evaluation	0.70
76090		Mammogram, one breast	0.70

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ADDENDUM—CODES SUBJECT TO COMMENT—Continued

CPT/ HCPCS code [1]	Mod	Descriptor	Proposed work RVU
76091		Mammogram, both breasts	0.87
76095		Stereotactic breast biopsy	1.59
88170		Fine needle aspiration	1.27
88171		Fine needle aspiration	1.27
90901		Biofeedback train, any meth	0.41
90911		Biofeedback peri/uro/rectal	0.89
90935		Hemodialysis, one evaluation	1.22
90937		Hemodialysis, repeated eval	2.11
90945		Dialysis, one evaluation	1.28
90947		Dialysis, repeated eval	2.16
90989		Dialysis training, complete	0.00
90993		Dialysis training, incompl	0.00
90997		Hemoperfusion	1.84
92018		New eye exam & treatment	2.50
93350		Echo transthoracic	1.48
94640		Airway inhalation treatment	0.00
94664		Aerosol or vapor inhalations	0.00
94665		Aerosol or vapor inhalations	0.00
96100		Psychological testing	0.00
96105		Assessment of aphasia	0.00
96110		Developmental test, lim	0.00
96115		Neurobehavior status exam	0.00
96117		Neuropsych test battery	0.00
97542		Wheelchair mngmnt training	0.45
99233		Subsequent hospital care	1.51
99273		Confirmatory consultation	1.19
99274		Confirmatory consultation	1.73
99291		Critical care, first hour	4.00
99291		Critical care, first hour	4.00
99291		Critical care, first hour	4.00
99292		Critical care, addl 30 min	2.00
99292		Critical care, addl 30 min	2.00
99292		Critical care, addl 30 min	2.00
99295		Neonatal critical care	16.00
99296		Neonatal critical care	8.00
99297		Neonatal critical care	4.00
99298		Neonatal critical care	2.75
99436		Attendance, birth	1.50
99440		Newborn resuscitation	2.93

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Federal Register

Friday,
June 8, 2001

Part IV

Environmental Protection Agency

40 CFR Parts 9, 141, and 142
National Primary Drinking Water; Filter Backwash Recycling Rule; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9, 141, and 142

[WH–FRL–6989–5]

RIN 2040–AD17

National Primary Drinking Water Regulations: Filter Backwash Recycling Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: In this document, EPA is finalizing the Filter Backwash Recycling Rule (FBRR). The purpose of the FBRR is to further protect public health by requiring public water systems (PWSs), where needed, to institute changes to the return of recycle flows to a plant's treatment process that may otherwise compromise microbial control. Today's final rule addresses a statutory requirement of the 1996 Safe Drinking Water Act (SDWA) Amendments to promulgate a regulation which ''governs'' the recycling of filter backwash water within the treatment process of PWSs.

DATES: This regulation is effective August 7, 2001. As discussed in the supplementary information section and consistent with sections 1412(b)(10) and 1445 of SDWA, regulated entities must comply with this rule starting December 8, 2003. For judicial review purposes, this final rule is promulgated as of 1 p.m. eastern time on June 8, 2001.

ADDRESSES: Public comments, the comment/response document, applicable **Federal Register** documents, other major supporting documents, and a copy of the index to the public docket for this rulemaking are available for review at EPA's Office of Water Docket: Docket W–99–10 Final Filter Backwash Recycling Rule, 401 M Street, SW., Rm. EB57, Washington, DC 20460 from 9:00 a.m. to 4:00 p.m., Eastern Time, Monday through Friday, excluding federal holidays. For access to docket materials or to schedule an appointment, please call (202) 260–3027.

FOR FURTHER INFORMATION CONTACT: For technical inquiries, contact Jeffery Robichaud, Office of Ground Water and Drinking Water (4607), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone (202) 260–2568. For general information contact the Safe Drinking Water Hotline, Telephone (800) 426–4791. The Safe Drinking Water Hotline is open Monday through Friday, excluding Federal holidays, from 9:00 a.m. to 5:30 p.m. Eastern Time.

SUPPLEMENTARY INFORMATION: *Regulated entities.* Entities potentially regulated by the FBRR are public water systems that use surface water or ground water under the direct influence of surface water (GWUDI), practice conventional or direct filtration, and recycle spent filter backwash, thickener supernatant, or liquids from dewatering processes. Regulated categories and entities include:

Category	Examples of regulated entities
Industry	Public Water Systems that use surface water or ground water under the direct influence of surface water.
State, Local, Tribal or Federal Governments	Public Water Systems that use surface water or ground water under the direct influence of surface water.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by the FBRR. This table lists the types of entities that EPA is now aware could potentially be regulated by this rule. Other types of entities not listed in this table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the definition of PWS in § 141.2 of title 40 of the Code of Federal Regulations and § 141.76 of today's final rule. If you have questions regarding the applicability of the FBRR to a particular entity, consult the person listed in the preceding section entitled **FOR FURTHER INFORMATION CONTACT.**

List of abbreviations/acronyms used in this document:

AWWA American Water Works Association
AWWSCo American Water Works Service Company
°C Degrees Celsius
CCR Consumer Confidence Report
CFR Code of Federal Regulations
CPE Comprehensive Performance Evaluation
DAF Dissolved Air Flotation
EPA Environmental Protection Agency
ESWTR Enhanced Surface Water Treatment Rule
FBRR Filter Backwash Recycling Rule
FR Federal Register
gpm Gallons per Minute
GWUDI Ground Water Under the Direct Influence of Surface Water
HRRCA Health Risk Reduction and Cost Analysis
ICR Information Collection Request
IESWTR Interim Enhanced Surface Water Treatment Rule
IRFA Initial Regulatory Flexibility Analysis
LT1ESWTR Long Term 1 Enhanced Surface Water Treatment Rule
MCLG Maximum Contaminant Level Goal
NDWAC National Drinking Water Advisory Council
NPDWR National Primary Drinking Water Regulation
NODA Notice of Data Availability
NTTAA National Technology Transfer and Advancement Act
OMB Office of Management and Budget
PBMS Performance-based Measurement System
PRA Paperwork Reduction Act
PWS Public Water System
RFA Regulatory Flexibility Act
SAB Science Advisory Board
SBA Small Business Administration
SBAR Small Business Advocacy Review
SBREFA Small Business Regulatory Enforcement Fairness Act of 1996
SDWA Safe Drinking Water Act
SDWIS Safe Drinking Water Information System
UMRA Unfunded Mandates Reform Act

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I. Summary

A. Why Is EPA Promulgating the Filter Backwash Recycling Rule (FBRR)?

When a facility recycles filter backwash water, it reintroduces contaminants back into treatment processes. Poor recycle practices can degrade influent water quality and impair treatment process performance. The 1996 Amendments to the Safe Drinking Water Act (SDWA) require EPA to promulgate a regulation that ''governs'' the recycle of filter backwash water within a treatment plant (42 U.S.C. 300g–1(b)(14)). Today's final rule addresses filter backwash water and two additional recycle streams of concern, sludge thickener supernatant and liquids from dewatering processes. The Agency believes that establishing such a regulation will improve performance at filtration plants by reducing the opportunity for recycle practices to adversely affect plant performance in a way that would allow microbes such as *Cryptosporidium* to pass through into finished drinking water.

B. What Are Filter Backwash Water, Sludge Thickener Supernatant, and Liquids From Dewatering Processes?

Throughout today's final rule, when the word recycle is used as a noun it refers to the three recycle streams (filter backwash water, sludge thickener supernatant, and liquids from dewatering processes) regulated under the FBRR.

Filter backwashing is an integral part of treatment plant operation. When filters need to be cleaned, water must be returned back up through the filtration media with sufficient force to separate particles from the filter media. The resulting water which was pushed back through the filter in the cleaning process is referred to as filter backwash water or spent filter backwash water. It contains many of the particles that were trapped in the filter during operation, including coagulants, metals, and microbes such as *Cryptosporidium*. Several studies have documented a range of *Cryptosporidium* oocysts concentrations in spent filter backwash from non-detects to over 15,000 oocysts/100 L, (EE&T, 1999).

Sedimentation basins and clarifiers are constructed to remove particles from a treatment process through gravity settling. When these units are employed to treat recycled water, the ''clear water'' that exits the units after particles have been allowed to settle out is called sludge thickener supernatant. While the sludge at the bottom of sedimentation basins and clarifiers contain the majority of the *Cryptosporidium* oocysts entering a unit, recent research has documented a range of concentrations of *Cryptosporidium* oocysts in thickener supernatant from 82 to 420 oocysts/100 L (EE&T, 1999).

Finally, some filtration plants employ dewatering processes to remove water from waste solids in order to reduce the solids volume to be disposed. This ''sludge'' typically comes from sedimentation basins and clarifiers and contains only one to two percent solids. The dewatering units press or centrifuge the sludge, removing liquids from solids, which increases the solids volume up to 90 percent. The liquids that are removed are referred to as liquids from dewatering processes. Since nearly all particles and solids are removed in sludge or slurry form from a treatment plant, the sludge or slurry will contain a substantial amount of the *Cryptosporidium* oocysts which have entered the plant since the dewatering unit was last cleaned. If this sludge or slurry is dewatered, there exists significant potential that the liquids from dewatering may contain elevated levels of *Cryptosporidium* oocysts. Although the Agency is unaware of specific effluent liquid oocyst data from dewatering processes, influent slurries (consisting of sedimentation basin sludges) have been shown to contain a range of *Cryptosporidium* oocyst concentrations, even as high as 2,600 oocysts/100 L (EE&T, 1999).

It should be noted that process solids recycle flows from softening and contact clarification units are not covered by today's final FBRR. However, if softening systems or contact clarification systems recycle any of the three recycle flows covered by the FBRR (filter backwash water, sludge thickener supernatant, and liquids from dewatering processes) then they must meet the requirements of the FBRR for these three recycle flows.

C. What Is Cryptosporidium?

Cryptosporidium is a protozoan parasite found in humans, many other mammals and also in birds, fish and reptiles. It is common in the environment and widely found in surface water supplies (Rose, 1988; LeChevallier and Norton, 1995; Atherholt et al., 1998; EPA, 2000a). In the infected animal, the parasite multiplies in the gastrointestinal tract. The animal then excretes oocysts of the parasite in its feces. These oocysts are tiny spore-like organisms 4 to 6 microns in diameter (too small to be seen without a microscope) which contain the sporozoites (infective form). The oocysts of *Cryptosporidium* are very resistant to adverse factors in the

environment and can survive dormant for months in cool, dark, moist soil or for up to a year in clean water. When ingested by another animal, they can reproduce in the intestinal tract and start a new cycle of cryptosporidiosis illness. Cryptosporidiosis is primarily a waterborne disease, but cryptosporidiosis has also been transmitted by consumption of contaminated food, unhygienic diaper changing practices (and other person-to-person contact), and contact with young farm animals.

Cryptosporidium oocysts are relatively resistant at normal temperatures and are not easily killed by commonly used disinfectants. Oocyst infectivity appears to persist under normal temperatures, although oocysts may lose infectivity if sufficiently cooled or heated (EPA, 2000a). For example, Fayer (1994) discovered that cleaned oocysts in distilled water heated to 72.4 °C for 1 minute and to 64.2 °C for two minutes were not infective to mice. Fayer and Nerad (1996) found that cleaned oocysts in distilled water cooled to −20 °C for eight hours and 70 °C for 1 hour were not infective to mice. However, oocysts may remain viable after freezing (Fayer and Nerad, 1996). The oocysts are relatively unaffected by chlorine and chloramines in the concentrations that are used for drinking water treatment. They are also resistant to the effects of 60 percent alcohol and many disinfectants commonly used in the home or animal husbandry.

D. What Are the Health Concerns Associated With Cryptosporidium?

When someone is infected with *Cryptosporidium,* symptoms can include watery diarrhea, stomach cramps, nausea, loss of appetite, and a mild fever. This disease is called cryptosporidiosis and is a major cause of reported waterborne disease outbreaks from rivers, lakes, waterparks, and swimming pools. The symptoms of cryptosporidiosis begin an average of seven days after infection. Persons with a normal, healthy immune system can expect their illness to last for two weeks or less, with constant or intermittent diarrhea. Even after symptoms cease, an individual can still pass *Cryptosporidium* in the stool for up to two months and may be a source of infection for others. Cryptosporidiosis is not treatable with antibiotics so prevention of infection is critical. People with weakened immune systems (those with HIV/AIDS, on cancer chemotherapy, or those who have received organ transplants) may have cryptosporidiosis for a longer period of time, and it can be life-threatening. Small children, pregnant women, or the elderly infected with cryptosporidiosis can quickly become severely dehydrated.

E. Does This Regulation Apply to My Water System?

Today's final rule applies to all public water systems that:

- Use surface water or ground water under the direct influence of surface water (GWUDI);
- Utilize direct or conventional filtration processes; and
- Recycle spent filter backwash water, sludge thickener supernatant, or liquids from dewatering processes.

F. How Will This Regulation Protect Public Health?

EPA has determined that the presence of microbiological contaminants is a health concern. If finished water supplies contain microbiological contaminants, disease outbreaks may result. Of the 12 waterborne cryptosporidiosis outbreaks that have occurred at drinking water systems since 1984, three (Carollton, GA, 1987; Talent, OR, 1992; and Milwaukee, WI, 1993) were linked to contaminated drinking water from water utilities where waste stream recycle was identified as a possible cause (Craun, 1998; EPA, 2000a). The largest of the known outbreaks occurred in Milwaukee and was responsible for over 400,000 illnesses and 50 deaths (Hoxie, et al., 1997; MacKenzie et al., 1994); other known outbreaks have occurred in smaller communities and have involved many fewer people.

The Surface Water Treatment Rule (SWTR) and Interim Enhanced Surface Water Treatment Rule (IESWTR) (63 FR 69478, December 16, 1998) set enforceable drinking water treatment technique requirements to reduce the risk of waterborne microbiological disease including *Cryptosporidium* from surface water. Today's final rule provides further necessary protection against *Cryptosporidium* for systems that practice recycle.

Today's rule ensures that the 2-log *Cryptosporidium* removal requirement established in the IESWTR and proposed in the Long Term 1 Enhanced Surface Water Treatment Rule (LT1ESWTR) (65 FR 19046, April 10, 2000) is not jeopardized by recycle practices. The rule requires (with some exceptions) that recycle be returned through the processes of a system's existing conventional or direct filtration (as defined in § 141.2 of the CFR) that the Agency has recognized capable of achieving 2-log (99 percent) *Cryptosporidium* removal. Today's rule also ensures that systems and States will have the recycle flow information necessary to evaluate whether site-specific recycle practices may adversely affect the ability of systems to achieve 2-log *Cryptosporidium* removal. Surges of recycle flow returned to the treatment plant may adversely affect treatment systems by creating hydraulically overloaded conditions (when plants exceed design capacity or State-approved operating capacity) that can lower performance of individual units within a treatment plant resulting in lowered *Cryptosporidium* removal efficiency.

II. Background

A. What Is the Statutory Authority for the FBRR?

The Safe Drinking Water Act (SDWA or the Act), as amended in 1986, requires EPA to publish a maximum contaminant level goal (MCLG) for each contaminant which, in the judgement of EPA, ''may have any adverse effect on the health of persons and which is known or anticipated to occur in public water systems'' (Section 1412(b)(3)(A)). MCLGs are to be set at a level at which ''no known or anticipated adverse effect on the health of persons occur and which allows an adequate margin of safety'' (Section 1412(b)(4)).

The Act was again amended in August 1996, resulting in the renumbering and augmentation of certain sections with additional statutory language. New sections were added establishing new drinking water requirements. Section 1412(b)(14) requires EPA to promulgate a regulation to govern the recycling of filter backwash water within the treatment process of a public water system. The Amendments require EPA to promulgate such a regulation no later than four years after the date of the enactment of the SDWA Amendments of 1996 unless this type of recycling has been addressed by EPA's Enhanced Surface Water Treatment Rule prior to the deadline.

B. What Is the Regulatory History for the FBRR?

The practice of filter backwash recycling has not previously been addressed in drinking water rules promulgated by the Agency. As noted earlier, the 1996 Amendments to the SDWA, required EPA to promulgate a regulation governing the recycling of filter backwash water. The Agency first presented information regarding filter backwash practices, data, and health risks in the November 3, 1997, Interim

Enhanced Surface Water Treatment Rule Notice of Data Availability (NODA) (62 FR 59486). In this NODA, EPA indicated that while both the SWTR and forthcoming IESWTR contained treatment technique requirements designed to address microbial pathogens such as *Cryptosporidium,* neither the SWTR or IESWTR addressed filter backwash recycling practices. In the NODA, EPA indicated that it did not plan to include separate provisions for regulating recycling of filter backwash water in the IESWTR, but planned to develop a regulation to address filter backwash recycling in conjunction with the Long Term 1 Enhanced Surface Water Treatment Rule (LT1ESWTR). The proposed LT1ESWTR and FBRR were published on April 10, 2000 (65 FR 19046).

C. How Were Stakeholders Involved in the Development of the FBRR?

The Agency initially conducted a broad literature search to gather research papers and information on the occurrence of *Cryptosporidium* and other materials in recycle flows. The literature search also sought information on how recycling practices may impact plant efficiency. The Agency worked with American Water Works Association (AWWA), the American Water Works Service Company (AWWSCo.), and Cincinnati Water Works to develop twelve issue papers on commonly generated recycle flows. These papers are found in the docket of today's final rule (EE&T, 1999).

EPA began outreach efforts to develop the FBRR in the summer of 1998. Two public stakeholder meetings, announced in the **Federal Register,** were held on July 22–23, 1998, in Lakewood, Colorado, and on March 3–4, 1999, in Dallas, Texas. In addition, EPA held several formal and informal meetings with stakeholders, trade associations, and environmental groups. Small entity representatives also contributed valuable input as part of the Small Business Regulatory Enforcement Fairness Act (SBREFA) panel process. The FBRR SBREFA panel was initiated in April of 1998 and officially convened in August of 1998. The panel's recommendations were incorporated into today's final rule.

During rule development EPA considered a range of different options. In addition to those found in the proposed rule, EPA also considered mandatory treatment of recycle streams and a ban on all recycle flows, but ultimately did not select these options. EPA determined that the rule would apply to the three largest recycle flows at treatment plants (spent filter backwash, sludge thickener supernatant, and liquids from dewatering processes), which constitute 98 percent of recycle flow at an average system.

In early June 1999, EPA mailed an informal draft of the FBRR preamble to approximately 100 stakeholders who attended either of the public stakeholder meetings. Members of trade associations and the SBREFA panel also received the draft preamble. EPA received valuable comments and stakeholder input from 15 State representatives, trade associations, environmental interest groups, and individual stakeholders.

During the comment period for today's rule, the Agency held a public meeting in Washington, DC on April 14, 2000. Additionally, the proposed rule was either presented or discussed in nearly 50 meetings across the U.S. (EPA, 2000i). Finally, EPA requested stakeholder comments by mailing approximately 200 copies of the proposed rule to stakeholders requesting comment. EPA received 67 comments from a variety of stakeholders including States, municipalities, Tribes, elected officials, consultants, trade groups, and private industry. These comments were reviewed and evaluated while developing today's final rule. Responses to all of the comments are found in EPA's Response to Comment Document for the FBRR (EPA, 2000j).

D. What Did the April 10, 2000 Proposal Contain?

The April 10, 2000 proposal (65 FR 19046) contained the Filter Backwash Recycling Rule provisions as well as the LT1ESWTR provisions. The proposed rulemaking package was entitled, ''The Long Term 1 Enhanced Surface Water Treatment and Filter Backwash Rule; Proposed Rule'' (EPA, 2000b). The Agency intends to promulgate the LT1ESWTR in a future **Federal Register** announcement, separate from today's final rule. The FBRR provisions of the proposal applied to all surface water and GWUDI systems which recycle regardless of population served. The proposal included the following requirements:

—Spent filter backwash water, sludge thickener supernatant, and liquids from dewatering processes were required to be recycled prior to the point of primary coagulant addition unless the State specified an alternative location;

—Conventional filtration systems with 20 or fewer filters that recycle spent filter backwash water, sludge thickener supernatant, or liquids from dewatering processes without treatment or equalization were required to perform a one month, one-time recycle self assessment. The proposed self assessment required hydraulic flow monitoring and certain data to be reported to the State. Upon review of these data, the State could require that modifications be made to the recycle practice in order to protect public health; and

—Direct filtration systems recycling to the treatment process were required to provide detailed recycle treatment information to the State. Upon review of this data, the State could require that modifications be made to the recycle practice in order to protect public health.

These three requirements have been modified in today's final FBRR as described in the following section.

III. Discussion of Today's Filter Backwash Recycle Rule Requirements

A. Where Does the FBRR Specify That Recycle Must Be Returned?

1. What Does Today's Rule Require?

The Agency's goal is to address risks associated with certain recycle practices in the least burdensome, most effective, and simplest means possible. Accordingly, today's final rule requires that recycled filter backwash water, sludge thickener supernatant, and liquids from dewatering processes must be returned to a location such that all processes of a system's conventional or direct filtration, as defined in § 141.2, are employed. Systems may apply to the State if they want to recycle at an alternate location.

2. What Was the Rationale and Basis for the Proposed Requirement?

The Agency proposed that spent filter backwash water, sludge thickener supernatant, and liquids from dewatering process be recycled prior to the point of primary coagulant addition unless the State specified an alternative location. In establishing this proposed requirement, EPA had two goals in mind. First, the Agency believes it is important that recycle practices be conducted in a manner that does not upset the chemical treatment and coagulation process vital to the performance and contaminant removal capability of a filtration plant. Second, the Agency also believes treatment plants must assure that *Cryptosporidium* oocysts in recycled water, as well as source water, receive the full benefit of well-operated treatment processes to achieve at least 2-log *Cryptosporidium* removal.

As indicated in the proposal, close to 80 percent of the systems which recycle, currently return recycle prior to the rapid mix unit and coagulation stage of

the treatment plant. Studies from many researchers (Patania et al., 1995; Edzwald and Kelly, 1998; Bellamy et al., 1993; Conley, 1965; Robeck et al., 1964; and Trussell et al., 1980) indicate that proper coagulation is paramount to optimal performance of treatment plants. In fact, pilot scale work performed by Dugan et al. (1999) showed that coagulation has a significant influence on the log removal of *Cryptosporidium*.

The ability for conventional and direct filtration plants to remove *Cryptosporidium* under appropriate coagulation conditions was demonstrated through eight studies (Patania et al., 1995; Nieminski and Ongerth, 1995; Ongerth and Pecoraro, 1995; LeChevallier and Norton, 1992; LeChevallier et al., 1991; Foundation for Water Research, 1994; Kelly et al., 1995; and West et al., 1994) that were described in greater detail in the proposal for today's final rule (EPA , 2000b). These eight studies demonstrated that conventional and direct filtration plants which employed coagulation, flocculation, sedimentation (in conventional filtration only), and filtration steps had the ability to achieve at least 2-log removal of *Cryptosporidium* when meeting specific turbidity limits. These studies formed the basis for the Agency's development of turbidity limits (0.3 NTU 95 percent of the time and a 1 NTU maximum) associated with the 2-log treatment technique in the IESWTR and the proposed LT1ESWTR. As noted earlier, none of the studies evaluated the practice of recycling on treatment performance.

In order to minimize the impacts of recycle on chemical treatment, minimize hydraulic disruption within the treatment processes due to recycle, and provide the appropriate level of treatment necessary to achieve at least 2-log removal of *Cryptosporidium* in recycle flows, the Agency believed it necessary to include as part of the proposed FBRR, a specific recycle return location requirement, while also allowing systems the ability to establish alternate recycle locations as approved by the State.

3. What Major Comments Were Received on the Proposal?

Many commenters agreed with the proposal and noted that requiring recycle to be returned prior to the point of primary coagulant addition was appropriate. Several others noted that recycle should be allowed concurrent with the point of primary coagulant addition. Still others, most notably EPA's Science Advisory Board (SAB), indicated that because of the site-specific characteristics of recycle, defining a single acceptable recycle return location was inappropriate since, in some circumstances, it could reduce the performance of the treatment system. Finally, a few commenters expressed concern regarding workload implications for States if too many requests for alternate recycle locations are received.

4. What Was the Basis for Revising the Proposal?

After evaluating the data submitted by commenters, EPA believes that the goal of this rule can be achieved more efficiently by slightly modifying the return location requirement. Rather than requiring recycle to be returned to a specific location, today's final rule requires recycle flows to pass through all processes of the system's representative treatment as defined in § 141.2 in order for conventional and direct filtration systems which recycle to maintain 2-log *Cryptosporidium* removal credit. For most systems, this requirement would allow the return of recycle concurrent with the point of primary coagulant addition. Today's final rule continues to allow States the opportunity to approve alternative recycle return locations for systems on a system-specific basis. Conventional filtration is defined in § 141.2 of the Code of Federal Regulations as a series of processes including coagulation, flocculation, sedimentation, and filtration resulting in substantial particle removal. Direct filtration is defined in § 141.2 of the Code of Federal Regulations as a series of processes including coagulation and filtration but excluding sedimentation resulting in substantial particle removal. As noted earlier, the ability for conventional and direct filtration plants to remove *Cryptosporidium* has been demonstrated in many studies. These studies demonstrated that conventional and direct filtration plants which employed coagulation, flocculation, sedimentation (in conventional filtration only), and filtration processes, had the ability to achieve 2-log removal of *Cryptosporidium* while meeting specific turbidity limits. EPA firmly believes these studies demonstrate a minimum of 2-log *Cryptosporidium* removal only when water passes through all processes of conventional or direct filtration treatment. Some studies have shown that when recycle is performed properly, namely when recycle is returned through all processes of the plant's existing treatment system and normal plant operations are not disrupted with hydraulic surges or increased overall plant flow, the return of recycle does not perceptively impair plant treatment with respect to *Cryptosporidium* or turbidity removal (Levesque et al., 1999 and Cornwell and MacPhee, 2001). Because continuing to ensure at least 2-log *Cryptosporidium* removal is the goal of this provision, EPA believes it appropriate to require that recycle be returned at least through existing processes which the Agency has determined to have the ability to achieve 2-log *Cryptosporidium* removal, instead of requiring that recycle be returned to a discrete location.

The Agency continues to recognize that some systems may be able to achieve 2-log or higher *Cryptosporidium* removal when recycling to other locations within the treatment plant. Therefore, the final rule continues to include a provision that States may approve alternate recycling locations for systems on a case-by-case basis. However, the Agency dropped an explicit requirement in the proposal that systems must apply to the State for approval of the change in recycle location before the system implements it, as the Agency believes that such a requirement is implicit in the regulatory language for today's final rule, and unnecessary as systems are unlikely to make a change to their location without approval from the State.

B. What Reporting Does the FBRR Require of Conventional Filtration Systems That Recycle?

1. What Does Today's Rule Require?

The Agency's goal is to address risks associated with recycle practices in the least burdensome, most effective, and simplest means possible. Accordingly, today's final rule requires that systems that practice conventional filtration and recycle spent filter backwash, sludge thickener supernatant, or liquids from dewatering processes, notify the State in writing that they practice recycle. When notifying the State, systems must also provide the following information:

—A plant schematic showing the origin of all recycle flows, the hydraulic conveyance used to transport them, and the location where they are recycled back into the plant; and

—Typical recycle flow in gallons per minute (gpm), highest observed plant flow experienced in the previous year (gpm), design flow for the treatment plant (gpm), and the State-approved operating capacity for the plant where the State has made such determinations.

Additionally, systems must collect and maintain the following information for review by the State, which may, after

evaluating the information, require a system to modify their recycle location or recycle practices:

(1) Copy of the recycle notification and information submitted to the State;

(2) List of all recycle flows and the frequency with which they are returned;

(3) Average and maximum backwash flow rate through the filters and the average and maximum duration of the filter backwash process in minutes;

(4) Typical filter run length and a written summary of how filter run length is determined (headloss, turbidity, time etc.);

(5) The type of treatment provided for the recycle flow; and

(6) Data on the physical dimensions of the equalization and/or treatment units, typical and maximum hydraulic loading rates, type of treatment chemicals used and average dose and frequency of use, and frequency at which solids are removed from treatment units where such units are used.

These requirements are identical to the requirements for direct filtration systems that recycle, as described in Section III.C. They are discussed in separate preamble sections because in the proposed rule, separate and distinct requirements for the two types of systems were proposed.

2. What Was the Rationale and Basis for the Proposed Requirement?

The Agency proposed that conventional filtration systems with fewer than 20 filters that do not provide treatment or equalization of their recycle streams would be required to develop a flow monitoring plan for submittal and approval by the State, conduct a month of flow monitoring, and develop and submit a self-assessment report to the State. The State would then be required to make a determination of whether modifications to a system's recycle practice should be required.

This component was designed to assist States in addressing the potential negative impact of hydraulic surge on treatment performance. The first component of today's final rule requires that recycle flows proceed through all steps of the treatment processes to ensure 2-log removal of *Cryptosporidium*. However, hydraulic surge can still upset treatment performance even when recycle is treated by all necessary steps of a treatment process (e.g., surges that cause hydraulic flow to exceed design or operating capacity).

Because of the high volume of water and short duration of a filter backwash recycle event (typically about 15 minutes long), a large volume of water may surge through the treatment plant. This hydraulic surge can potentially overload treatment capability by challenging the ability of each process within a system including the filters. Some studies have demonstrated (Glasgow and Wheatley, 1998; McTigue *et al.,* 1998; and Myers *et al.,* 2000) that increasing loading rates through surges to filters can have an adverse effect on finished water quality. McTigue *et al.,* reported that when filter loading rates in a pilot plant were doubled from 2 gpm to 4 gpm instantaneously, *Cryptosporidium* counts in finished water jumped from non detect to 18 oocysts/100 L. When filter loading rates were doubled from 4 gpm to 8 gpm instantaneously, *Cryptosporidium* counts in finished water jumped from non detect to 50 oocysts/100L, resulting in a reduction in performance from 5-log *Cryptosporidium* removal to 3.5-log *Cryptosporidium* removal. Pilot work completed by Myers *et al.,* showed that when hydraulic surges occurred, particle counts increased. When hydraulic flow was instantaneously increased from 2 gpm to 3 gpm, particle counts rose from 17 particles/mL to 27 particles/mL. When the flow was raised from 2 gpm to 4 gpm, particle counts rose from 17 particles/mL to 36 particles/mL. Many commenters to the IESWTR noted that increased loading rates to filters (in excess of approved design rates) would contribute to poor performance of filters (EPA, 1998l).

Although hydraulic surging can have a adverse effect, systems that practice equalization or treatment of their recycle streams can mitigate the effect that recycle may have on the performance of the treatment systems. Limited data (Cornwell and Lee, 1996) have shown that equalization of recycle streams minimizes the risk of hydraulic upset. Proper equalization can serve to avoid abrupt changes in the flow rates and the water quality. Several studies have recommended maintaining recycle flow at or below 10 percent of the plant flow (Cornwell and Lee, 1994; McGuire, 1997; Pederson and Calhoun, 1995; and Levesque et al., 1999).

Treatment reduces the number of microbial constituents a recycle flow may reintroduce into the primary treatment process and therefore, reduce the risk associated with passing oocysts if hydraulic surges occur. Work by a variety of individuals (Grubb and Arnold, 1997; Levesque et al., 1999; and Parker et al., 1999;) has demonstrated the utility of treatment of recycle streams prior to being returned to the primary treatment plant. In addition, as indicated previously, some studies have shown that when recycle is performed in accordance with the requirements of the FBRR, *Cryptosporidium* removal is not impaired, even without separate treatment of recycle streams.

Given the variety and site-specific nature of recycle practices throughout the country, the Agency believed it necessary to require conventional filtration systems to notify States that they practice recycle, and provide information the State could utilize to evaluate whether a treatment plant may be susceptible to hydraulic disruptions as a result of recycling.

In the proposal, the Agency attempted to identify the subset of systems that would be most susceptible to hydraulic surges by only requiring that systems without equalization or treatment (referred to as ''direct recycle'') meet the reporting requirements. The Agency further limited the applicability of these requirements (including a one-time requirement to submit a recycle self-assessment) to those direct recycle systems that employ 20 or fewer filters to meet production requirements during a selected month, and recycle spent filter backwash water, thickener supernatant, and/or liquids from dewatering process within the treatment process. The self-assessment required that a monitoring plan, one month of hydraulic flow monitoring, and a self-assessment report containing additional recycle information be submitted to the State. After reviewing the self-assessment, the State would have been required to make a determination whether to require modifications to a system's recycle practice in order to protect public health and report the determination to EPA. The self-assessment was designed to provide the State with adequate information to make this determination.

3. What Major Comments Were Received?

The Agency received many comments on the Direct Recycle Reporting in the proposed rule. The proposed rule only applied to conventional filtration plants which did not practice equalization or treatment of recycle and which utilized fewer than 20 filters to meet demand. Many commenters believed that the operational values used in the analysis conducted by the Agency to arrive at a 20 filter cut-off did not accurately represent the true range of values witnessed throughout the country. Similarly, many commenters noted that excluding systems that treat or equalize recycle flows was inappropriate because of the lack of clearly defined, widely-used parameters for the definitions of equalization and treatment of recycle.

The Agency also received significant comment on the proposed hydraulic flow monitoring associated with this requirement. Many commenters disagreed with the appropriateness of hydraulic flow monitoring, citing a range of problems with the process including the amount of data which would be collected, determining the month in which monitoring should take place, and the time of day monitoring should take place. States noted that submittal of self-assessment reports and requirement for a State determination would result in an increased burden, and, that given resource limitations, could be problematic.

4. What Was the Basis for Revising the Proposal?

After evaluating the information submitted by commenters, EPA believes that the goal of this requirement can be achieved more efficiently by slightly modifying this requirement. Rather than requiring only certain conventional filtration systems to develop, obtain State approval of, and implement a hydraulic flow monitoring program, the Agency believes that all conventional filtration systems that practice recycle can assemble existing information on recycle flow volumes, treatment/equalization and other parameters that is adequate for States to evaluate whether recycle modifications are necessary. Some of the information would be reported by all affected systems to the State, which will facilitate State identification of those systems where recycle practices warrant closer scrutiny. Additional information would be maintained on-site by the system and available to the State for review.

Today's final rule now applies to all conventional filtration systems that recycle. In requiring only those systems that did not provide treatment or equalization of their recycle streams and which utilized less than 20 filters to comply with the proposed requirement, the Agency was attempting to identify the subset of systems where hydraulic surge was a particular risk. Given the wide variability among system operations as noted by commenters, the Agency believes it to be more protective of public health to require all conventional filtration systems to comply.

The Agency has also modified flow monitoring and the self-assessment portions of the requirement in the proposal. EPA established hydraulic flow monitoring as a means for developing information to evaluate whether hydraulic surge may cause a plant to exceed its operating capacity and threaten treatment performance. The self-assessment was intended to serve as a vehicle for providing this information and additional recycle data to the State. The comments highlighted the technical concerns and burden associated with having systems conduct the flow monitoring, develop the self-assessment, and duplicate existing information submitted to the State. EPA believes this same goal can be achieved more efficiently with a modified approach. Today's final rule requires systems to notify the State that they practice recycle, and include, along with a schematic of the system's recycle process, four key pieces of information (typical recycle flow (gpm), highest observed plant flow experienced in the previous year (gpm), design flow for the treatment plant (gpm), and the State-approved operating capacity for the plant where the State has made such determinations). This information will be submitted to the State, so States may evaluate whether recycle practices have the potential to cause a hydraulic surge that may cause a plant to exceed its operating capacity. Systems will not be required to perform flow monitoring, but will still be required to collect certain additional recycle data (as described previously) and keep it on file for State review during sanitary surveys, other inspections (e.g., comprehensive performance evaluations (CPEs)), or other State activities, rather than submit it in a special report to the State. An ancillary benefit of this modification is significantly reduced burden for systems and States because of the removal of the monitoring, associated monitoring plan, and State approval provisions.

C. What Reporting Does the FBRR Require of Direct Filtration Systems That Recycle?

1. What Does Today's Rule Require?

The Agency's goal is to address risks associated with recycle practices in the least burdensome, most effective, and simplest means possible. Accordingly, today's final rule requires that systems that practice direct filtration and recycle spent filter backwash, sludge thickener supernatant, or liquids from dewatering processes, notify the State in writing that they practice recycle. When notifying the State, systems must also provide the following information:

—A plant schematic showing the origin of all recycle flows, the hydraulic conveyance used to transport them, and the location where they are recycled back into the plant; and

—Typical recycle flow (gpm), highest observed plant flow experienced in the previous year (gpm), design flow for the treatment plant (gpm), and the State-approved operating capacity for the plant where the State has made such determinations.

Additionally, systems must collect and maintain the following information for review by the State, which may, after evaluating the information, require a system to modify their recycle location or recycle practices:

(1) Copy of the recycle notification and information submitted to the State;

(2) List of all recycle flows and the frequency with which they are returned;

(3) Average and maximum backwash flow rate through the filters and the average and maximum duration of the filter backwash process in minutes;

(4) Typical filter run length and a written summary of how filter run length is determined (headloss, turbidity, time etc.);

(5) The type of treatment provided for the recycle flow; and

(6) Data on the physical dimensions of the equalization and/or treatment units, typical and maximum hydraulic loading rates, type of treatment chemicals used and average dose and frequency of use, and frequency at which solids are removed from treatment units where such units are used.

These requirements are identical to the requirements for conventional filtration systems that recycle, as described in Section III.B. They are discussed in separate preamble sections because in the proposed rule, separate and distinct requirements for the two types of systems were proposed.

2. What Was the Rationale and Basis for the Proposed Requirement?

The Agency proposed that all direct filtration systems that recycle submit a report to the State that would include information on recycle practices. The State would then be required to make a determination of whether modifications to a system's recycle practice would be required.

This component was designed to assist States in addressing the potential negative impact of hydraulic surge and inadequate treatment on direct filtration treatment performance. The first component of today's final rule requires that recycle flows be returned to an appropriate place in the treatment system to ensure that they are given adequate treatment and achieve 2-log removal of *Cryptosporidium.* However, the practice of recycle can still upset treatment performance if not performed properly. Consequently, the Agency developed the direct filtration system requirements to address the following two concerns.

First, as discussed with respect to conventional filtration systems that recycle, during the short duration of a filter backwash recycle event (typically about 15 minutes long), a large volume of water may surge through the treatment plant. This surge can potentially overload treatment capability by challenging the ability of each step within a system (e.g., surges that cause hydraulic flow to exceed design or operating capacity). Reduced filter efficiency can lead to *Cryptosporidium* oocysts passing through to the finished water.

Second, treatment of recycle streams is of utmost importance for direct filtration systems. By definition, direct filtration does not have a sedimentation or solids removal step in the primary treatment train. Any solids which enter the process either are deposited on the filter or travel through the filter. If the recycle flow is not adequately treated before being returned to the primary treatment train, significant numbers of the oocysts captured on a filter during a filter run will be returned to the plant. These oocysts are again loaded onto the filters, increasing the risk that disinfectant-resistant pathogens such as *Cryptosporidium* can slip through filtration, thereby posing a public health risk.

Given the variety and site-specific nature of recycle practices throughout the country, the Agency believed it necessary to require direct filtration systems to notify States that they practice recycle, and provide information the State could utilize to evaluate whether a treatment plant may be susceptible to hydraulic disruptions as a result of recycling, and whether the existing recycle practices sufficiently address potential health risks. This information would allow States to focus resources and prioritize systems where recycle may be a concern.

3. What Major Comments Were Received?

Many States commented that information required to be submitted as part of the proposed Direct Filtration Reporting was in many cases duplicative of information already available to the State. States also noted that submittal of direct filtration reports would result in an increased burden, and that given resource limitations this could be problematic.

Additionally, several commenters, including the EPA's Science Advisory Board, noted that it would be unlikely for a direct filtration system to continue operations and recycle without employing a solids removal step in the recycle train. EPA agrees that this would be true for systems that recycle on a more or less continuous basis. EPA based assumptions on data from an AWWA Fax Survey (AWWA, 1998) which indicated that eight percent of direct filtration systems that recycled used equalization but not treatment. EPA believes that the Direct Filtration Reporting requirement of today's final rule will allow systems and States to evaluate recycle practices and determine whether existing recycle practices sufficiently address potential health risks.

4. What Was the Basis for Refining the Proposal?

After evaluating the information submitted by commenters, EPA believes that the goal of this requirement can be achieved more efficiently by slightly modifying this requirement. Rather than requiring direct filtration systems to prepare and submit a report on the adequacy of recycle flow treatment, the Agency believes that these systems can notify the State that they recycle and submit some basic flow information. The direct filtration systems would assemble and maintain on-site additional information on recycle flow volumes and treatment/equalization and other parameters that is adequate for States to determine if recycle modifications are necessary.

The final rule requires systems to notify the State that they practice recycle, and include, along with a schematic of the systems recycle process, four key pieces of information (typical recycle flow (gpm), highest observed plant flow experienced in the previous year (gpm), design flow for the treatment plant (gpm), and if applicable the State-approved operating capacity for the plant). This information will be submitted to the State, so States may evaluate whether recycle practices have the potential to cause a hydraulic surge that may cause a plant to exceed its operating capacity. Systems would still be required to collect certain additional recycle data (as described previously) and keep it on file for State review during sanitary surveys, other inspections (e.g., CPEs), or other State activities rather than submit it in a special report to the State. An ancillary benefit of this modification is significantly reduced burden for systems and States.

D. What Is the Compliance Schedule for the FBRR?

1. What Does Today's Rule Require?

Section 1412(b)(10) of SDWA provides that systems must comply with new drinking water rules 36 months after promulgation unless the Administrator determines that an earlier time is practicable. The Administrator or an authorized State may extend the compliance date by an additional 24 months if capital improvements are necessary.

The Agency developed the requirements of today's final FBRR to provide flexibility for States and systems to implement and comply with the rule. Today's final rule requires that systems must recycle spent filter backwash water, thickener supernatant, or liquids from dewatering processes through the processes of a system's existing conventional or direct filtration system as defined in § 141.2 or an alternate recycle location approved by the State no later than June 8, 2004. Systems that need to make capital improvements to modify their recycle location must complete activities by June 8, 2006. The Agency believes that granting an additional 24 months to the compliance date is appropriate under 1412(b)(10). The Agency estimates that as many as 400 systems are expected to make changes to their recycle location and will require additional time to secure financing for their capital improvements. These improvements may include preliminary planning activities, development of alternatives, selection of consultants and contractors, receipt of State approval and/or permits, and finally installation of new piping, pumps, processes, and instrumentation.

The reporting requirements of today's final rule must be completed no later than December 8, 2003. The schedule for submitting the reporting contained in today's final rule was slightly modified from the proposal to maintain a consistent order of activities and to ensure that systems submit basic recycle information to the State prior to the compliance date for the recycle return location requirement. These reporting requirements were established pursuant to the authority of Section 1445 of SDWA to ensure that States have the appropriate information from systems to determine compliance with the recycle return location requirement of today's final rule.

2. What Major Comments Were Received?

As discussed in the previous sections, the Agency received significant comment on all three proposed provisions. Today's final rule includes some modifications of the proposed provisions, and the compliance schedule has been adjusted accordingly. One argument made by several commenters was that EPA should not require systems or States to undertake

activities before three years from the date a rule is promulgated because it would result in ''early implementation'' of the rule. EPA notes that the recycle return location requirement of today's final rule does not require compliance until June 8, 2004, three years after promulgation of the rule in the **Federal Register** as required by Section 1412(b)(10) of SDWA. Only minimal reporting is required, pursuant to the authority of Section 1445 of SDWA, at two and a half years after promulgation of today's final rule.

Several commenters indicated that guidance documents would play an important role in implementing and understanding the requirements of the FBRR. In addition to an implementation guidance manual, the Agency is currently developing additional guidance to aid systems and States in complying with the FBRR. EPA intends to solicit input from a variety of stakeholders during the development of the guidance documents, and will ensure that the documents undergo significant technical review by industry experts.

E. What Public Notification and Consumer Confidence Report Requirements Are Contained in the FBRR?

Today's final rule modifies the Public Notification (PN) requirements found in Appendix A and B of subpart Q of Part 141 to include two public notification requirements associated with the FBRR. Today's final rule establishes public notification of a Tier 2 treatment technique violation for failure to comply with the requirements of § 141.76(c) of today's final rule. Additionally, the FBRR establishes public notification of a Tier 3 monitoring and testing violation for failure to notify the State and include the appropriate information collected as part of § 141.76(b) or failure to collect and maintain recycle information as part of § 141.76(d).

Today's rule does not specifically modify the Consumer Confidence Report (CCR) Requirements found in subpart O of part 141. However, consumer confidence reports must contain any violations of treatment techniques or requirements of NPDWRs as specified in § 141.153(d)(6) and § 141.153(f). This includes any such violations of the FBRR.

Updated CCR and PN appendices can be found on the Agency's website at *http://www/epa.gov/safewater/tables.html.*

IV. State Implementation

A. What Special State Primacy Requirements Does the FBRR Contain?

Today's final rule contains one special primacy requirement that a State must meet in order to receive primacy for the rule. A State's application must contain a description of the proper rules or other authority possessed by the State to use Sanitary Surveys, comprehensive performance evaluations (CPEs), other inspections or other activities to evaluate recycle data maintained by systems, and require modifications to recycle practices as necessary. The Agency recognizes that there are numerous mechanisms a State could use to evaluate recycle practices including Sanitary Surveys, CPEs, and other inspection. However, a State must also have the authority to require systems to modify recycle practices after an evaluation has been completed. The proposed rule contained two additional special primacy requirements, which related to approval of recycle locations other than prior to the point of primary coagulant addition and to recycle self-assessments. However, both of these special primacy requirements were related to recycle provisions that have been modified as a result of comments on the proposal. Resultant changes to the recycle provisions have obviated the need for these two special primacy requirements, since recycle is no longer required to be returned prior to the point of primary coagulant addition and recycle self-assessments have been removed from the final rule.

B. What State Information Collection, Recordkeeping and Reporting Requirements Does the FBRR Contain?

Today's final rule includes no specific State information collection, reporting, or recordkeeping requirements. The proposal included State reporting requirements; however changes to the final FBRR provisions (as a result of comments on the proposed rule) have obviated the need for the State self-assessment determination and direct filtration determination reports since these requirements are no longer contained in the final rule. Furthermore, the Agency decided to remove the State reporting requirement associated with the recycle return location as a result of comments on the proposed rule. However, today's rule modifies § 142.14 to require States to keep on file system-specific decisions made under § 141.76 such as approval of alternate recycle locations.

C. How Must a State Obtain Interim Primacy for the FBRR?

To maintain primacy for the Public Water Supply Supervision (PWSS) program and to be eligible for interim primacy enforcement authority for future regulations, States must adopt today's final rule. A State must submit a request for approval of program revisions that adopt the revised MCL or treatment technique and implement regulations within two years of promulgation, unless EPA approves an extension per § 142.12(b). Interim primacy enforcement authority allows States to implement and enforce drinking water regulations once State regulations are effective and the State has submitted a complete and final primacy revision application. To obtain interim primacy, a State must have primacy with respect to each existing NPDWR. Under interim primacy enforcement authority, States are effectively considered to have primacy during the period that EPA is reviewing their primacy revision application.

V. Economic Analysis (Health Risk Reduction and Cost Analysis)

This section summarizes the Health Risk Reduction and Cost Analysis in support of the FBRR as required by section 1412(b)(3)(C) of the 1996 SDWA. In addition, under Executive Order 12866, Regulatory Planning and Review, EPA must estimate the costs and benefits of the FBRR. EPA has prepared an estimate of the costs and benefits to comply with the requirements of this Executive Order and the SDWA Health Risk Reduction and Cost Analysis (USEPA, 2001). This final analysis will be published on the Agency's web site, at *http://www.epa.gov/safewater*. It can also be found in the docket for this rulemaking.

EPA has estimated the total annualized cost for implementing the FBRR and analyzed the total benefits that result from the rule. Total annual costs for the rule are estimated at either $5.84 million or $7.2 million in 2000 dollars, depending on whether a three percent or a seven percent discount rate is used to annualize capital and start-up costs. The cost estimate includes capital costs for treatment changes and start-up and annual labor costs for reporting activities. More details, including the basis for these estimates and alternate cost estimates using different cost of capital assumptions are described later in this section. The benefits associated with the FBRR are discussed qualitatively, but remain unquantified because of data limitations.

A. What Are the Costs of the FBRR?

In estimating the costs of today's final rule, the Agency considered impacts on public water systems and on States (including territories and EPA implementation in non-primacy States) and Tribes. The FBRR will result in increased costs to public water systems for reading and understanding the rule, reporting recycle practices to the State, and capital improvements to recycle return locations at up to 400 systems. States will also face implementation costs associated with reading and understanding the rule, obtaining primacy, and evaluating system's recycle reports and recycle practices. The recycle provisions apply to all surface water and GWUDI systems that recycle filter backwash, thickener supernatant, or liquids from dewatering. EPA estimates that the annualized cost of today's final rule will be $5.84 million or $7.2 million (annualized using a three percent or seven percent discount rate respectively). Total capital and associated O&M costs associated with modifications to recycle locations at an estimated 371 systems are $45.2 million, and represent $5.5 million or $6.8 million annually (annualized over 20 years using a three percent or seven percent discount rate, respectively). The recycle return provision of today's final rule accounts for 95 percent of total annualized costs. Public Water System expenditures for all provisions are greater than 99 percent ($5.8 million at a three percent discount rate or $6.7 million at a seven percent discount rate) of total annualized costs; State expenditures make up less than 1 percent ($0.07 million at a three percent discount rate or $0.098 million at a seven percent discount rate). The national estimate of annual system costs for the recycle provisions is based on estimates of system-level costs for the rule and estimates of the number of systems expected to incur each type of cost.

Although EPA has evaluated the cost to drinking water systems and States of all provisions of the rule, there are some costs that the Agency was not able to quantify such as indirect costs to systems. These costs may result if States require systems to make additional changes to their recycle practice based on the data collected under this rule. Additionally, there are uncertainties surrounding rule assumptions that may affect the quantified cost estimates. For example, EPA estimated the number of systems that may be affected by this rule based on survey information. If the surveys underestimated the numbers of systems required to change the return location of their filter backwash, then the cost of this requirement would be underestimated. However, it is also possible that the surveys overestimated the number of systems required to make changes and this would result in an overestimation of rule costs.

B. What Are the Household Costs of the FBRR?

The mean annual cost per household is $0.19 and the total annual cost per household is less than $1.70 for 99 percent of the 31.4 million households potentially affected by today's final rule. The remaining one percent of households will experience a range of costs between $1.70 and approximately $100 per year. Only 321 of the 31.4 million households potentially affected by the FBRR (.00001 percent) are expected to incur costs of approximately $100 per year.

C. What Are the Benefits of the FBRR?

The primary benefits of today's final rule come from reductions in the risk of illness from microbial pathogens in drinking water. In particular, FBRR focuses on reducing the risk associated with disinfection resistant pathogens, such as *Cryptosporidium.*

Available literature research demonstrates that increased hydraulic loading or disruptive hydraulic currents, such as may be experienced when plants exceed State-approved operating capacity or when recycle is returned directly into the sedimentation basin, can disrupt filter (Cleasby, 1963; Glasgow and Wheatley, 1998; McTigue *et al.*, 1998) and sedimentation (Fulton, 1987; Logsdon, 1987; Cleasby, 1990) performance. However, the literature does not quantify the extent to which performance can be lowered and, more specifically, does not quantify the decrease in *Cryptosporidium* removal that may be experienced during direct recycle events. Specifically, there is a lack of treatment performance data to accurately model the oocysts removal achieved by individual full-scale treatment processes and the impact recycle may have on treatment unit *Cryptosporidium* removal and resulting finished water quality. However, as indicated previously, some studies have shown that when recycle is performed in accordance with the requirements of the FBRR, *Cryptosporidium* removal is not impaired.

The goal of the FBRR is to reduce the potential for oocysts getting into the finished water and causing cases of cryptosporidiosis. Other disinfection-resistant pathogens may also be removed more efficiently due to implementation of these provisions. Exposure to other pathogenic protozoa, such as *Giardia,* or other emerging microbial pathogens is likely to be reduced by the this rule as well.

In addition to preventing illnesses, this rule is expected to have other non-health related benefits. These benefits result from avoiding non-health related costs associated with waterborne disease outbreaks. During an outbreak, local governments and water systems must issue warnings and alerts and may need to provide an alternative source of water. Systems also face negative publicity and possibly legal costs. Businesses have to supply their customers and employees with alternative sources of water and some, especially restaurants, may even have to temporarily close. Households also have to either boil their water, purchase water, or obtain water from another source. The monetary costs associated with an outbreak can be difficult to quantify and will vary with respect to a host of criteria. However, one study of a *Giardia* outbreak in Luzerne County, Pennsylvania estimated these non-health related outbreak costs to be quite significant (Harrington et al., 1985). This study estimated losses to individuals due to actions taken to avoid the contaminated water at between $19 million and $49 million, in 1984 dollars. ($31M–$81M in 2000$). Losses due to averting actions for restaurants and bars totaled $1 million and $0.6 million for schools and other businesses, in 1984 dollars. The burden for government agencies was $230,000 and the outbreak cost the water utility an estimated $1.8 million, again in 1984 dollars.

D. What Are the Incremental Costs and Benefits of the FBRR?

Analytical limitation in the estimation of monetized benefits for the FBRR prevented the Agency from quantitatively describing the incremental benefit of the various regulatory alternatives considered for this rulemaking. The RIA supporting the final FBRR provides detailed information on the incremental costs of various rule components.

E. Are There Benefits From the Reduction of Co-Occurring Contaminants?

Improvements in recycle practices may also reduce exposure to Giardia lamblia and emerging disinfection resistant pathogens, such as microsporidia, Toxoplasma, and Cyclospora. The frequency and extent that FBRR would reduce risk from these other contaminants has not been quantitatively evaluated because the

Agency lacked removal efficiency data for these various technologies as well as co-occurrence data.

F. Is There Increased Risk From Other Contaminants?

The Agency has not identified any increased risk from other contaminants as a result of promulgating the FBRR.

G. What Are the Uncertainties in Risk, Benefit and Cost Estimates for the FBRR?

EPA has included a detailed discussion of the possible sources of uncertainty in risk, benefit and cost estimates in the cost-benefit analysis. As noted earlier, the risk and benefits have been expressed qualitatively for this rule, and associated sources of uncertainty include occurrence of *Cryptosporidium* oocysts in source waters and finished waters, reduction of *Cryptosporidium* oocysts due to improved treatment, viability and infectivity of *Cryptosporidium* oocysts, and the characterization of risk. Uncertainty associated with costs include assumptions with respect to changes a system might make to their point of recycle, assumptions about costs of labor, maintenance, and capital, and the number of systems expected to undertake certain activities. The Agency believes that the qualitative risks and benefits, and the quantitative costs have been accurately portrayed. Discussions and analysis of risks, benefits, and costs indicate where uncertainty may be introduced and to the extent possible, the effect uncertainty may have on analysis (EPA, 2001).

H. What Is the Benefit/Cost Determination for the FBRR?

The Agency has determined that the benefits of the FBRR justify their cost on a qualitative basis. The FBRR will reduce the potential for improper recycle practices to upset treatment plant performance during recycle events. Today's rule will therefore help prevent *Cryptosporidium* oocysts and other contaminants from entering finished drinking water supplies and causing endemic illness or costly waterborne disease outbreaks.

The Agency strongly believes that returning *Cryptosporidium* to the treatment process in recycle flows, if performed improperly, can create additional public health risk. Therefore, the Agency is requiring that recycle flows be returned to the point such that all steps of a system's conventional or direct filtration will be employed to ensure that the system continues to achieve at least a 2-log removal of *Cryptosporidium*. As indicated previously, some studies have shown that when recycle is performed in accordance with the requirements of the FBRR, *Cryptosporidium* removal is not impaired. Additionally, today's rule also will aid States and systems by ensuring that they have the requisite information to evaluate whether a treatment plant may be susceptible to hydraulic disruptions as a result of recycling, and whether the existing recycle practices sufficiently addresses potential health risks.

VI. Other Requirements

A. Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et seq.

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute 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 organizations, and small governmental jurisdictions.

The RFA provides default definitions for each type of small entity. It also authorizes an agency to use alternative definitions for each category of small entity, ''which are appropriate to the activities of the agency'' after proposing the alternative definition(s) in the **Federal Register** and taking comment. 5 U.S.C. 601(3)–(5). In addition to the above, to establish an alternative small business definition, agencies must consult with SBA's Chief Counsel for Advocacy.

For purposes of assessing the impacts of today's rule on small entities, EPA considered small entities to be PWSs serving fewer than 10,000 persons. This is the cut-off level specified by Congress in the 1996 Amendments to the Safe Drinking Water Act for small system flexibility provisions. In accordance with the RFA requirements, EPA proposed using this alternative definition in the **Federal Register** (63 FR 7620, February 13, 1998), requested comment, consulted with the Small Business Administration (SBA), and expressed its intention to use the alternative definition for all future drinking water regulations in the Consumer Confidence Reports regulation (63 FR 44511, August 19, 1998). EPA has thus used this alternative definition in this final rule.

After considering the economic impacts of today's final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities.

In accordance with section 603 of the RFA, EPA prepared an initial regulatory flexibility analysis (IRFA) for the proposed rule (see 65 FR 19046, 19126–27), and convened a Small Business Advocacy Review (SBAR) Panel to obtain advice and recommendations from representatives of small entities that would potentially be regulated by the rule in accordance with section 609(b) of the RFA. A detailed discussion of the Panel's advice and recommendations is found in the Panel Report found in the docket for today's final rule (EPA, 1998k). A summary of the Panel's recommendations is presented in the proposal (65 FR 19046, 19127–19130).

EPA originally developed an IRFA and convened an SBAR Panel because one of the preliminary alternatives being evaluated by the Agency was a ban on the recycle of spent filter backwash. This preliminary alternative would have resulted in substantial costs to all conventional and direct filtration systems that practiced recycle including small entities. After development of the IRFA and completion of the SBAR Panel, the Agency determined that a ban on recycle was not an appropriate alternative and removed it from consideration. The Agency re-evaluated the economic effects on small entities after publication of the April 10, 2000 FBRR proposal and was able to certify that today's final rule will not have a significant economic impact on a substantial number of small entities.

Of the 3,840 small entities potentially affected by the FBRR, 93 percent are expected to incur average annualized costs of less than $50. This equates to approximately 0.001 percent of average annual revenue. The remaining 7 percent (278 systems) are expected to incur average annualized costs of approximately $2,200, or 0.08 percent of average annual revenue. The Agency has included a detailed description of this analysis in the Regulatory Flexibility Screening Analysis prepared for the final rule (USEPA, 2000f).

B. Paperwork Reduction Act

The Office of Management and Budget 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 number 2040–0224. The information collected as a result of this rule will allow the States to determine appropriate requirements for specific systems, in some cases, and to evaluate compliance with the rule. For the first three years

after the effective date of the FBRR, the major information requirements are the required notification to States by systems that recycle, including a plant schematic and flow information that must accompany the notification. The information collection requirements in section 141.76, for systems, and section 142.14, for States, are mandatory. The information collected is not confidential.

The preliminary estimate of aggregate annual average burden hours for the first three years after the effective date of the FBRR is 66,363. For systems these hours consist of reading and understanding the rule, mobilization and planning, and preparation of the State notifications. For States these hours consist of reading and understanding the rule, obtaining primacy, mobilization and planning, and staff training. The annual average aggregate cost estimate over the first three years is $0 for capital, and $0 for operation and maintenance. The burden hours per response annually is 8.4 hours. The frequency of response (average responses per respondent) is 4.0 annually. The estimated number of likely respondents is 1,986 (the product of burden hours per response, frequency, and respondents does not total the annual average burden hours due to rounding).

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

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15. The OMB control number(s) for the information collection requirements in this rule will be listed in an amendment to 40 CFR part 9 in a subsequent **Federal Register** document after OMB approves the ICR.

C. Unfunded Mandates Reform Act of 1995

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 UMRA section 202, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures by State, local, and Tribal governments, in the aggregate, or 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 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.

EPA has determined that this rule does not contain a Federal mandate that may result in expenditures of $100 million or more for the State, local and Tribal governments, in the aggregate, or the private sector in any one year. The estimated annual cost of this rule is $5.84 million at a three percent discount or and $7.2 million at a seven percent discount rate. Thus today's rule is not subject to the requirements of sections 202 and 205 of the UMRA.

EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments. Of the 1,574 small government entities potentially affected by the FBRR, 93 percent are expected to incur average annualized costs of less than $50 dollars. This equates to approximately 0.002 percent of average annual revenue. The remaining 7 percent (114 systems) are only expected to incur average annualized costs of approximately $2,200 dollars or 0.09 percent of average annual revenue. Thus, today's rule is not subject to the requirements of section 203 of UMRA.

Nevertheless, EPA has tried to ensure that State, local, and Tribal governments had opportunities to provide comment. EPA consulted with small governments to address impacts of regulatory requirements in the rule that might significantly or uniquely affect small governments. As discussed next, a variety of stakeholders, including small governments, were provided the opportunity for timely and meaningful participation in the regulatory development process. EPA used these opportunities to notify potentially affected small governments of regulatory requirements being considered.

EPA began outreach efforts to develop the FBRR in the summer of 1998. Two public stakeholder meetings, which were announced in the **Federal Register**, were held on July 22–23, 1998, in Lakewood, Colorado, and on March 3–4, 1999, in Dallas, Texas. Stakeholders include representatives of State, local and Tribal governments, environmental groups and public and private public water systems. In addition to these meetings, EPA has held several formal and informal meetings with stakeholders including the Association of State Drinking Water Administrators. A summary of each meeting and attendees is available in the public docket for this rule. EPA also convened a Small Business Advocacy Review (SBAR) Panel in accordance with the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) to address small entity concerns including those of small local governments. The SBAR Panel allows small regulated entities to provide input to EPA early in the regulatory development process. In early June 1999, EPA mailed an informal draft of the FBRR preamble to the approximately 100 stakeholders who attended one of the public stakeholder meetings. Members of trade associations and the SBREFA Panel also received the draft preamble. EPA received valuable suggestions and stakeholder input from 15 State representatives, trade associations, environmental interest groups, and individual stakeholders. The majority of concerns dealt with

reducing burden on small systems and maintaining flexibility.

To inform and involve Tribal governments in the rulemaking process, EPA presented the FBRR at three venues: the 16th Annual Consumer Conference of the National Indian Health Board, the annual conference of the National Tribal Environmental Council, and the EPA/Inter Tribal Council of Arizona, Inc. tribal consultation meeting. Over 900 attendees representing Tribes from across the country attended the National Indian Health Board's Consumer Conference and over 100 Tribes were represented at the annual conference of the National Tribal Environmental Council. At the first two conferences, an EPA representative conducted two workshops on EPA's drinking water program and upcoming regulations, including the FBRR.

At the OGWDW/Inter Tribal Council of Arizona meeting, representatives from 15 Tribes participated. The presentation materials and meeting summary were sent to over 500 Tribes and tribal organizations. Additionally, EPA contacted each of the 12 Native American Drinking Water State Revolving Fund Advisors to invite them, and representatives of their organizations to the stakeholder meetings described previously.

During the comment period for today's final rule, the Agency held a public meeting in Washington DC on April 14, 2000 (EPA,2000d). Additionally, the proposed rule was either presented or discussed in nearly 50 meetings across the US. Finally, EPA mailed approximately 200 copies of the proposed rule to stakeholders requesting comment. EPA received 67 comments from a variety of stakeholders including 24 States, 21 municipalities, one Tribe, one elected official, two consultants, eight trade groups, and four private industries.

In addition, EPA will educate, inform, and advise small systems, including those run by small governments, about the FBRR requirements. The Agency is developing plain-English guidance that will explain what actions a small entity must take to comply with the rule. Also, the Agency has developed fact sheets that concisely describe various aspects and requirements of the FBRR. These fact sheets are available by calling the Safe Drinking Water Hotline at 800–426–4791.

D. National Technology Transfer and Advancement Act

As noted in the proposed rule, section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTAA), Public Law No. 104–113, Section 12(d) (15 U.S.C. 272), directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTAA directs EPA to provide Congress, through the Office of Management and Budget, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This action does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards. We did not receive any comments identifying potentially-applicable voluntary consensus standards that we should consider using either.

E. Executive Order 12866: Regulatory Planning and Review

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

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

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

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

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

Pursuant to the terms of the Executive Order 12866, it has been determined that this rule is a ''significant regulatory action.'' As such, this action was submitted to OMB for review. Changes made in response to OMB suggestions or recommendations have been documented in the public record.

F. Executive Order 12898: Environmental Justice

Executive Order 12898 establishes a Federal policy for incorporating environmental justice into Federal agency missions by directing agencies to identify and address disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority and low-income populations. The Agency has considered environmental justice related issues concerning the potential impacts of this action and consulted with minority and low-income stakeholders.

On March 12, 1998, the Agency held a stakeholder meeting to address various components of pending drinking water regulations and how they may impact sensitive sub-populations, minority populations, and low-income populations. Topics discussed included treatment techniques, costs and benefits, data quality, health effects, and the regulatory process. Participants included national, State, Tribal, municipal, and individual stakeholders. EPA conducted the meetings by video conference call between 11 cities. This meeting was a continuation of stakeholder meetings that started in 1995 to obtain input on the Agency's drinking water programs. The major objectives for the March 12, 1998 meeting were:

—Solicit ideas from stakeholders on known issues concerning current drinking water regulatory efforts;
—Identify key issues of concern to stakeholders, and;
—Receive suggestions from stakeholders concerning ways to increase representation of communities in EPA regulatory efforts.

In addition, EPA developed a plain-English guide specifically for this meeting to assist stakeholders in understanding the multiple and sometimes complex issues surrounding drinking water regulation.

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

Executive Order 13045: ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be economically significant as defined under Executive Order 12866, and; (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of

the planned rule on children and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

While this final rule is not subject to the Executive Order because it is not economically significant as defined in Executive Order 12866, we nonetheless have reason to believe that the environmental health or safety risk addressed by this action may have a disproportionate effect on children. As a matter of EPA policy, we therefore have assessed the environmental health effects of *Cryptosporidium* on children. The results of this assessment are contained in cost-benefit analysis supporting the FBRR (EPA, 2001). A copy of the analysis and supporting documents is available for public review in the Office of Water docket at 401 M St. SW., Washington, DC.

The risk of illness and death due to cryptosporidiosis depends on several factors, including age, nutrition, exposure, genetic variability, disease and immune status of the individual. Mortality resulting from diarrhea shows the greatest risk of mortality occurring among the very young and elderly (Gerba *et al.,* 1996). For *Cryptosporidium,* young children are a vulnerable population subject to infectious diarrhea (CDC 1994). Cryptosporidiosis is prevalent worldwide, and its occurrence is higher in children than in adults (Fayer and Ungar, 1986).

Cryptosporidiosis appears to be more prevalent in populations such as infants, that may not have established immunity against the disease and may be in greater contact with environmentally contaminated surfaces (DuPont, *et al.,* 1995). An infected child may spread the disease to other children or family members. Evidence of such secondary transmission of cryptosporidiosis from children to household and other close contacts has been found in a number of outbreak investigations (Casemore, 1990; Cordell *et al.,* 1997; Frost *et al.,* 1997). Chapell *et al.,* (1999) found that prior exposure to *Cryptosporidium* through the ingestion of a low oocyst dose provides protection from infection and illness. However, it is not known whether this immunity is life-long or temporary. Data also indicate that either mothers confer short term immunity to their children or that babies have reduced exposure to *Cryptosporidium,* resulting in a decreased incidence of infection during the first year of life. For example, in a survey of over 30,000 stool sample analyses from different patients in the United Kingdom, the 1–5 year age group suffered a much higher infection rate than individuals less than one year of age. For children under one year of age, those older than six months of age showed a higher rate of infection than individuals aged fewer than six months (Casemore, 1990).

EPA has not been able to quantify the health effects for children as a result of *Cryptosporidium*-contaminated drinking water. However, the result of the FBRR will be a reduction in the risk of illness for the entire population, including children. Because available evidence indicates that children may be more vulnerable to Cryptosporidiosis than the rest of the population, the FBRR would, therefore, result in greater risk reduction for children than for the general population.

H. Consultations With the Science Advisory Board, National Drinking Water Advisory Council, and the Secretary of Health and Human Services

In accordance with section 1412 (d) and (e) of the SDWA, the Agency discussed or submitted possible FBRR requirements to the Science Advisory Board, National Drinking Water Advisory Council (NDWAC), and to the Secretary of Health and Human Services and requested comment from the Science Advisory Board (SAB) on the FBRR.

On March 13th and 14th, 2000 in Washington, DC, the Agency met with the Science Advisory Board during meetings open to the public where several of the Agency's drinking water rules were discussed. A copy of the SAB's comments are found in the docket (EPA, 2000n).

On May 10th, 2000 in San Francisco, California, the Agency presented the FBRR to NDWAC. A copy of the materials presented to the NDWAC as well as the charge presented to the council are found in the docket (EPA, 2000g). A copy of NDWAC's recommendations are also found in the docket (NDWAC, 2000).

EPA invited the Secretary of Health and Human Services to the April 14th, 2000 informational meeting regarding the proposed Long Term 1 Enhanced Surface Water Treatment and Filter Backwash Rule and consulted with the Center for Disease Control (CDC) during June 20, 2000 and October 10, 2000, conference calls with the Center's Working Group on Waterborne Cryptosporidiosis. The meeting notes for these calls are found in the docket for today's rule (CDC, 2000b). CDC's role as an Agency of the Department of Health and Human Services is to provide a system of health surveillance to monitor and prevent outbreak of diseases. With the assistance of States and other partners, CDC guards against international disease transmission, maintains national health statistics, provides immunization services and supports research into disease and injury prevention.

Only SAB provided substantive comments on the FBRR. SAB had several recommendations including recommending against requirements that would alter the design of direct recycle systems and recommending against requiring that washwater flows be recycled ahead of the point of coagulant addition. Today's final FBRR is consistent with the recommendations of the SAB.

I. Executive Order 13132: Executive Orders on 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.''

This final rule does not have federalism implications. It 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. Today's final rule does not have a substantial direct effect on local and State governments because it is not expected to impose substantial direct compliance costs. The rule imposes annualized compliance costs of approximately $3.78 or $4.64 million (at 3 percent and 7 percent discount rates, respectively) per year for local and State governments. Only $0.07 or $0.98 million (at 3 percent and 7 percent discount rates respectively,) of these costs are attributable to States, while $0.64 or $0.82 million (at 3 percent and 7 percent discount rates, respectively) is attributable to approximately 1,575 local governments serving fewer than 10,000 persons and the remaining $4.7 million or $5.8 million (at 3 percent and 7 percent discount rates, respectively) is attributable to approximately 980 local governments serving 10,000 or more persons. Furthermore, the rule does not

have a substantial direct effect on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government as specified in Executive Order 13132 because the rule does not change the current roles and relationships of the Federal government, State governments and local governments in implementing drinking water programs. Thus, Executive Order 13132 does not apply to this rule. Although the Executive Order does not apply to this rule, EPA did consult with State and local officials in developing this rule. In addition to our outreach efforts described earlier, on May 30, 2000, the Agency held a meeting in Washington, DC with ten representatives of elected State and local officials to discuss how new Federal drinking water regulations (FBRR, LT1ESWTR, Ground Water Rule, Radon Rule, Radionuclides Rule, and Arsenic Rule) may affect State, county, and local governments. Throughout the consultation, stakeholders asked EPA for clarification of basic concepts and rule elements. EPA addressed these issues throughout the consultation and provided background and clarification to promote better understanding of the issues. For example, stakeholders asked EPA to describe what Cryptosporidium is and how individuals are diagnosed with cryptosporidiosis. A detailed summary of this consultation meeting and the concerns raised is found in the docket (EPA, 2000h). No significant concerns were raised regarding the FBRR.

J. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

On November 6, 2000, the President issued Executive Order 13175 (65 FR 67249) entitled, ''Consultation and Coordination with Indian Tribal Governments.'' Executive Order 13175 took effect on January 6, 2001, and revokes Executive Order 13084 (Tribal Consultation) as of that date. EPA developed this final rule, however, during the period when Executive Order 13084 was in effect; thus, EPA addressed Tribal considerations under Executive Order 13084.

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

Today's rule does not significantly or uniquely affect the communities of Indian Tribal governments, nor will it impose substantial direct compliance costs on them. This rule will affect fewer than 22 of the 987 (2 percent) total tribal drinking water systems. Of these 22 systems, 20 are estimated to incur annualized compliance costs of less than $50 per year or 0.001 percent of average annual revenue. The remaining two systems are estimated to incur annualized compliance costs of approximately $2,200 per year or 0.08 percent of average annual revenue. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

K. Likely Effect of Compliance With the FBRR on the Technical, Financial, and Managerial Capacity of Public Water Systems

Section 1420(d)(3) of the SDWA as amended requires that, in promulgating a NPDWR, the Administrator must include an analysis of the likely effect of compliance with the regulation on the technical, financial, and managerial capacity of public water systems. This analysis can be found in the FBRR cost-benefit analysis (EPA, 2001).

Overall water system capacity is defined in EPA guidance (EPA, 1998j) as the ability to plan for, achieve, and maintain compliance with applicable drinking water standards. Capacity has three components: technical, managerial, and financial.

Technical capacity is the physical and operational ability of a water system to meet SDWA requirements. Technical capacity refers to the physical infrastructure of the water system, including the adequacy of source water and the adequacy of treatment, storage, and distribution infrastructure. It also refers to the ability of system personnel to adequately operate and maintain the system and to otherwise implement requisite technical knowledge. Managerial capacity is the ability of a water system to conduct its affairs to achieve and maintain compliance with SDWA requirements. Managerial capacity refers to the system's institutional and administrative capabilities. Financial capacity is a water system's ability to acquire and manage sufficient financial resources to allow the system to achieve and maintain compliance with SDWA requirements. Technical, Managerial, and Financial capacity can be assessed through key issues and questions, including:

Technical Capacity

Source water adequacy	Does the system have a reliable source of drinking water? Is the source of generally good quality and adequately protected?
Infrastructure adequacy	Can the system provide water that meets SDWA standards? What is the condition of its infrastructure, including well(s) or source water intakes, treatment, storage, and distribution? What is the infrastructure's life expectancy? Does the system have a capital improvement plan?
Technical knowledge and implementation	Is the system's operator certified? Does the operator have sufficient technical knowledge of applicable standards? Can the operator effectively implement this technical knowledge? Does the operator understand the system's technical and operational characteristics? Does the system have an effective operation and maintenance program?

Managerial Capacity	
Ownership accountability	Are the system owner(s) clearly identified? Can they be held accountable for the system?
Staffing and organization	Are the system operator(s) and manager(s) clearly identified? Is the system properly organized and staffed? Do personnel understand the management aspects of regulatory requirements and system operations? Do they have adequate expertise to manage water system operations? Do personnel have the necessary licenses and certifications?
Effective external linkages	Does the system interact well with customers, regulators, and other entities? Is the system aware of available external resources, such as technical and financial assistance?
Financial Capacity	
Revenue sufficiency	Do revenues cover costs? Are water rates and charges adequate to cover the cost of water?
Credit worthiness	Is the system financially healthy? Does it have access to capital through public or private sources?
Fiscal management and controls	Are adequate books and records maintained? Are appropriate budgeting, accounting, and financial planning methods used? Does the system manage its revenues effectively?

Generally, systems affected by this rule are not required to make significant modifications to the treatment process to meet FBRR requirements. Therefore, most systems are not expected to experience a significant impact on their technical, financial, or managerial capacity.

L. Plain Language

Executive Order 12866 requires each agency to write its rules in plain language. Readable regulations help the public find requirements quickly and understand them easily. They increase compliance, strengthen enforcement, and decrease mistakes, frustration, phone calls, appeals, and distrust of government. Of the several techniques typically utilized for writing readably, using a question and answer format, and using the word, ''you'' for whoever must comply, do the most to improve the look and sound of a regulation. The preamble for today's final rule uses the first principle and was developed using a plain language question and answer format. Today's final rule language does not use these principles since the rule only modifies or adds to existing regulatory language that is in the previous regulatory language format. However, EPA has made every effort to write the rule in as clear, concise, and unambiguous manner as possible.

M. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)), provides that agencies shall prepare and submit to the Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget, a Statement of Energy Effects for certain actions identified as ''significant energy actions.'' Section 4(b) of Executive Order 13211 defines ''significant energy actions'' as ''any action by an agency (normally published in the **Federal Register**) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking: (1)(i) That is a significant regulatory action under Executive Order 12866 or any successor order, and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) that is designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action.''

We have not prepared a Statement of Energy Effects for this final rule because this rule is not a significant energy action, as defined in Executive Order 13211. While this rule is a significant regulatory action under Executive Order 12866, it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

N. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective August 7, 2001.

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List of Subjects

40 CFR Part 9

Reporting and recordkeeping requirements.

40 CFR Part 141

Environmental protection, Chemicals, Indians-lands, Intergovernmental relations, Reporting and recordkeeping requirements, Water supply.

40 CFR Part 142

Environmental protection, Administrative practice and procedure, Chemicals, Indians-lands, Reporting and recordkeeping requirements, Water supply.

Dated: May 23, 2001.

Christine Todd Whitman,

Administrator.

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

PART 9—[AMENDED]

1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.*, 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326–1330, 1324, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.*, 6901–992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

2. In § 9.1 the table is amended by adding under the indicated heading the new entry in numerical order to read as follows:

§ 9.1 OMB Approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control No.
* * * * *	
National Primary Drinking Water Regulations	
* * * *	
141.76	2040–0224
* * * * *	

PART 141—NATIONAL PRIMARY DRINKING WATER REGULATIONS

3. The authority citation for part 141 continues to read as follows:

Authority: 42 U.S.C. 300f, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–4, 300j–9, and 300j–11.

4. Subpart H is amended by adding § 141.76 to read as follows:

§ 141.76 Recycle Provisions.

(a) *Applicability.* All subpart H systems that employ conventional filtration or direct filtration treatment and that recycle spent filter backwash water, thickener supernatant, or liquids from dewatering processes must meet the requirements in paragraphs (b) through (d) of this section.

(b) *Reporting.* A system must notify the State in writing by Decemeber 8, 2003, if the system recycles spent filter backwash water, thickener supernatant, or liquids from dewatering processes. This notification must include, at a minimum, the information specified in paragraphs (b)(1) and (2) of this section.

(1) A plant schematic showing the origin of all flows which are recycled (including, but not limited to, spent filter backwash water, thickener supernatant, and liquids from dewatering processes), the hydraulic conveyance used to transport them, and the location where they are re-introduced back into the treatment plant.

(2) Typical recycle flow in gallons per minute (gpm), the highest observed plant flow experienced in the previous year (gpm), design flow for the treatment plant (gpm), and State-approved operating capacity for the plant where the State has made such determinations.

(c) *Treatment technique requirement.* Any system that recycles spent filter backwash water, thickener supernatant, or liquids from dewatering processes must return these flows through the processes of a system's existing conventional or direct filtration system as defined in § 141.2 or at an alternate location approved by the State by June 8, 2004. If capital improvements are required to modify the recycle location to meet this requirement, all capital improvements must be completed no later than June 8, 2006.

(d) *Recordkeeping.* The system must collect and retain on file recycle flow information specified in paragraphs (d)(1) through (6) of this section for review and evaluation by the State beginning June 8, 2004.

(1) Copy of the recycle notification and information submitted to the State under paragraph (b) of this section.

(2) List of all recycle flows and the frequency with which they are returned.

(3) Average and maximum backwash flow rate through the filters and the average and maximum duration of the filter backwash process in minutes.

(4) Typical filter run length and a written summary of how filter run length is determined.

(5) The type of treatment provided for the recycle flow.

(6) Data on the physical dimensions of the equalization and/or treatment units, typical and maximum hydraulic loading rates, type of treatment chemicals used and average dose and frequency of use, and frequency at which solids are removed, if applicable.

5. Appendix A to Subpart Q of Part 141 is amended by adding a new entry ''8.'' in numerical order under I.A. to read as follows:

APPENDIX A TO SUBPART Q OF PART 141.—NPDWR VIOLATIONS AND OTHER SITUATIONS REQUIRING PUBLIC NOTICE [1]

Contaminant	MCL/MRDL/TT violations [2]		Monitoring and testing procedure violations	
	Tier of public notice required	Citation	Tier of public notice required	Citation
1. Violations of National Primary Drinking Water Regulations (NPDWR): [3]				
A. Microbiological Contaminants				
* * * *	*	*	*	*
8. Filter Backwash Recycling Rule violations	2	141.76	3	141.76
* * * *	*	*	*	*

Appendix A—Endnotes

1. Violations and other situations not listed in this table (e.g., reporting violations and failure to prepare Consumer Confidence Reports), do not require notice, unless otherwise determined by the primacy agency. Primacy agencies may, at their option, also require a more stringent public notice tier (e.g., Tier 1 instead of Tier 2 or Tier 2 instead of Tier 3) for specific violations and situations listed in this Appendix, as authorized under § 141.202(a) and § 141.203(a).

2. MCL—Maximum contaminant level, MRDL—Maximum residual disinfectant level, TT—Treatment technique.

3. The term Violations of National Primary Drinking Water Regulations (NPDWR) is used here to include violations of MCL, MRDL, treatment technique, monitoring, and testing procedure requirements.

* * * * *

6. Appendix B to Subpart Q of Part 141 is amended by revising B and entry ''7.'' under B. to read as follows:

APPENDIX B TO SUBPART Q OF PART 141.—STANDARD HEALTH EFFECTS LANGUAGE FOR PUBLIC NOTIFICATION

Contaminant	MCLG [1] mg/L	MCL [2] mg/L	Standard health effects language for public notification
National Primary Drinking Water Regulations (NPDWR):			
* * * *	*	*	*
B. Surface Water Treatment Rule (SWTR), Interim Enhanced Surface Water Treatment Rule (IESWTR) and Filter Backwash Recycling Rule (FBRR) violations:			
* * * *	*	*	*
7. Cryptosporidium (IESWTR/FBRR).			
* * * *	*	*	*

Appendix B—Endnotes

1. MCLG—Maximum contaminant level goal.
2. MCL—Maximum contaminant level.

* * * * *

PART 142—NATIONAL PRIMARY DRINKING WATER REGULATIONS IMPLEMENTATION

7. The authority citation for Part 142 continues to read as follows:

Authority: 42 U.S.C. 300f, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–4, 300j–9, and 300j–11.

8. Section 142.14 is amended by removing the word ''and'' at the end of the paragraph (a)(4)(ii)(A)(*7*) and revising paragraph (a)(4)(ii)(A)(*8*) and adding paragraph (a)(4)(ii)(A)(*9*) to read as follows:

§ 142.14 Records kept by States.

(a) * * *
(4) * * *
(ii) * * *
(A) * * *

(*8*) Section 141.75(b)(2)(iv)—Any decision to allow reduced reporting by a filtered public water system; and

(*9*) Section 141.76—Any decisions made to approve alternate recycle locations, require modifications to recycle return locations, or require modifications to recycle practices.

* * * * *

9. Section 142.16 is amended by adding paragraph (i) to read as follows:

§ 142.16 Special primacy requirements.

* * * * *

(i) *Requirements for States to adopt 40 CFR part 141, § 141.76 Recycle Provisions.* In addition to the general primacy requirements enumerated elsewhere in this part, including the requirement that the State provisions are no less stringent than the federal requirements, an application for approval of a State program revision that adopts 40 CFR part 141, § 141.76 Recycle Provisions must contain the information specified in this paragraph: (1) State practices or procedures. (i) Section 141.76(d) of this chapter—States must have the proper rules and authority to use Sanitary Surveys, comprehensive performance evaluations (CPEs), other inspections, or other activities to evaluate recycle data maintained by systems under § 141.76(d) of this chapter and require modifications to recycle practices.

(ii) [Reserved]

(2) [Reserved]

[FR Doc. 01–13776 Filed 6–7–01; 8:45 am]

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